Dragon, Karen E. (CDC/NIOSH/EID)

From: cecolton@mmm.com
Sent: Friday, August 31, 2007 4:48 PM
To: NIOSH Docket Office (CDC)
Subject: Docket Number NIOSH - 036

Attachments: August 31 Letter on TIL concept.doc

August 31 Letter on TIL concep...

Please file the attached comments to NIOSH docket 036. A hard copy will follow in US mail.

Thanks,

(See attached file: August 31 Letter on TIL concept.doc)

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August 31, 2007

NIOSH Docket Officer
RE: NIOSH DOCKET –NIOSH - 036
Robert A. Taft Laboratories, M/S C34
4676 Columbia Parkway
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NIOCINDOCKET@CDC.GOV.

RE: TIL Concept – Docket Number NIOSH - 036

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 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 the National Institute for Occupational Health and Safety (NIOSH) with our comments on the proposed Standard Concept for TIL, dated January 17, 2007 and related documents.

NIOSH's proposed concept to evaluate respirator fit as part of the certification process to address the concern that only 53% of employers conduct fit testing is seriously flawed and not supported by 3M. 3M offers the following comments and recommendations regarding the TIL Program Concept, TIL Technical Concept, Statistical Aspects of Formulating the TIL Concept, and the Standard Test Procedure to be used for the 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 add our comments and knowledge to docket 036. If NIOSH has any questions on these comments or wishes to further explore this position, we welcome the opportunity for further dialog.

Sincerely,

Original signed by Michael Runge

Michael L. Runge
Director of Quality and Regulatory Affairs
3M Occupational Health & Environmental Safety Division

MLR:CEC/llb
Enclosures

3M Comments on the TIL Program Concept, TIL Technical Concept, Statistical Aspects of Formulating the TIL Concept, and the Standard Test Procedure to be used for the Total Inward Leakage Test for Half-mask Air Purifying Particulate Respirators

August 31, 2007

The following comments are in response to revised documents and comments from the public meeting of June 26, 2007 regarding the Total Inward leakage (TIL) Concept for Half-mask respirators. The documents are:

- TIL Program Concept
- TIL Technical Concept
- Statistical Aspects of Formulating the TIL Concept, and
- Standard Test Procedure to be used for the Total Inward Leakage Test for Half-mask Air Purifying Particulate Respirators
- Presentation at the June 26, 2007 Public Meeting

I. General Comments

There are two major deficiencies in the proposed TIL Concept that must be resolved before moving to the rulemaking stage can even be considered. First, NIOSH has indicated that the "TIL" value (which is actually the inverse of a quantitative fit factor) is not the same as present APF values, but that this number "will account for differences between laboratory test conditions and workplace conditions." This suggests that NIOSH believes quantitative fit tests are somehow correlated with the protection the respirator will provide. In contrast, the Program Concept states that:

- the proposed testing "is intended to quantify the ability of respirators to fit individuals. . ." and
- "not intended to . . . predict the workplace protection offered by respirators during actual use."

The Program Concept is correct, and the "TIL" concept is diametrically opposed and for this reason is fatally flawed. No available data suggest that the "TIL" value can account for the differences between laboratory and field conditions. Workplace data indicate that passing any of the current fit tests assures adequate protection. Higher fit factors, however, do not always translate to higher protection in the workplace. Several studies have shown that workers achieving "better fit," (i.e., fit factors well in excess of 100) do not achieve correspondingly better protection than workers with fit factors just above the threshold of 100.[1-4] At the public meeting, NIOSH showed a slide indicating fit factors for filtering facepieces are lower than they are for elastomerics. Actual workplace data, however, which are measurements of real-world protection, dispute this position and shows that filtering facepieces are at least as protective as elastomerics [See Occupational Health and Safety Administration (OSHA) final rule on APFs].[5]

A second major flaw in the "TIL" concept is the provision that respirators will be fitted on face sizes the respirator is designed to fit. This requirement is meaningless, since there are no data to indicate what facepieces fit which cells in the proposed fit test panel. No

correlation between the facial size measurements defining each cell and respirator size has ever been demonstrated. At the public meeting, NIOSH indicated a correlation between facepiece size and facial measurements need not exist. It is our position that this is absolutely not true when used to certify that a facepiece fits individuals in a particular cell. As will be shown below, huge amounts of variability can exist between individuals falling into a cell because the face and the required two dimensional measurements do not predict fit to a three dimensional structure, i.e., the face and respirator fit.

The only value of the NRFTP is its indication, using these two measurements of face lengths and face widths, that a huge proportion of the population is represented in this testing. Nevertheless, manufacturers have never designed respirators to just fit these two dimensions. As pointed out by the Institute of Medicine, a relationship between these two facial dimensions and respirator fit has never been established.[6] In fact all these two dimensional measurements provide, is to ensure that people representing a large percentage of the population are selected for performing fit tests but is not necessarily related to how well a respirator fits. NIOSH could have used dimensions such as height and body weight of respirator users to come up with a panel ensuring the same end result. As long as no correlation exists between these facial measurements and respirator facepiece sizes, using the panel to assign facepiece sizes introduces variability into the test that is not product variability, and hence does not relate to how well these products fit; the supposed goal of this proposed test requirement. Finally, the proposed method may reject respirators from being certified that are not designed to fall within in the NIOSH panel cells.

We have provided data that show the extreme variability in fit factors that often exist among individuals in the same cell. This occurs because two dimensions can not predict a three dimensional characteristic, i.e., respirator fit. For this reason and 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 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. That is why individual user fit testing is the only way to determine which respirator model and size is appropriate for each worker.

As a consequence, no manufacturer can specify that a particular facepiece fits a particular person, i.e., some one in a specific cell, and no manufacturer would be willing to make this warranty. This could constitute a warranty from NIOSH that a respirator fits faces in a particular cell with the result of less (not more) fit testing. In a recent e-mail from a customer, we were asked about the status of the TIL Concept because, "This change [NIOSH TIL Test] would require manufacturers to ensure that the majority [of respirators] fit right out of the box." Moreover, because of the lack of correlation of fit to any particular cell, it could result in a false sense of security.

Table 1 contains results for people that fit the measurements for fit test panel cell #3 which NIOSH indicates as a small. This table shows for person 1 that a medium sized

respirator provides a higher fit factor and for person 2 that all sizes fit with a large size giving the higher fit factor and only subject 3 achieved the fit according to what one might expect, i.e., the small size, followed by a medium, with the large not providing an acceptable fit. These values are averages for the test subjects.

Table 1. Fit Test Panel Cell #3 Results

Person	**Respirator Facepiece Size**		
	Small	**Medium**	**Large**
1	9	1600	
2	953	3200	48800
3	2550	343	16

NIOSH should be concerned as well because a respirator certified as a small to fit Cell 3, may not. Therefore, NIOSH's credibility is at stake as well as the manufacturer's.

Table 2 shows fit testing results from four different people. These results cause a degree of confusion regarding who is a "Cell 4" face. Subject 1 should wear the medium and subject 4 should wear the large yet they are all indicated as small faces by the NIOSH Respirator Fit Test Panel.

Table 2. Fit Test Panel Cell #4 Results

Person	**Respirator Facepiece Size**		
	Small	**Medium**	**Large**
1	1940	8700	68
2	11500	1240	
3	1050	5	
4		1320	82700

The NIOSH proposal does not indicate how it will compensate for the variability among individuals within a panel cell. This is also another factor that contributes to variability between the manufacturer's pre-submission data and NIOSH testing and why 3M does not support this concept. 3M does not believe the principal component analysis will control all facial variables.

Finding the proper fit is very much like fitting the glass slipper in Cinderella, when Prince Charming had his subjects try it on. Similarly, because it is impossible to predict how well a respirator will fit faces in a panel cell reliably, 3M has been ensuring that faces fit its respirators in the best manner available today, which is generally:

- the user determines if the facepiece is of the general proper shape and size for the wearer's face,
- the user tries it on, performs a user seal check and if passed,
- performs a fit test.

Conclusion of General Comments

NIOSH should withdraw the concept paper and proceed no further unless and until a) a correlation between fit factors greater than 100 and workplace protection factors can be shown, and b) a correlation between panel cell number and respirator size can be shown.

II. Specific Comments

The following specific comments support our opposition to the Total Inward Leakage (TIL) Concept for Half-mask respirators. Our comments address the following areas:

Pass/Fail Criteria

No rationale is presented to support the suggested penetration criterion of ≤5% or any other criterion. NIOSH must provide its rationale and provide data to demonstrate the chosen value will increase worker protection. It also appears that the pass/fail criterion may have been set because of infrequent audit testing by NIOSH. This is an inappropriate basis for setting a pass/fail criterion.

Resources to Implement

3M does not believe NIOSH has the resources to implement this test requirement in a timely manner without jeopardizing new submissions and providing new and innovative devices to respirator users. Historically, NIOSH has had difficulty in securing test subjects for every cell size in a timely manner. The lack of a readily available test pool has resulted in lengthy product approval delays and subsequent product availability to users.

Incomplete Information

NIOSH has not provided all of the information required to completely review this concept. The missing information includes Appendix B and C regarding the statistical aspects as well as other missing information identified in this document.

Increase Burden on Respirator Users

To successfully specify which fit test panel cells a facepiece belongs, NIOSH would need to train all employers in the proper use of the measuring equipment and how to take the measurements. The proposed requirement would result in an increased burden in time and training for employers attempting to use face size measurements. 3M believes

employers will be reluctant to take these steps and add the additional time required into their fit test programs when trying the facepiece on and performing a fit test is much simpler and more effective. This proposed concept actually places more road blocks to the employer performing individual fit testing rather than facilitating it which is the crux of the issue as identified by NIOSH. The practical method that has been used in the past is both easy and convenient.

Review of Failed Tests

NIOSH does not have procedures addressing how to deal with failed tests. NIOSH has provided this information or detailed procedures for the analysis of the data in other concepts. For example, NIOSH's RB-APRS-ASRS-STP-CBRN-0352, Revision 0.2, October 24, 2005 gives explicit instructions for review of failed tests. Section 5.4.9 of that Standard describes extensive procedures to be followed immediately after each individual test failure to ensure that the failure is valid. Section 7.3 of that Standard describes a thorough review of the data and test system to confirm the validity of an overall certification failure.

Similarly, RB-APRS-ASRS-STP-CBRN-0352 describes clearly how the data are to be analyzed, including examples. In particular, each Laboratory Respiratory Protection Level (LRPL) value for each test subject is considered individually to decide whether the respirator passes the certification test. The "TIL" STP refers to triplicate measurements of "TIL." The description of the proposed statistical analysis given by Mr. Landsittel at the Public Meeting implies that the triplicate measurements on each test subject will yield a single "TIL" value. The type of average, however, is not identified. In addition, the acceptance criteria for reproducibility need to be identified. For example, procedures for handling when the 3 tests on a given subject yield "TIL" values of 0.01%, 0.01% and 16% or 0.01%, 2%, and 13%.

Test Variability

The proposed concept has many sources of variability that have either not been identified or controlled so that this test only takes into account product variability. It is critical that certification test results properly assess the parameter being tested and not other factors such as testing variability. Table 3 illustrates test variability in the NIOSH benchmark testing. The two respirators (9210 and 9211) are identical except one has an exhalation valve and the other does not. A test that looks at only fit variability should achieve similar results between the two. Our laboratory finds similar results. NIOSH should use standard statistical techniques such as gage R & R (Reproducibility and Repeatability) to demonstrate test robustness. There are several sources of variability:

1. Fit Panel Size

In the proposed technical concept NIOSH changed the size of the test panel from 25 subjects to 35 subjects and suggested 50 subjects, but never presented any data showing the effect of this change. NIOSH must do testing comparing the 35 and 50 member panel

before proceeding with this concept. This is one variable which NIOSH has made no effort to determine its effect on the test results.

2. Test Exercises

The exercises that should be used are the ones described by OSHA. There is a long history of the performance of these exercises by manufacturers and respirator users, resulting in less exercise variability and will allow for better comparisons of data and more meaningful results. The exercises used in the benchmark testing were not the OSHA exercises.

3. Probe Tightness

No method for checking that the probes are leak-tight before performing the fit test has been identified by NIOSH. This could result in a failure not attributable to poor fit but due to a leaky probe

4. Site to Site Variability

Section 4.1 of the STP indicates that NIOSH is planning on having more than one testing facility. 3M agrees that maintaining calibration of equipment is an important aspect to ensuring the test repeatability/reproducibility from one facility to another. However, it is just one of many aspects. NIOSH needs to add additional procedures for ensuring that the results obtained at one NIOSH testing facility are reproducible at other NIOSH facilities as well as at manufacturers' laboratories. If the test cannot be shown to be reproducible, then the test is not suitable as a test for certification. The value of pre-submission data could be questionable.

Slide 18 of NIOSH Meeting presentation (W. Newcomb presentation) indicates that several characteristics were evaluated in establishment of the test method, among them, "Ability to give accurate, repeatable results," and "Ease of duplication (i.e., intra-lab reproducibility)"; however, there is no explicit discussion of accuracy or repeatability nor is there any discussion of intra-lab (nor inter-labs for that matter) reproducibility. Furthermore, we are not aware of any definition of accuracy for fit test measurements – there is no independent standard for respirator fit (or TIL) and it would be virtually impossible to establish one.

NIOSH needs to investigate the reproducibility of these tests by performing round robin testing.

5. Test Subject Training

Section 5.5 does not specify training similar to what OSHA requires employers to perform on how to don, fit, and perform the user seal check. The goal of this test is not to evaluate the user's instructions. NIOSH does evaluate user instructions in other areas of the certification program.

During a fit test the employer's trainer would not let employees perform a fit test until the trainer is satisfied the employee has put it on correctly rather than let the untrained employee decide they have donned the respirator correctly.

Incentive for getting the test subject in a NIOSH panel to don the respirator correctly is an issue. A user in the workplace has the incentive that they want to be protected from a hazard – there is a real benefit to make sure it fits correctly. A test subject in a NIOSH panel has no such incentive – there is no inherent benefit to them whether the respirator fits well or not, so there is nothing to compel them to be conscientious about donning the respirator correctly.

Evidence of the impact of this gap between results following the NIOSH protocol and what untrained wearers achieve is demonstrated by reviewing 3M's data on novice users. In these tests novice users (those having never worn a respirator, receiving no training or corrections if errors are made) achieve higher fit factors than NIOSH trained users. This shortcoming in NIOSH's approach must be corrected before NIOSH proceeds with this concept.

6. Respirator Reuse

Section 5.7 indicates that for the 3 tests that the test subject shall doff the respirator after the first test and then redon the same respirator and repeat the test. This procedure may be testing re-use rather than fit unless it is not 'returned to its original configuration' between trials.

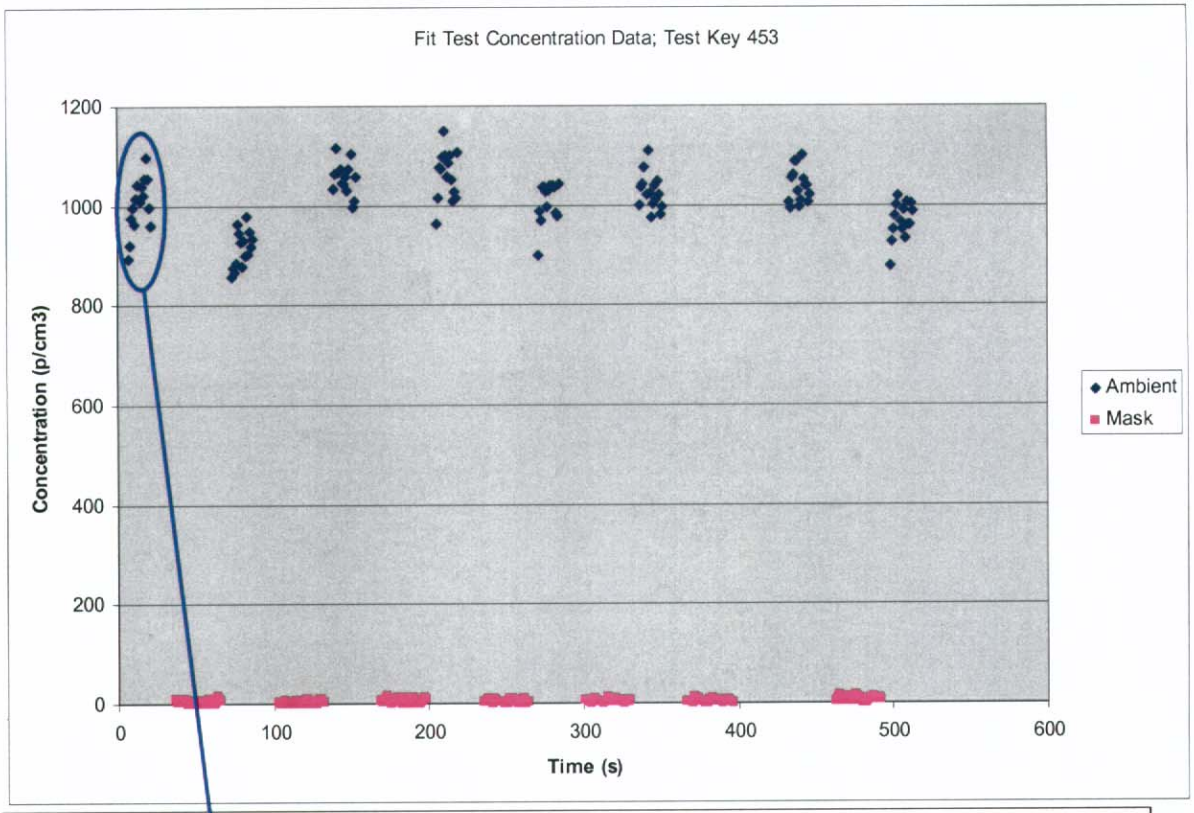
7. Challenge Concentration

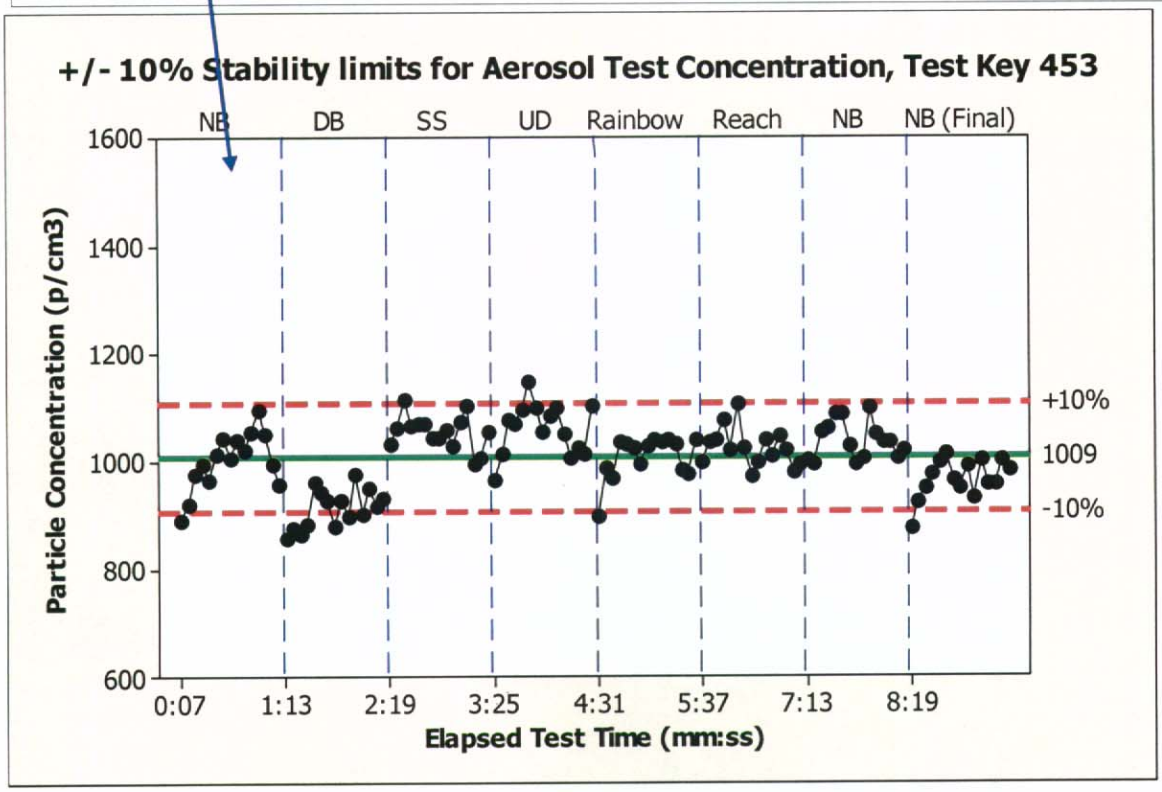
The use of a test chamber is not required. It is 3M's position that use of an enclosure (chamber) is imperative. It is 3M's experience that lack of an enclosure and resultant fluctuations in ambient concentration contribute to the variability of fit tests. NIOSH has indicated in other standards the importance of maintaining a stable challenge concentration. Data obtained during the NIOSH benchmark study indicates that the TIL procedure should have a similar requirement, yet it is absent in the proposal.

Section 3.2.4 of RB-APRS-ASRS-STP-CBRN-0352 states, "The chamber aerosol concentration shall not vary as a function of time more than ± 10 percent over the duration of a single test trial (approximately 15 minutes). The test chamber shall be capable of maintaining spatial uniformity within ± 10 percent in the vicinity of the respirator being tested." The need for such a requirement is best illustrated by consideration of specific examples from the NIOSH benchmark study.

An example of a test with an ambient concentration that is essentially stable is shown in the charts below for Test Key 453 of the NIOSH benchmark testing. The top chart shows the raw data from the test for both the ambient and in-mask measurements. In the bottom chart the in-mask data has been removed and the ambient concentration data is plotted in

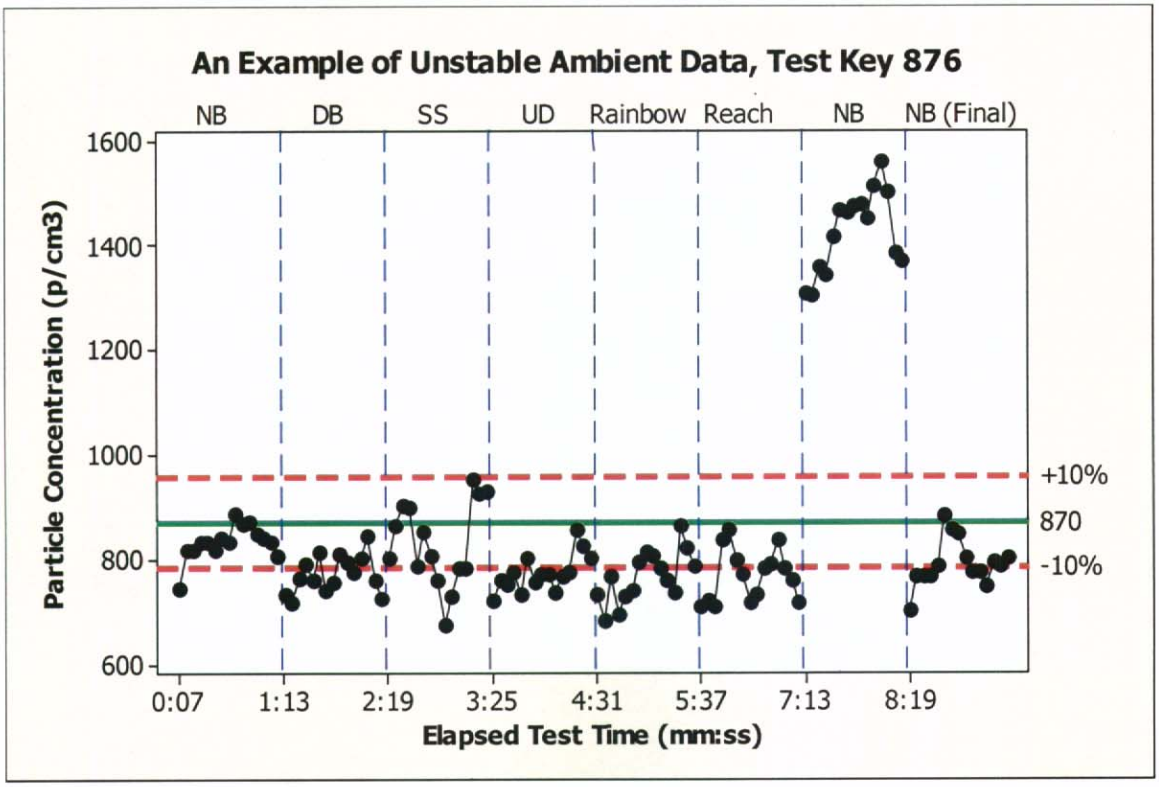
adjacent sections separated by a dashed blue line. The first set of 15 data points is from the ambient concentration measurement immediately before the first in-mask (Normal Breathing) sample. The second data subset was measured immediately prior to the in-mask sample for Deep Breathing, and so on for subsequent sections of the chart. The horizontal green line represents the average concentration over the entire test; the dashed red lines represent ±10% of the mean concentration. Although there are some points that fall outside the limits, the concentration is reasonably stable. These results suggest that maintaining the ambient concentration within ±10% of the mean concentration is feasible.



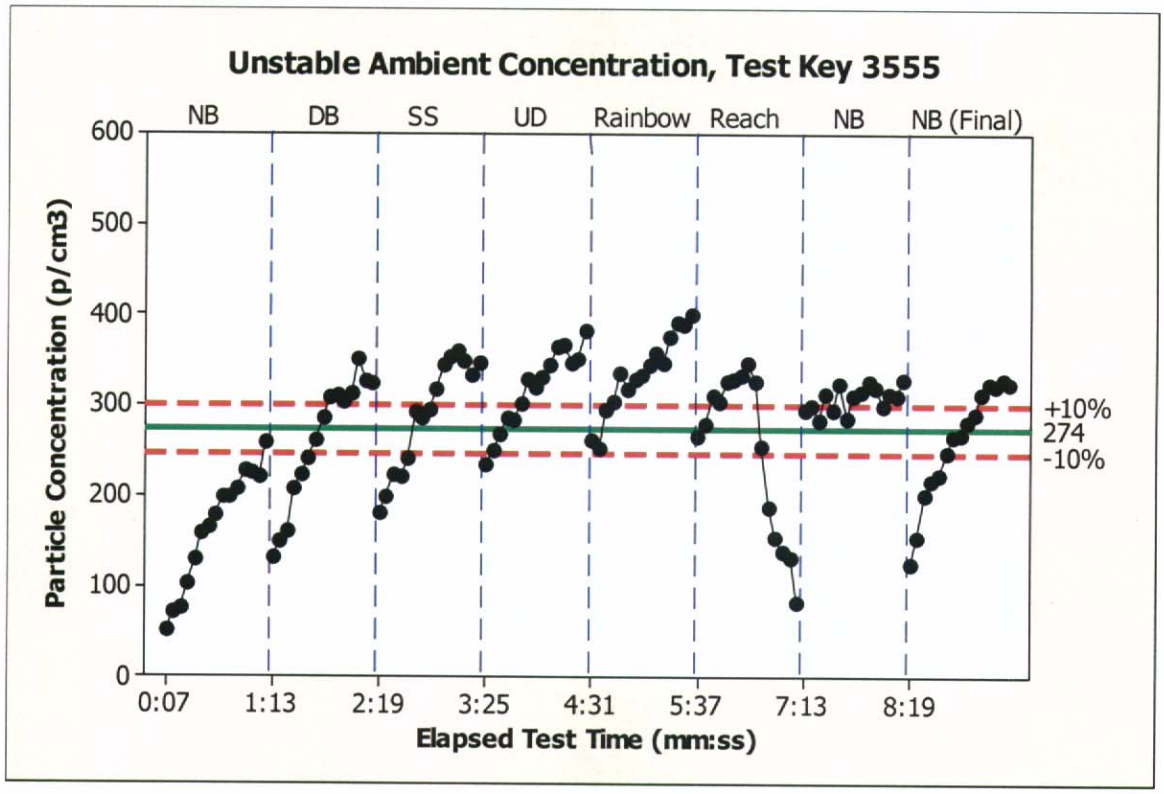


There are several examples in the benchmark data set in which the range of ambient concentrations exceeds ± 10 percent of the average. For example, in Test Key 876 the

ambient concentration exhibits a step change increase after the 'Reach to Floor and Ceiling' exercise (just prior to the 2nd Normal Breathing exercise) followed by a step change decrease for the final in-mask measurement of normal breathing. This raises questions as to whether the ambient concentration really did double in 90 seconds and then drop even more quickly or if it is an artifact of sampling. Interestingly, the test protocol provides a longer stabilization time immediately prior to the 2nd Normal Breathing sampling period (compared with the other sampling periods). This may indicate that the high concentration is the true reading and the protocol does not provide sufficient time for the other ambient concentrations to reach the correct level. Any change in the ambient concentration directly affects the fit factor by the same proportion, raising questions as to what is the true fit factor.



Another example of unstable ambient concentration data is from NIOSH Test Key 3555. In this case, the concentration never achieves stability for any of the ambient measurements except, possibly, in the case of the data immediately prior to the 2nd Normal Breathing exercise. For the other subsets of data the ambient reading changes continuously during the 15 second sampling interval. These data suggest again that the protocol does not allow enough time for the concentration to stabilize. The NIOSH test protocol must ensure stable readings. NIOSH needs to identify a person such as the test operator to be responsible for ensuring that the ambient concentration is stable prior to each exercise. NIOSH must institute steps to ensure that the data are reviewed for validity and how it will account for the variability of the data in the reported fit factors.



These are two examples among many Test Keys that exhibit some form of instability in the ambient concentration measurement. These examples highlight the need for some statement about the required stability of the ambient concentration as well as the precision for measurements. Given that the TIL is the ratio of the in-mask to ambient concentration, then any uncertainty in the measurement of the ambient concentration is directly reflected in the TIL. The effect is proportionately greater for respirators with low fit factors and for low ambient particle concentrations

Summary

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 only 53% of 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 enforcing the importance of conducting individual fit tests

In addition, NIOSH authors have stated that users would benefit more from using a respirator with good "fitting characteristics" without fit testing, than wearing a respirator with poor "fitting characteristics"[7] for which they have been fit tested. No data support this statement. 3M believes these statements along with the proposed "TIL" concept will only undermine the performance of fit tests by employers for respirator wearers. Also, NIOSH has never defined "fitting characteristics" in any objective way that a wearer could use.

Our data and NIOSH benchmark testing show wildly inconsistent fit test results on subjects within the same cell raising issues that need to be resolved before this concept should move forward.

If there is any validity to the NIOSH benchmark testing, we would expect results somewhat similar to our novice user data or better for the same respirator designs. Novice users were people that had never worn a respirator and were allowed to read the instructions before donning but were not given any training nor were improper donnings or user seal checks corrected.

Table 3. NIOSH Benchmark Testing Repeated on the Same Facepiece.

NIOSH 9211		NIOSH 9210	
NIOSH Benchmark Data		NIOSH Benchmark Data	
GM	40	GM	106
GSD	2.9	GSD	4.9
5th %ile	7	5th %ile	8

Table 4. Testing Comparing NIOSH Testing with "Trained" Wearers to that of Untrained Wearers on the 3M 1870 Respirator.

3M 1870		
NIOSH Benchmark Data		Novice Users Study 1870
GM	87	101
GSD	5.7	2.7
5th %ile	5	19

The 1870 is the same design as the 9210, and only differs in headband color.

Table 5. Testing Comparing NIOSH Testing with "Trained" Wearers to that of Untrained Wearers.

3M 8210			
	NIOSH Benchmark Data 8210	Novice Users Study 8210	NIOSH Benchmark Data1860
GM	65	181	95
GSD	4.1	3.5	4.4
5th %ile	6	23	8

The 1860 is the same design as the 8210, but differ in color.

The novice users achieved better fits than did the trained panel at NIOSH. These results don't make much sense. It seems that in general the NIOSH tests are even more variable than expected. The NIOSH results for the 1870, 9210 and 9211 should be very similar if the test is to have any predictive value. An observation during the Novice User study is that the motivation of test subjects seems to affect the test outcome.

We also have WPF data on three of these respirators:

- 9211--GM 233, 5th %ile 24, GSD 4 (this one failed NIOSH benchmark test!)
- 8210--50th %ile rank >1100, 5th %ile >71,
- 8511--GM 119, 5th %ile 19, GSD 3

(NIOSH benchmark GM 108, GSD 4.6, 5th %ile 9)

These results indicate that they are more protective than the APF of 10 would indicate, yet NIOSH testing indicates the fit on the panel would not be acceptable. In addition the variability in the NIOSH testing is no less than the variability in a WPF study, where nothing is controlled. A "TIL" test this uncontrolled is unacceptable as a certification test.

Using the NIOSH data, it seems one possible outcome of the TIL program would be prohibiting the sale of respirators that perform well in actual use conditions, such as the 9211 which has a WPF of 233 (GM) a fifth percentile WPF of 24. This potential outcome would result in a disservice to end users by removing adequately performing respirators from the market due to shortcomings in NIOSH's testing methods rather than in the product.

References

1. **Colton, C.E., A.R. Johnston, H.E. Mullins, and C.R. Rhoe** (1989) Workplace Protection Factor Study on a Full Facepiece Respirator. Paper presented at the American Industrial Hygiene Conference, St. Louis, MO.

2. **Dixon, S.W. and T.J. Nelson** (1984) Workplace protection factors for negative pressure half-mask facepiece respirators. *J. Int. Soc. Resp. Prot. 2(4)*:347-361.

3. **Gaboury, A., D.H. Burd and R.S. Friar** (1993) Workplace protection factor evaluation of respiratory protective equipment in a primary aluminum smelter. *Appl. Occup. Environ. Hyg. 8(1):* 19-25

4. **Myers, W., M.J. Peach, K. Cutright and W. Iskander** (1984) Workplace Protection Factor measurements of Powered Air-Purifying Respirators at a Secondary Lead Smelter: Results and Discussion. *Am. Ind. Hyg. Assoc. J. 45(10)*: 681-688.

5. "Assigned Protection Factors," *Federal Register 71*: 164 (August 24, 2006) pp. 50160-50165.

6. **Institute of Medicine of the National Academies**. (2007) Assessment of the NIOSH Head-and-Face Anthropometric Survey of U. S. Respirator Users. National Academies Press: Washington, D.C. p. 10.

7. **Coffey CC, RB Lawrence, DL Campbell, Z Zhuang, CA Calvert, PA Jensen** (2004) Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J. Occup. Environ. Hyg.*1: 262-271.