Dragon, Karen E.

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Sent: Friday, October 01, 2004 12:54 PM
To: NIOSH Docket Office
Cc: Newcomb, William E.; Boord, Leslie F.; Cristine Fargo; Craig Colton
Subject: TIL comments

NIOSH Docket Office:

Please see the attached ISEA comments on the NIOSH proposed Total Inward Leakage (TIL) Proposal. If you have any questions please contact me via email or call me at 703-525-1695. Thank you

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INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

Comments on Protocol for the Total Inward Leakage Testing of Half-mask Respirators

Guidelines for External Reviewers of Test Procedures and Protocols:

1. Are the procedures clearly stated and logically consistent? (Describe inconsistencies.) *Although the procedures are clearly stated, NIOSH has not disclosed how they will set the passing criteria (pass/fail level and passing percentage). NIOSH has not elucidated the statistical analyses that will be used in validating the protocol. It is extremely difficult to adequately evaluate the protocol without knowing the other details and criteria that will ultimately be used to certify respirators in accordance with these protocols.*

2. Is the test procedure consistent with the goals and aims of the test objectives? *Although the test procedure is consistent with the stated objective in the protocol, it is not consistent with the underlying goal expressed in the TIL concept, which is to set minimum criteria for manufacturers to ensure adequate fit of the respirators.*

3. Are the methods and analytic approach sound? *No. See discussions on sections 5 and 6.2.*

4. Are procedures described to protect human subjects during the testing? *Although the test procedure is consistent with the stated objective it is not consistent with the underlying goal which is to set minimum criteria for manufacturers to ensure adequate fit of the respirators.*

5. Will anticipated test results provide NIOSH with data necessary to justify potential modifications to existing standards? *No. NIOSH certified respirators that are presently on the market and have been properly fit tested to users do not need to be modified. The successful completion of the TIL test does not indicate whether a respirator can provide an adequate fit to a certain population. In addition, since the variability in these measurements will be great, it is questionable if the data will be adequate to justify modifications to the standards.*

6. Does the procedure provide a clear and consistent approach? *The procedure is clear, however, the interpretation of the test results is not.*

7. Can the methodology described be conducted in a time frame that would be considered reasonable to manufacturers? *This is hard to determine, as this will depend on NIOSH's ability to line up test panels. Based on the LRPL testing as part of the CBRN testing, it is clear that this can not be done in what we think is a reasonable time frame. The proposed testing is more extensive than the CBRN LRPL tests in that the test protocol requires three individual donnings for each respirator: in total, 75 tests for each respirator. While ISEA feels redonning is an important element in the test protocol, a total of 75 tests with 25 subjects seems excessive.*

8. Please describe concerns or inconsistencies. *The test protocol does not control for many variables making it virtually impossible to be a reproducible test. In addition, the potential cost of this test is a concern. The cost to NIOSH for the fit test volunteers alone is ($50 x 25 subjects = $1,250).*

9. Please provide additional comments that may be relevant to your evaluation of this test procedure and protocol. *See comments below.*

Protocol

p.3 I. A: The third paragraph indicates that human testing was done on all half masks equipped with particulate air purifying elements under 30 CFR 11. We believe this statement to be in error. Half mask respirators with dust/mist filters did not undergo human subject isoamyl acetate testing.

p. 7 II A: The protocol uses the term "protect" which is ambiguous. This term is not defined and other readers may define "protect" differently. This term needs to be changed to "meeting the required performance level" or "reduce the exposure of a contaminated atmosphere sufficiently, ..." No data are presented in this protocol that indicates protection levels will be measured.

Appendix A Consent to Participate in a Research Study

Page A-2 item 2 General Risks: The statement "Because the respirator has a mask, you may have some trouble seeing clearly". Is unclear and offers no guidance to users. Consider rewording to state, "Because the respirator is a mask, there may be vision clarity changes" We think NIOSH is trying to convey the fact the respirators may limit one's vision, the following is another possible suggestion to clarify this: "Be aware that wearing any respirator may effect your vision, and may take some getting used to."

Page A-8, TIL Testing Description: The sentence, "There are no added contaminants" is not clear. Either this sentence should be deleted or explained. It is already stated that the respirator will be tested in a room containing ambient air. NIOSH may wish to consider changing the wording to, "You will wear the respirator for about 15 minutes in a room containing normal air free of any contaminants".

The selection of participants for the panel, should include a statement that the fit test panel should not be prejudiced in any manner that could affect the fit test results. For example, a representative or family member of a manufacturer cannot participate on the fit test panel.

III. Use of information: Perhaps "America's workers" would be better than "American workers" as all workers should be protected, not just those that are citizens.

Appendix B Respirator Screening

Part A, Question 8 has no space to be checked as required by the question.

Part H, Past Medical History, p B-9: Item 2 says, "Was exercise performed? " Does NIOSH mean: "Was a stress test performed?" This question may need to be asked more clearly?

Appendix C Respirator Pre-Test Questionnaire

The need for the absence of facial hair and other conditions that interfere with the respirator face seal is not addressed in the protocol. A question in the respirator Pre-Test Questionnaire that requires the subject to report the last time that the face was shaved, should be included.

Appendix C-1 Pre-Test Questionnaire: Another question should be added to determine the last time the person smoke or ate. This would help assure that the person did not mistakenly smoke or eat within 30 minutes of the test.

Appendix F Total Inward Leakage Test for Half-Mask Respirators

It is not clear why the TIL (Total Inward Leakage) test was selected for use in this protocol. The TIL test determines penetration through both the filter and the faceseal. As discussed below, there are problems and limitations with using the Portacount Plus instrument for this type of test.

The Portacount Plus uses ambient air, or rather the dust particles present in air, as the test agent. The status of the test atmosphere will vary to a great extent from minute to minute in any local environment, both as to concentration and the particle size distribution. There are variations from one location to another. Such variations are likely to make it difficult or impossible for both the manufacturers and NIOSH to attain comparable results when testing the same model respirator.

Varying environmental conditions make it impossible to control the size distribution of the particles measured. This becomes especially critical when using 95 or 99% filters. Filter penetration, and thus TIL (Total Inward Leakage), will change as the test atmosphere changes. In other words, there could be large variations in the TIL factor measured for each donning of the respirator caused by the uncontrolled particle size distribution in the ambient air.
In addition, different people will result in different filter penetration. Thus using TIL instead of fit will add greater variability to the measurement. In fact variability will be introduced from:

- Uncontrolled test atmosphere,
- Changing filter penetrations as a result of atmosphere variability and test subject,
- Limitations on measurement to ratios of 1000,
- Inability of 1 person in a grid to predict fit for everyone in that grid,
- Probe placement and design, and
- Donning variability.

Depending upon the size distribution of the particles present at the time of the test, the TIL factor measured may vary greatly even though there has been no change in the fit of the mask, nor in the filter efficiency.

Using a 100% efficiency filter with the same facepiece as above, virtually the entire measured leakage will be the result of the faceseal and not the filter, providing very different test results for the same facemask. As a result comparisons of the same face mask with different filters becomes meaningless.

Issues:

- How do we compare the same facepiece with different filters? Will NIOSH set different criteria for the same facepiece that uses a range of filters?

- How do we accurately compare the variations using the same filter for multiple donnings without lowering the required TIL?

- The variations noted are not a function of the respirator, but rather the challenge (dust laden ambient air). Why introduce this variable?

There are two ways to remedy this inconsistency. One would be to set different criteria for each respirator combination, i.e. each level of filter which fits on a respirator would have to be tested and different acceptable TIL levels set for each of these combinations. We believe this would require a much greater amount of data collection and work than necessary for the same facepiece. It would result in higher standard deviations for each combination of filter and facepiece.

Regardless of any testing that NIOSH will perform using this protocol, it is still necessary for the employer to perform a fit test on each wearer to ensure that the respirator selected fits adequately in the workplace. Because bench certification tests have already been performed to prove the filter performance, this protocol should be revised to provide data on the quality of the faceseal, not TIL.

An alternative and more practical approach is to test with the Portacount Plus instrument equipped with the Companion and utilize an NaCl generator in a test room. This combination produces much more controlled conditions for testing. First the TSI NaCl generator is used to create a wide range of particles. The Portacount Companion then removes all particles except those in the 40 nanometer (0.04 micrometer) range. Most filters efficiently capture these super small particles because they operate in the size region where diffusion capture predominates. Any variation between 95%, 99%, and 100% filters is thereby minimized. This is essentially testing facepiece fit only, generating Fit Factor data. Using this approach will result in smaller standard deviations. The Portacount Plus with Companion should work for any type of respirator fitted with any particulate filter.

- Section 2.1: The protocol indicates the equipment to be used is a CNC in an ambient atmosphere. This is not appropriate as the "ambient atmosphere" is not sufficiently stable or reproducible from location to location and day to day to allow for respirator manufacturers to pretest product as required by 42 CFR 84 with the expectation that NIOSH will be able to reproduce the results. Secondly, this adds a variable to the measurement that is compounded by the differences in filter efficiency of the products being tested when an uncontrolled atmosphere is used. Filter penetration will change with each test even if all other variables remain the same.

  This section also mentions this test will determine the level of protection afforded by the respirator. This statement is very ambiguous, as the "type" of protection is not indicated. If this is to relate to "workplace protection" no correlation of test results, i.e., laboratory protection" with this equipment and test method to the workplace were provided. We suggest the statement be changed to something like "the laboratory performance level" instead of "level of protection."

- Section 3.1.1 This section indicates the Portacount Plus and associated facepiece adapters will be used. There are no facepiece adapters appropriate for filtering facepiece respirators. All of the adapters for use with the Portacount require replaceable filters. Filtering facepiece respirators will need to be individually probed in order to be tested in the manner described. No description of respirator probing methods or probe specifications is indicated. See also comment at Section 4.5.

- Section 4.3: We believe respirator manufacturers have provided practical means for sizing the respirator by requiring the wearer to don them, perform user seal checks and pass a fit test prior to use.

- Section 4.4: The TIL protocol implies that grid size will be used to select the respirator. However, current respirator manufacturer information does not indicate which grid the respirator is to fit. Using face grid size for selection requires all respirator users to purchase sets of calipers to make the measurements. It is hard to imagine that NIOSH would contemplate complicating the selection procedure this much when earlier it indicated that particle size sampling was too difficult to require for filter selection.

- Section 4.5: For an elastomeric half mask respirator, the procedure should use a manufacturer's mask that is factory-probed, a manufacturer's probe adapter kit or filter, or some other manufacturer approved means of setting up the mask to be fit tested with the PortaCount®. If NIOSH does the probing on an elastomeric half mask, there is a chance that the probe may not be properly inserted, resulting in possible leakage around the probe and therefore, erroneous test results. If NIOSH insists on the technician doing the probing, the manufacturer must be permitted to provide instrumentation and/or oversight to assure that the probing procedure does not result in a mask that leaks around the site of the probe.

- Section 5. Procedure:
  - An important step must be added for the technician to evaluate facial hair and physical deformities on the test subject. Even one day's heavy facial hair growth on a male subject can cause fit testing failure.
  - Section 5.6: Exercises, especially new ones like "reach the floor and ceiling," need to be more specifically explained in the protocol to define the fitting extremes that the respirator will be subjected to (so that a manufacturer can design to meet the fit challenge). That includes specifying cycle times. Also, what is the reason for "reach the floor and ceiling" exercise as opposed to "jogging in place" or "bending over"? There should be a justifiable reason to deviate from established protocols.
  - Grimace: The protocol does not describe how the results form the grimace exercise will be handled in the data collection. Section 6.1 indicates it will be calculated in to the results. The concern is that the reason for the addition of this exercise to test protocols has been lost with time. Historically, it was never expected that the respirator would not leak during this exercise. In fact, it was expected to leak grossly during this exercise. This exercise was performed prior to the second normal breathing exercise to see if when the face seal was broken, if would re-seat to a leakage level comparable to the first normal breathing. The results were never to be used in the calculation.[1,2]

1. Lowry, P.L., L.D. Wheat, and J.M. Bustos: Quantitative fit-test method for powered air-purifying respirators. *Am. Ind. Hyg Assoc. J. 40*:291-299 (1979).

2. Respirator Studies for the National Institute for Occupational Safety and Health, July 1, 1974-June 30, 1975. LA-6386-PR. August 1976. p. 39

- Section 6.2: Filter class, e g., P95, N 100, should also be recorded if TIL is to be determined.

Appendix G NIOSH – NPPTL Respirator Fit Test Panel

First, the title of the Appendix indicates confusion about what the test is measuring. Most of the protocol refers to TIL, yet this appendix refers to fit testing. While we believe fit testing should be the measurement instead of TIL, the title of this appendix is not consistent with the rest of the document. It should be called the "Respirator TIL Test Panel" or the protocol changed to assess fit to be in agreement with the rest of the document.

The new "fit test" panel expands the size ranges from the original Las Alamos panel. It incorporates a wider range of facial fit challenges to the respirator facepiece. Manufacturers offer a number of different styles of face seal on their facepieces. The early OSHA standards identified that different models and/or manufacturer's brands of facepiece should be offered to the employee. This would ensure a range of fit and comfort to the individual respirator wearer. It appears that this standard is mandating that every respirator model must fit everyone in the panel approximately the same. This approach raises several questions:

- Is this saying that any tested medium facepiece would provide any medium face an effective fit?
- Could this lead to less workplace fit testing because organizations believe that NIOSH has already done it for them?
- Will this force manufacturers to consider designing their facepieces to pass the tests rather than allow for variable designs which would also address the comfort of the wearer and differences in ethnicity?
- What plan does NIOSH have for the employee whose face size is not included in the grid, but yet the respirator may fit?

A revised Controlled Negative Pressure fit test has recently been identified as an appropriate fit test protocol. It is not addressed in this standard, but we encourage NIOSH to perform correlation testing.

The TIL Draft indicates that if a manufacturer offers 3 sizes of facepiece, the medium must also fit part of the small users (panels 3&4) as well as part of the large panel (panels 7&8). We have seen during testing at Edgewood that this concept has been applied for the LRPL as well. In a number of those instances, the same individual who fits into those cross over panels is expected to get an equally effective fit in both the small and medium facepiece or in the medium and large facepiece. In fact in several cases, because a smaller or larger subject could not be found the same subject would be tested in *two* sizes of the same model of facepiece. In the real world, an individual would first be tested in a size they select as being most comfortable and if it did not fit, they would then be offered a smaller or larger size.

A broader face size panel, may compel manufacturers to offer additional sizes. If a manufacturer offers 4 sizes of facepiece, which panels will be required for each size?

Since the manufacturer must stipulate which boxes the respirator is designed to fit, how does a user identify which boxes they fit into?

We believe that the goal of standards should be that users achieve a good fit with their respiratory protective device, not that they should mandate which blocks a given facepiece will fit. There is a wide range of facial features and conditions that would affect facepiece fit. This proposal is attempting to mandate designs which fit universally in lieu of the requirement for individualized face fitting as a part of a respiratory protection program.

Recommendations/Summary
To summarize we believe:

- Face fit measurement would better effectuate the intent of the "concept" than TIL tests.
- Face fit measurement will reduce the variability in the test measurement as opposed to the TIL measurement.
- A controlled generated atmosphere must be used.
- Filter penetration needs to be a consideration between filter classes.
- Pass/fail levels and statistical treatment of the data needs to be identified in order to evaluate appropriateness of the test method.
- Use of the panel will result in respirators designed to fit the panel instead of the work force. This has already occurred as a result of using the Los Alamos panel to some degree.
- The exercise, "Reach for the ceiling and floor" should be changed to bending over.
- Grimace results should not be used in calculating the overall measurement.

Thank you for your consideration.

Sincerely,

Janice C. Bradley, CSP
Technical Director