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From: cecolton@mmm.com
Sent: Monday, October 19, 2009 1:23 PM
To: NIOSH Docket Office (CDC)
Cc: Szalajda, Jonathan V. (CDC/NIOSH/NPPTL)
Subject: Comments to docket #168

Attachments: Written comments for TIL Other concepte October19 2009.pdf



Written comments
for TIL Other...

(See attached file: Written comments for TIL Other concepte October19 2009.pdf)

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October 19, 2009

NIOSH Docket Officer
NIOSH Docket # 168
Robert A. Taft Laboratories MS-C34
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**RE: Docket #168, Total Inward Leakage for Respirators other than
Filtering Facepiece and Half Masks**

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 and fit of respirators and assisted customers with the development and administration of effective respirator programs. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to offer the following comments and recommendations regarding the draft Concept on Total Inward Leakage (TIL) for Respirators other than Filtering Facepiece and Half Masks published August 25, 2009.

3M supports NIOSH in its effort to update the requirements for respirator performance. We appreciate the opportunity to add our comments to the docket and look forward to the development of a fair, protective, and useful concept.

NIOSH Docket Officer
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Sincerely,

A handwritten signature in black ink, appearing to read "Robert A. Weber". The signature is written in a cursive style with a prominent initial "R".

Robert A. Weber
Laboratory Manager, Regulatory Affairs
3M Occupational Health & Environmental Safety Division

3M Comments on Total Inward Leakage for Respirators other than Filtering Facepiece and Half Masks dated August 25, 2009

Questions for Consideration

At the September 17, 2009 public meeting, NIOSH posed the following questions for consideration and discussion and requested specific input.

1. *Should the TIL pass/fail be based on the type of respiratory inlet covering, the intended use of the respirator or other?*

The TIL should be based on the type of respiratory inlet covering for respirators within a specific type, for example PAPRs. Workplace protection factor studies (WPF) have shown that the most significant variable affecting protection has been the respiratory inlet covering design and **not** the mode of operation, the type of filters (where appropriate) being used, or the work being performed. The OSHA APFs are based on the respiratory inlet covering within a respirator classification. While the correlation of the proposed TIL to APF has not been established, it would be reasonable for them to be based on the same criterion because they both look at total respirator performance.

For example, WPF studies on negative pressure respirators with half facepieces and full facepieces show it is not the mode of operation, but rather the facepiece that is important. The WPF values of full facepieces are considerably different than those of half facepieces.^(1,2)

For powered air purifying respirators (PAPR) which have the same minimum airflow requirement, WPF studies have shown that it is the respiratory inlet covering, rather than the air flow that is important.⁽³⁾ One WPF study on a PAPR with a loose fitting facepiece (see definition in ANSI Z88.2) found a fifth percentile WPF of around 53. When the respiratory inlet covering for this respirator was converted to a loose fitting helmet (again as defined by ANSI Z88.2) and tested in the same environment on the same workers the investigators found a fifth percentile of over 1000. The respiratory inlet covering was the only variable factor.

WPF studies conducted on the same half facepiece respirator with different filters and cartridges found the fifth percentile WPFs were not different.^(4,5)

In WPF studies with filtering facepieces where the same respirator has been studied in different work environments, including different work levels, the fifth percentile WPF values were not significantly different.^(6,7) These studies are all in the OSHA docket on APFs and are among the studies used for the basis of OSHA's APF rulemaking.

2. *Are there any other test agents that can be used which will work for some or all types of respirators that are safe, environmentally friendly and can be accurately measured at the desired concentration?*

Equipment has been used for measuring other test agents like polyethylene glycol (PEG), and diethyl hexyl sebacate (DEHS) with better sensitivity than that currently used by NIOSH. In addition, one of the potential candidates for consideration by NIOSH is not environmentally friendly. Sulfur hexafluoride has been identified as a "greenhouse" gas in the Kyoto Protocol. Sulfur hexafluoride should not be considered.

3. *Is there test equipment available that can reliably measure the concentration of the test agent(s) of choice that are not overly expensive to own, operate, or maintain?*

No. For high performing devices (i.e, respirators with high APFs) you need equipment that has high sensitivity and a wide dynamic range. This type of equipment is expensive.

4. *Should NIOSH consider accepting TIL test results from independent laboratories?*

If this means NIOSH would seek assistance from independent laboratories for doing its testing, then this should only be allowed if the independent laboratory has demonstrated competency. This should clearly not eliminate, however, the requirement for the manufacturer to provide pre-submission TIL test data. NIOSH will need to perform correlation studies for all of the test materials if independent laboratories are permitted to perform TIL testing.

5. *Should the standard set of exercises employed by fit testing process be used for all TIL testing, or should it be different for various types? Why?*

The exercises should be based on the type of respiratory inlet covering on the respirator. For loose-fitting respiratory inlet coverings, i.e. hoods, helmets, loose-fitting facepieces, and suits, this means the grimace exercise, which is designed to assess any break in the seal between the respirator facepiece and the face, is not appropriate here and should be eliminated since it provides no meaningful data. Similarly, it is of no use for tight-fitting hoods and helmets for the same reasons. Running in place (while not proposed by NIOSH, this exercise has been used) is also not appropriate for supplied air respirators because the distance a wearer run is limited by the hose length and by the fact that most workplaces prohibit running for safety reasons. In fact, running is questionable for any respirator. We believe NIOSH should reserve proposing exercises to future versions of this concept where it can be dealt with more appropriately.

6. *Do the options for available respirators dictate what exercises can be done?*

Yes. See comment above.

7. What will be the strategy for the placement of sample ports for other classes of respirators? Where will the sample point terminate with respect to the test subject for each class of respirator?

The sampling concerns are essentially the same for all respirators. For example, one should sample at the same location in a full facepiece regardless if it is a negative pressure, powered air purifying, or supplied air respirator or an SCBA. If there is a nose cup sampling should be conducted inside the nose cup. All respirators should be probed midway between the nose and mouth on the midline in order to collect a non-biased sample. Ideally this probe will also be as close to the face without the lips interfering with the sample. Some investigators have used canulas in which claims have been made that the canulas get the same result with the probes, but they are easier to use and lighter in weight so there is less of an effect on the respirator by using it.

Specific Comments on the Concept

Sources of Inward Leakage

In the first paragraph of this section, NIOSH does not mention face seal leakage as a part of inward leakage. Face seal leakage, however, is addressed under supplied air respirators. To clear up any questions, NIOSH should define Total Inward Leakage. It is also not clear if the measurements on negative pressure full facepiece respirators will be total inward leakage or only fit leakage. If this is the case, then calling this total inward leakage is a mistake. We believe NIOSH has made this mistake with the naming of the tests for filtering facepiece and half mask respirators. Those tests refer to testing N95 respirators with the Portacount Companion which eliminates (reduces to a small value) filter penetration for practical purposes, because it only measures particles in a given size range. Knowing this, it is unclear why looking at just face seal leakage is called Total Inward Leakage by NIOSH. NIOSH personnel can verify this by testing an N95 respirator on a person with the Portacount, which measure all particles sizes, and then without removing the respirator, test the same person on the Portacount with the Companion. One will find that the inward leakage will be higher when fit tested with the Portacount than with the Portacount-Companion combination. Therefore, the latter method can not be total if the inward leakage amount is lower.

1. Selecting test subjects

In this section, NIOSH groups types of respiratory inlet coverings. We believe NIOSH has confused these terms, and suggest the following groupings instead:

- a) Tight fitting full facepiece. "Full" needs to be added in order to indicate the method applies to full facepieces only because NIOSH is working on a different method for half masks. Using just "tight-fitting" creates confusion because it also describes the half masks and filtering facepiece respiratory inlet coverings.
- b) Loose-fitting respiratory inlet coverings – hoods and helmets

- c) Loose-fitting respiratory inlet coverings – loose fitting facepieces. This category of respiratory inlet covering needs to be recognized by NIOSH separately from loose-fitting hoods and helmets because OSHA standards recognize it as a different inlet covering with a different performance value. The same performance requirement for both categories is not appropriate. Using these two categories (b and c) allows for separation when discussing these types of respiratory inlet coverings.
- d) Tight-fitting hoods and helmets ~~neck dam respiratory inlet covering~~. The use of “neck dam” is not appropriate for a couple of reasons. First “neck dam” is not a type of respiratory inlet covering. “Neck dam” refers to the type of neck seal typically provided on a tight-fitting hood or helmet. Secondly, the use of neck dam is a descriptive term for the type of seal making this term a design specification instead of a performance specification. “Tight-fitting” makes the listing a performance specification which can be measured by fit or inward leakage.
- e) Loose fitting body suits. NIOSH is working on a concept for respiratory protective devices with this type of respiratory inlet covering so it should be included in this concept. It should be listed separately from the other loose-fitting respiratory inlet coverings as the performance requirement will probably be different.

Page 3, Line 8. It states “...to be taken to determine their panel placement...” It should be changed to “to be taken to determine their placement in the panel...”

2. Test configurations

Configurations should be defined or perhaps the word respirator assembly could be used which is a term that is already in use.

3. Test agents

The determination that salt was best was a NIOSH determination. There have been other determinations made where salt was not thought to be the best agent so this should be specifically identified as a NIOSH recommendation.

Corn oil has its advantages and disadvantages. If testing respirators with corn oil, you will be limited to testing only R- or P- series filters on particulate respirators. This also points out that NIOSH may not be sure what they are planning on measuring: total inward leakage or just face seal leakage. With “heavy” use of corn oil, slipping hazards can be introduced as well as other house keeping issues.

It is mentioned that the respirator will need to be modified in order to conduct the test, but the modification should be minimal such that the results are not affected. This requirement eliminates sulfur hexafluoride as the modification has to prevent SF₆ penetration through the filters. It should only be acceptable for atmosphere-supplying respirators.

4. Test protocols, a) Test performance

We believe NIOSH needs to rethink their statement about the establishment of TIL requirements warranting change in the OSHA Assigned Protection Factors (APFs). It took OSHA 24 years to establish APFs. It is naïve on NIOSH's part to think a laboratory test that has not been correlated to the workplace will result in changes to APFs set by OSHA. Rulemaking is not necessarily quick or easy. NIOSH needs to rethink what this means for its performance requirements. This is a laboratory test that may be only evaluating fit, such as the benchmark testing on half masks, and no level to protection has been established. The term NIOSH has used in the past, LRPL (Laboratory Respirator Protection Level), at least describes its limitations in that it only applies to the laboratory. It is no different than a laboratory filter test in many ways. Its relationship to protection in the workplace is unclear as well. The APF does not change when different levels of filters are placed on the respirator.

b) Test exercises

The proposed exercises are not appropriate for all of the respirators that NIOSH proposes to test. Grimace is not an appropriate or needed exercise for loose fitting respiratory inlet coverings.

We suggest that the time limitation be removed in the "turning the head" exercise and "moving head up and down" exercise to prevent the test subject from hyperventilating. At this pace some people start taking breaths rapidly because the time to move the head from side to side or up and down is so short. We encourage using the OSHA language. OSHA states, "The head should be held at each extreme momentarily so the subject can inhale at each side" and "The subject shall be instructed to inhale in the up position (i.e., when looking at the ceiling)" for "side to side" and "up and down," respectively. This allows the subject to take their time and not over breathe or deep breathe.

References

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3. Stokes, DW, AR Johnston and HE Mullins. Workplace protection factor study on a powered air-purifying respirator. Paper presented at the American Industrial Hygiene Conference. Montreal, Quebec, Canada June 1987.
4. Weber, RA and HE Mullins. Measuring performance of a half mask respirator in a styrene environment. *AUHAJ* 61:415-421 (2000).
5. Colton, C.E., H.E. Mullins, and J.O. Bidwell. 1994. Workplace Protection Factors of a Half Facepiece High Efficiency Filter Respirator in Different Environments.

6. Colton, C.E. and J.O. Bidwell. 1999. A Comparison of the Workplace Performance of a Dust/Mist and Two N95 Particulate Half Facepiece Respirators on Half Facepiece Respirators. American Industrial Hygiene Conference and Exposition 1999. Abstract #34.
7. Janssen, L, J Bidwell and N McCullough. Performance of and N95 filtering facepiece respirators in a grinding operation. *J. Int. Soc. Respir. Prot.* 24:21-31 (2007).