

PUBLIC SUBMISSION

As of: October 01, 2010
Received: September 30, 2010
Status: Pending_Post
Tracking No. 80b63658
Comments Due: September 30, 2010
Submission Type: Web

Docket: HHS_FRDOC_0001
Recently Posted HHS Rules and Notices.

Comment On: HHS_FRDOC_0001-0078
Total Inward Leakage Requirements for Respirators

Document: HHS_FRDOC_0001-DRAFT-4524
Comment on FR Doc # 2010-09085

Submitter Information

Name: Ching-tsen Bien
Organization: LAO Consulting, Inc.

General Comment

See attached file(s)

Attachments

HHS_FRDOC_0001-DRAFT-4524.1: Comment on FR Doc # 2010-09085
HHS_FRDOC_0001-DRAFT-4524.2: Comment on FR Doc # 2010-09085

LAO Consulting, Inc.
Industrial Hygiene
1855 West Queens Ct.
Crofton, MD 21114
410-721-3468

September 30, 2010

Electronic Submission

NIOSH Docket Office
Docket No. 036
Robert A. Taft Laboratories
4676 Columbia Parkway
MS-C34
Cincinnati, OH 45226

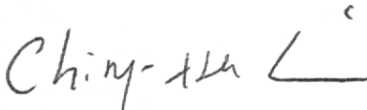
Dear Sir or Madam:

Subject: Comments on Docket No. 036

I am submitting my comments on the proposed regulation of total inward leakage (TIL) requirements for half-mask air-purifying respirators. Based on the review of comments received on the NIOSH docket on the TIL, there are few submissions from industrial users or respiratory professionals. The bulk of comments are submitted by the respirators manufacturers. NIOSH should extend the commenting period and actively solicit comments from users, industrial hygienists and safety professionals that form the members of the ANSI Z88 Respiratory Protection committee and the AIHA Respiratory Protection committee.

I appreciate the opportunity to submit comments on this proposal. Please contact me if you have any questions regarding my comments.

Sincerely,



Ching-tsen Bien, P.E., CIH

LAO Consulting, Inc.
Industrial Hygiene
1855 West Queens Ct.
Crofton, MD 21114
410-721-3468

**Comments on the NIOSH Proposed Rule on Total Inward
Leakage Testing of Half-mask Respirators**

On page 56149 of the October 30, 2009 Federal Register, NIOSH encourages public comments with four questions on the total inward leakage (TIL) proposal. These questions mainly address the economic cost of implementing the proposed TIL testing regulations. I would like to address other issues that are important in determining the effectiveness of approved respirators for your consideration.

A. The TIL Concept

The filter testing regulation in 42 CFR 84 is a vast improvement over the silica dust/mist testing methods proscribed in 30 CFR 11. Particulate filters are tested against a 0.2 μm NaCl aerosol at a very high flow rate of 85 liters per minute. The filters are also preconditioned at high temperature and humidity before testing¹. The filter penetration is measured in real time. Under these strict test conditions, even the least efficient N-95 class filters would allow minimal penetration under most use conditions. There is no need to test the filter leakage. NIOSH should devote effort in evaluating facesal leakage of approved respirators. The test aerosol would minimize the filter penetration at the size range of 0.6 to 1.0 μm range.

B. Testing Instrument and Aerosol

The TSI PortaCount/N-95 Companion is the required instrument for measuring the TIL. The PortaCount was developed under a contract with the U.S. Army to fit test military personnel for combat duties. It is a miniature version of the TSI's condensation nuclei counter. Compactness, ease of use, and lack of a test enclosure are requirements for a field equipment. Using the ambient aerosol as a challenge is an advantage since no aerosol generator is required. As a measuring instrument for respirator certification, however, PortaCount has the following limitations:

1. The respirator fit testing is a point event; it only requires that the particle concentration is sufficient for conducting a test. For respirator certification, the size and concentration of the test aerosol must be stable and uniform inside the test chamber. However, the number of particles in the ambient varies from place to place and from time to time. This variation would affect the test results. The Occupational Safety and Health Administration (OSHA) is one of the largest users of PortaCount. Based on my observations when I worked for OSHA, the PortaCount readings fluctuated when the fan of the ventilation system was turned on or off in the test room. Also, the variation of ambient particle concentrations would affect the test results. If the ambient particle concentration varies between the

NIOSH and the manufacturer's testing locations, it would be difficult to resolve the issue when one respirator passes the test at the manufacturer's test site and fails the test at the NIOSH laboratory. Also, high humidity would change the particle size of the sodium chloride aerosol generated by the required TSI particle generator. There is no requirement to specify the humidity range of the test site.

2. Fit testing of half-mask respirators is specified in the proposal. It includes elastomeric facepiece and filtering facepiece respirators. The same equipment would be used for testing both types of respirators. The Portacount companion has been selected as the measuring instrument. The Portacount Companion was specifically developed for fit testing filtering facepieces. The maximum fit factor achieved is 200. The Lawrence Livermore Laboratory has conducted fit testing of various makes of half-mask elastomeric and filtering facepiece respirators². The test results indicate that three tested elastomeric respirators achieved fit factors between 1,800 and 2,200. Warren Myers of West Virginia University has conducted a fit testing study on six commonly used half-mask respirators³. The test results indicate that many test respirators can achieve a minimum fit factor over 10,000. Both studies use the Portacount and the same exercise regimen in the TIL proposal. It appears that a 200 limit of maximum fit factor achieved by the Portacount/ N-95 Companion is not able to differentiate between the good and poor performing respirators. The TSI instructions for the particle generator specify that it can only be used in a small room. However, it has not defined what "small" means. The room size controls the particle concentration and it can affect the test results. In the comments submitted to the TIL docket, TSI Inc., the manufacturer of the PortaCount/N-95 companion, did not recommend the use of their product for TIL measurements⁴.

The generated aerosol and the controlled negative pressure (CNP) methods are other available quantitative fit testing methods. The CNP method cannot fit test filtering facepieces. The generated aerosol is commonly used in respirator performance studies. The assigned protection factor (APF) values listed in the NIOSH Respirator Decision Logic and the OSHA APF standard are derived from the generated aerosol system using a forward scattering photometer for penetration measurements. NIOSH should consider adopting the generated aerosol system, using the system developed by the Lawrence Livermore National Laboratory (LLNL)⁴. The test aerosol should have a concentration of 15 mg/m³ with a variation of less than 20% across the test chamber. The mass median aerodynamic diameter (MMAD) of the test aerosol should be between 0.6 to 1.0 µm with a geometric standard deviation of less than 2.0. There are criticisms on the generated aerosol systems. However, these individuals have not used a good generated aerosol system developed by the Los Alamos National Laboratory (LANL) or the Lawrence Livermore National Laboratory (LLNL). They used high quality aerosol generator and photometers. The LLNL even utilized an impactor to minimize lung deposition of testing aerosols.

It should be noted that the TSI Inc., the manufacturer of the instrument specified by NIOSH in the TIL proposal, made comments on the use of PortaCount N95-Companion as the instrument required in the NIOSH TIL proposal⁵. TSI stated that "The PortaCount N95-Companion was not designed or intended for laboratory or respirator certification purposes. We see no reason for NIOSH to specify the use of the N-95 -Companion for respirator certification purposes since instrumentation with higher precision is readily available. Examples include the Portacount alone or photometer based

instrumentation like NIOSH currently used for CBRN respirator certification. Indeed oil-based /photometer fit test systems are widely considered to be the "Gold Standard." TSI is flattered by NIOSH's selection of the PortaCount /N95-Companion for the TIL program, but we think that the Gold Standard would prove to be a superior choice. The TIL measurements are meant to determine total human dosage. As such, TIL must be a mass -based measurement made with mass-based instrument such as a photometer. . . There is no accurate way to relate particle concentration to mass concentration." TSI also stated that the PortCount /N-95 companion is lower cost than the generated aerosol/photometer system (the Gold Standard). However, the instrument cost is much less than the program cost for conducting the required number of fit tests. Specifying the best test instrumentation available will better serve all involved over the long run. At the OSHA hearing on the revision of the respiratory protection standard, Robert da Roza, OSHA's expert witness, stated that: "The photometer response is not linear with number of particles. It's linear with basically the volume or the mass of the total particles that you have." ⁴

C. Exercise Regimen

Three types of respirator performance evaluations methods are available: quantitative fit testing (QNFT), simulated workplace protection factor testing (SWPF) and workplace protection factor (WPF) testing. The Quantitative fit testing using the generated aerosol was developed by the Los Alamos Scientific Laboratory (LASL) to determine the performance of different classes of respirators. The test only evaluates the face seal leakage or fit of the respirator by using the high-efficiency particulate air (HEPA) filters, which permit very little leakage by the submicrometer test aerosol. The exercises performed by the test subject are sedentary static tests similar to the exercises required in the TIL proposal. Since workers perform a variety of task involving dynamic body movement and at higher work rate, the QNFT or TIL test results may not predict actual respirator performance in the workplace. In the mid 1980s, NIOSH proposed to use WPF as a part of respirator certification program. In response to the comments received, NIOSH held a public meeting on this subject in 1991⁶. The presentations and discussions exchanged at the meeting reached the following conclusions^{7,8}:

- While there have been several field studies: test protocols are different in most cases; environmental test conditions are poorly defined; the number of test subjects and usable data is limited for any single study; particle size is not always measured even though particle size and contaminant of concern seems to influence the measured WPF.
- This raises questions regarding the interpretation of any single study and the comparison of different studies
- It is not clear that test results can be extrapolated between different situations.
- Field testing would introduce: uncontrollable test conditions; a high level of uncertainty; and a large number of poorly defined variables.
- To conduct meaningful workplace testing of respirators, testing needs to be standardized. This provides a level playing field for all manufacturers and allows the regulator and the user to interpret the results and make comparisons. Standardized tests would prevent manufacturers from shopping around for a workplace that will provide test conditions that are favorable to their product. These needs are best met by controlled and reproducible simulated workplace testing.

Based on these conclusions, NIOSH decided not to require WPF study as a part of certification program.

In the mid 1980s, the Occupational Safety and Health Administration and the Nuclear Regulatory Commission (NRC) jointly sponsored a simulated workplace testing program⁹. The study was performed by the Los Alamos National Laboratory (LANL). The purpose of the study was to determine the respirator performance under extremes of environmental conditions when workers perform tasks similar to actual work situations. Both the negative pressure half-mask and full facepiece respirators, and positive pressure respirators, such as tight and loose fitting facepiece powered air-purifying respirators (PAPR), supplied air hood and pressure demand supplied air respirator (SAR) were selected for testing.

The study was performed in a large controlled environmental chamber, which had enough space for two test subjects to perform, at the same time, a variety of exercises that simulate actual work conditions such as step up and back down a two-step platform; move oiled gravel between two bins; pound nails into an overhead board; move and lay cinder blocks; and pound a board with a sledge hammer. Each exercise lasted between 5 to 10 minutes with five minutes break between each exercise. Three temperature variations: 0, 21, and 32°C, and two relative humidity levels, 15 and 85% formed six different testing conditions. The test aerosol concentration in the chamber had an average concentration of 25 mg/m³ with an average MMAD of 0.67 micrometer. Test subjects wore safety glasses, hard hats, cloth coveralls, and boots during the test.

The test results indicated that except for the loose fitting facepiece PAPR, the performance of positive pressure respirators is not affected by environmental conditions. The performance of the negative pressure half-mask respirator deteriorated under high temperature and humidity. The average SWPF at 21 °C and 15% relative humidity was 2,900. It was reduced to 80 under 32°C and 85% relative humidity. The facepiece slid from the face under high temperature and humidity. At the 2004 NIOSH public meeting on the TIL proposal, one union member raised the question regarding the performance of the respirator under extremes of temperature and humidity. Most parts of the country have high humidity in the summer and the southern states have extended months of high temperature and high humidity. The 42 CFR 84 requires filters to be preconditioned under high temperature and humidity before testing. Testing the respirator under high temperature and humidity should be a requirement of the TIL regulation.

The European BS EN 140:1999 standard on half-mask and quarter mask respirators has a fit testing requirement that the test subject walks on a treadmill at a speed of 6 km/hr. It has the following exercise sequences: walk for 2 minutes without head movement or talking, turning head from side to side (15 times) for 2 minutes, moving head up and down (15 times) for two minutes, reciting the alphabet or an agreed text out loud for 2 minutes, and walking for 2 minutes without head movement or talking. The leakage over each exercise period is recorded.

The European standard, BS EN 140:1999, also has a practical performance requirement¹⁰. The test subjects are required to walk on a treadmill at a speed of 6 km/hr. for 5 minutes, crawling on the level for 5 minutes, and filling and emptying a small basket with chippings for 10 minutes. Many American respirator manufacturers sell respirator in the EU countries. Their products must meet this EN 140 requirement.

The minimum facepiece leakage test requirements specified in § 84-205 of 42 CFR 84 specifies four exercises: nodding and turning head, callisthenic arm movements, running in place, and pumping with a tire pump into a 28-liter container. Each exercise lasts two minutes.

D. Exercise Time

The proposed exercises include static facial and head movements, and bending at the waist in a test room having only ambient air. A total of eight exercises are required and each exercise is performed for 30 seconds. The proposed exercises are not much different from the quantitative fit testing used for respirator facepiece selection. These static exercises do not induce facepiece leakage. A TIL test that only performs for 4 minutes under static conditions would not ensure that the respirator would perform adequately at the workplace where workers have extensive body movement and work duration can last the whole shift.

The QNFT protocol developed by the Los Alamos Scientific Laboratory required an exercise time interval of 2 minutes¹¹. The European EN 140 standard requires an exercise time period of two minutes¹⁰. The Industrial Safety Equipment Manufacturers Association (ISEA) also recommended a two-minute exercise time interval¹². Bowing to the demands of the employers, OSHA reduced the exercise time to one minute in the respirator fit testing regulations. The minimum facepiece test requirements specified in § 84-205 of 42 CFR 84 specifies eight minute exercise time¹. There is no study to indicate that a 30-second exercise interval would yield the same results when the exercises are performed at one-minute or two-minute intervals.

E. Passing Fit Factors

Warren Myers from West Virginia University has conducted a QNFT study for Mine Safety Appliance Company (MSA) of commonly used half-mask elastomeric facepiece respirators³. Facepieces manufactured by Aerro, MSA, North, Survivair, 3M, and Willson were selected for testing. MSA has submitted the study report to the OSHA's respiratory protection docket. A total of 13 respirators were tested. Each mask has three sizes. Fit factors were measured on a 25-member anthropometric test panel. Test subjects, both male and female, were selected to fit the facial characteristics of the Los Alamos half-mask anthropometric test panel. The exercises performed by the test subject are similar to the TIL proposal. The fit tests were performed on the TSI Portacount. The results indicated that fit factors varied between 100 and 61,000. The geometric mean of each mask varied between 1,400 and 6,600. The fifth percentile fit factor varied from 100 to 1,150. By removing the two lowest performing devices, the geometric mean fit factors have been increased to between 2,000 and 6,600. The fifth percentile fit factor varied from 290 to 1,150. The passing fit factor in the TIL proposal should be based on the available data. The fit factors reported from the Myers study would be representative of the half-mask respirators available today. A passing factor should be high enough to weed out poor performing respirators. The proposed passing fit factor of 100 is too low and it does not set a confidence interval to account for the variation in fit factor obtained from a large number of test subjects. A geometric mean passing factor of 500 with a 95% confidence interval of 100 should exclude poor performing respirator from being certified. A 95% confidence interval is often reported for the workplace protection factors achieved in a workplace study.

Conclusions

1. The proposed PortaCount/N-95 Companion instrument is not suitable for conducting the TIL test according to TSI, its manufacturer. Generated aerosol systems with better photometers, such as the one used by LLNL or LASL, is the choice instrument.
2. The required four-minute sedentary static exercises do not relate the actual worker's dynamic movements in the workplace.
3. The performance of a half-mask respirator would deteriorate under high temperature and humidity use conditions. The TIL proposal has not addressed this problem.
4. The proposed passing fit factor is too low and it does not set a confidence interval accounting for the variability of fit factors achieved by a group of test subjects.

Recommendations

1. The LLNL or LANL generated aerosol/ forward scattering photometer system should be used to conduct the TIL test. The test aerosol should have a MMAD of $1\ \mu\text{m}$ or less with a geometric standard deviation of less than 2. The test chamber should have an aerosol concentration between 15 and 25 mg/m³ with a variation less than 20 with the test chamber.
2. Dynamic exercises involving extensive body movements should be the required exercises. Examples are: walking on a treadmill at a speed of 6 km/hr, filling and emptying a small basket with chippings; pounding nails into an overhead board; moving and laying cinder blocks, callisthenic arm movements; and pumping with a tire pump into a 28-liter container. At least four exercises should be performed and each exercise should last five minutes, with a break between exercises.
3. The TIL test should be conducted at a temperature of 32° C and a relative humidity of 85% to reflect the workplace environment.
4. A minimum TIL passing fit factor should be a geometric mean of 500, and the fifth percentile fit factor should be 100.
5. Test subjects should wear safety glasses, hard hats, cloth coveralls, and boots during the test. These are the typical clothing and equipment workers wear at the workplace.
6. Since OSHA has required fit testing for respirator use. NIOSH should consider reducing the number of test subjects and repetitions to reduce compliance cost.
7. If NIOSH decides to keep the PortaCount/N-95 Companion as the test instrument, please consider adopting the exercises specified in EN 140 and §84-205 of the 42 CFR 84 since these are required exercises for respirator certification.

The American workforce would benefit from NIOSH's action of adopting more realistic TIL testing requirements.

REFERENCES

1. Approval of Respiratory Protective Devices, § 84-181 (c). Code of Federal Regulations 42 CFR Part 84. U.S. Government Printing Office, Washington, D.C. (1997).
2. Johnson, J. S.: Testimony of James S. Johnson at the OSHA Public Meeting on Assigned Protection Factors. OSHA H-049C Docket Ex.16-9-1 (2004).
3. Myers, W.R.: "Fit Testing Quality Assurance Report for MSA on Half Facepiece Respirators: Phase II Report," prepared for Mine Safety Appliances Co., Pittsburgh, PA (March 1993).
4. DaRoza R: Testimony at the OSHA Proposed Rulemaking of Respiratory Protection Standard, pp. 77-102, Jun7, 1995.
5. Weed, J: TSI Comments on NIOSH NPPTL Total Inward Leakage Proposal. Docket No. NIOSH 036, August 29, 2007.
6. NIOSH: Prerulemaking Technical Conference on the Assessment of Performance Levels for Industrial Respirators, January 9-11, 1991.
7. Ettinger, H.J.: Final Report: Role of Workplace Testing of Respirators as a Condition of Certification for the Federally Mandated NIOSH Respiratory Protective Equipment Certification Program (1991).
8. Hinds, W.C.: Role of Workplace Performance Testing in the Certification of Respirators. Report and Recommendations (1991).
9. Skaggs, B, J.; Loibl, J.M.; Carter, K.D.; and Hyatt, EC: Effect of Temperature and Humidity on Respirator Fit Under Simulated Work Conditions. Los Alamos National Laboratory, NUREG/CR-5090, LA-11236. (1988).
10. Respiratory Protective Devices – Half Masks and Quarter Masks – Requirements, Testing, Marking, BS EN 140:1999.
11. Hyatt, E. C.: Respirator Protection Factors. Los Alamos Scientific Laboratory, UC-41 (1976).
12. Industrial Safety Equipment Association: Comments submitted to OSHA Docket H-049A, #46. (December 8, 1981).