

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

From: Woodhull, Dee [dee.woodhull@orcww.com]
Sent: Monday, March 29, 2010 4:07 PM
To: NIOSH Docket Office (CDC)
Cc: White, Frank
Subject: NIOSH Docket Number 137
Attachments: ORC Comments on TIL Rule.docx

Dear NIOSH Docket Officer:

Please accept these comments into Docket Number 137: Total Inward Leakage Requirements for Half-Mask Air-Purifying Respirators.

Thank you.

Sincerely,

Dee Woodhull, CIH, CSP

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March 29, 2010

NIOSH Docket Officer
NIOSH Docket #137
Robert A. Taft Laboratories,
MS-C34, 4676
Columbia Parkway,
Cincinnati, OH 45226

Re: Notice of Proposed Rulemaking (NPRM) --
Total Inward Leakage Requirements for
Respirators (FR Doc. E9-26008)
October 29, 2009

Dear Sir/Madam:

ORC Worldwide welcomes this opportunity to provide comments on the National Institute of Occupational Safety and Health (NIOSH) notice of proposed rulemaking (NPRM) seeking input from the community of respirator manufacturers, suppliers, and users on its intent to establish new requirements for total inward leakage (TIL) for half-mask air-purifying particulate respirators. The proposed requirements specify TIL minimum performance requirements and testing to demonstrate that these respirators meet users' expectations to provide effective respiratory protection against toxic dusts, mists, fumes, fibers, and biological and infectious aerosols encountered in the workplace.

ORC Worldwide is an international management and human resources consulting firm whose Washington, D.C. office has for more than 35 years specialized in providing a wide array of occupational safety and health consulting services to businesses operating in the U.S. Currently, more than 120 large (mostly Fortune 500) employers in diverse industries are members of ORC's Occupational Safety and Health Networks. The focus of these networks is to promote effective occupational safety and health programs and practices in business and to facilitate constructive communication between business and government agencies responsible for establishing national occupational safety and health policy. The activities of ORC's Occupational Safety and Health Networks are based on the premise that providing safe and healthful working conditions is the mutual concern of employers, employees and government agencies.

ORC applauds NIOSH's efforts to improve the reliability of respiratory protection available to employers and employees. All ORC member companies, with rare exception, at one time or another have provided their employees with half-mask air-purifying respirators to augment protective measures against workplace dusts and toxins. They rely on NIOSH to provide assurance that an approved respirator truly provides the expected protection. Testing conducted by NIOSH to determine actual performance revealed that face piece seals on approximately 30 per cent of the of half-mask air-purifying class of respirators did not provide a fit factor of 100, as required by OSHA, on "substantial" numbers of test subjects. This is not surprising because manufacturers are not currently required by NIOSH testing and approval protocols to test the fit factor of half-mask air-purifying respirators. It is clear that additional measures are needed to address this deficiency.

Establishing minimum performance requirements for total inward leakage on half-mask air-purifying respirators is a good and necessary first step toward improving worker health and safety programs. ORC agrees that improving respirator fit performance will very likely decrease the amount of time and money employers must spend to ensure that each employee has a properly-fitting respirator. Currently, failure to achieve acceptable fit is an issue that requires ORC member companies to extend the fit-testing process and keep extra respirator models in stock. Better fit-testing success can improve the cost-effectiveness of respirator programs as well as overall productivity.

ORC also agrees that better fit characteristics can raise the level of protection for employees who do not have the benefit of fit-testing prior to exposure to contaminants in the workplace. This also applies to situations in which respirators would be provided during a disease outbreak or terrorist attack, when time and resource constraints may preclude fit testing.

ORC has the following responses to the questions posed in the NPRM:

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 80-90 per cent of intended users should be able to achieve adequate TIL performance for a specific respirator model to be approved. ORC believes that the standard of performance for NIOSH-approved respirators should be high, given that the intended purpose is to provide protection against health threats. Although the proposed improvement in TIL over the current state of respirator protection reliability is a modest improvement, it is a positive step. NIOSH should continue to work to raise respirator fit reliability in future rulemaking.

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 per cent or higher probability) that the respirator would not be approved?

The proposed point of near certain rejection is 50 per cent or greater of intended users. In light of the goals of this rulemaking, which are to provide more effective respiratory protection to intended users, and specifically to achieve adequate TIL performance for 80-90 per cent of intended users for a given respirator model, more demanding standard is required. A 99 per cent or higher probability of rejection should be assigned to those respirators that fail to achieve a sufficient fit for 30 per cent of the population of intended users in order to receive NIOSH approval.

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?

Given that the overall annual cost to manufacturers of testing is small relative to overall annual sales revenue, (0.2 per cent of revenue) as discussed in the NPRM, emphasis should be placed on obtaining accurate information above conserving testing costs. The NPRM proposes that 35 test subjects be used. Doubling the number of test subjects over that proposed would provide a substantial increase in the accuracy of results without placing undue financial burden on manufacturers. Respirator models are to be tested when they first

enter the marketplace and again when design changes affecting fit are made, therefore annual testing of every model would not be necessary.

The proposed implementation schedule is appropriate. ORC does not believe that the proposed 3-year limit on the sale and distribution by approval holders of respirators certified under the current requirements will incur burdens of any kind on ORC member companies. Our recommendation would be for manufacturers and suppliers of such respirators to be required to label those respirators as not subject to the TIL rule so they can be distinguished from respirators that do meet the TIL requirements.

ORC appreciates the opportunity to present these comments in response to the NPRM and would be happy to discuss any of these comments further with NIOSH and NPPTL staff.

Sincerely,

A handwritten signature in black ink, appearing to read "Frank A. White". The signature is written in a cursive style with a large initial "F" and "A".

Frank A. White
Senior Vice President