

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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**PROPOSED PETITION DECISION OF THE
OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD
(PETITION FILE NO. 492)****INTRODUCTION**

The Occupational Safety and Health Standards Board (Board) received a petition on February 13, 2007, from Mr. Tim Roberts (Petitioner). The Petitioner requests the Board to amend Title 8, California Code of Regulations, Sections 1529, 1532, 1532.1, and 1535 of the Construction Safety Orders; Sections 5144, 5190, 5198, 5200, 5202, 5207, 5208, 5210, 5211, 5212, 5213, 5214, 5217, 5218, and 5220 of the General Industry Safety Orders; and Section 8358 of the Ship Building, Ship Repairing, and Ship Breaking Safety Orders in regards to Assigned Protection Factors (APFs) for Respirators. APFs specify the highest multiple of a contaminant's permissible exposure limit at which an employee is permitted to use a particular class of respirator.

Labor Code section 142.2 permits interested persons to propose new or revised standards concerning occupational safety and health, and requires the Board to consider such proposals, and render a decision no later than six months following receipt. Further, as required by Labor Code section 147, any proposed occupational safety or health standard received by the Board from a source other than the Division of Occupational Safety and Health (Division) must be referred to the Division for evaluation, and the Division has 60 days after receipt to submit a report on the proposal.

SUMMARY

The Petitioner requests that the APF for filtering facepiece respirators in the Respiratory Protection standard and the applicable substance specific standards in the Construction Safety Orders, General Industry Safety Orders, and the Ship Building, Ship Repairing, and Ship Breaking Safety Orders be reduced from 10 to 5, or less. Reducing the APF from 10 to 5 would prohibit the use of filtering facepiece respirators for protection against concentrations of airborne contaminants that exceed 5 times the permissible exposure limit (PEL). Based on federal Occupational Safety and Health Administration (OSHA) Final Rule [71 Federal Register 50122-50192 (August 24, 2006)], the Board adopted revisions to the APF table on January 18, 2007, and the changes became operative on March 6, 2007. Those changes established an APF of 10 for filtering facepiece respirators. The Petitioner asserts that the APF for filtering facepiece respirators should be reduced because the face-seal between the user's face and respirator facepiece is not sufficiently reliable to reasonably ensure that contaminated air will not leak through the face-seal in an amount that causes the wearer to be exposed above the PEL when contaminant concentrations outside the respirator exceed 5 times the PEL. The Petitioner supports this assertion with several arguments, including the following:

1. The Workplace Protection Factor (WPF) studies cited in the preamble to the federal OSHA Final Rule on APFs are not representative of the total population of filtering facepiece respirators, which have a variety of shapes and designs; and, the vast majority of the WPF studies were supported in part, or in whole, by one large respirator manufacturer.
2. The test sites for the WPF studies cited in the preamble to the federal OSHA Final Rule on APFs are not representative of American worksites or working conditions in regards to humidity, work hours, workload, and contaminant concentrations.
3. The WPF studies cited in the preamble to the federal OSHA Final Rule on APFs did not include any published studies of filtering facepiece respirators tested under 42CFR Part 84, which is the standard that respirators must meet to be approved by the National Institute for Occupational Safety and Health (NIOSH).
4. The federal rulemaking on APFs did not consider recently published WPF studies which indicate an APF of 10 for filtering facepiece respirators is too high.
5. State and federal OSHA Asbestos Standards prohibit the use of filtering facepiece respirators for protection against asbestos.
6. The state and federal OSHA Cotton Dust Standards specify an APF of 5 for filtering facepiece respirators.
7. It is difficult if not impossible for the respirator user to perform a positive or negative pressure face-seal check on filtering facepiece respirators as required by the Respiratory Protection Standard.

DIVISION'S EVALUATION

The Division's evaluation report dated April 11, 2007, states that the Petitioner has assembled an argument of sufficient credibility to warrant further study of the request to lower the APF for filtering facepiece respirators to 5. The Division notes that the federal OSHA Final Rule includes a discussion of continuing the prohibition on the use of filtering facepiece respirators for asbestos, and in that discussion, federal OSHA states that the contention that filtering facepieces are at least as efficient as elastomeric facepieces is "controversial." The Division concurs with the Petitioner that two recent studies that are not included in the federal OSHA analysis would support a lower APF for filtering facepiece respirators, and the Division recommends a review of more recent scientific research in this area.

The Division report reviews respirator studies cited in the Petition and the Final Rule which indicate that not all models of filtering facepiece respirators achieve a protection factor of 10. The report notes that federal OSHA's response to these studies is that individual fit tests, which the respiratory protection standard requires employers to perform on each respirator user, adequately ensure a filtering facepiece respirator will achieve a protection factor of 10. The Division suggests that the Board may want to evaluate the data and discuss whether when used, the respirator will provide a protection factor of 10. The Division acknowledges that the Petitioner makes valid points regarding his assertion that the data federal OSHA relied upon in determining APFs was incomplete, potentially biased, and/or not representative. However, the Division also acknowledges federal OSHA made valid points in response to such criticisms when it concluded that the data was the best available. Therefore, the Division recommends that

the Petition be granted to the extent that an advisory committee be convened to review the scientific basis for keeping or changing the APF for filtering facepiece respirators.

STAFF'S EVALUATION

The Petitioner provides several reasons for requesting that the APF for filtering facepiece respirators be reduced from 10 to 5 or less. The Petitioner's comments can be broadly categorized as related to one of the following arguments: 1) the data that federal OSHA relied upon is incomplete; 2) the methods used to collect and select the data did not ensure that the data was unbiased; and 3) the APF of 10 is not consistent with several published studies and other respirator standards. These arguments were also presented by the Petitioner during the federal OSHA rulemaking for the APF final rule. In the sixty-four page final rule published August 24, 2006, federal OSHA responded to the Petitioner's comments and similar comments submitted by other interested parties.

During the APF rulemaking federal OSHA conducted an extensive review of protection factor studies and related literature, developed criteria for evaluating protection factor studies, and selected twenty WPF studies that were then quantitatively analyzed to derive the APFs for filtering facepiece and elastomeric half-mask respirators. The final rule did not identify which, if any, of the sixteen published WPF studies that federal OSHA relied upon were supported by respirator manufacturers. It did, however, indicate that three unpublished WPF studies that federal OSHA relied upon were provided by the 3M company. These three 3M company studies account for 38 percent of the WPF measurements of filtering facepieces in the half mask respirator database.

A comment was made that the data presented in the studies evaluated by federal OSHA indicate that not all filtering facepieces achieved an APF of 10. Five studies reviewed by federal OSHA included five models of filtering face piece respirators that failed to achieve a WPF of 9. Three of these studies met federal OSHA's selection criteria and were included in the database. Two studies were not included in the database because they did not meet federal OSHA's criteria. Commenters also stated that not all configurations (e.g., cups, duckbills, fold flats) of filtering facepiece respirators have been studied. Federal OSHA acknowledged that its analyses did not encompass all configurations or models of filtering facepiece respirators.

The American Chemistry Council stated that federal OSHA's APFs should be based on Simulated Workplace Protection Factor (SWPF) studies and that the APFs derived from the federal OSHA rulemaking should be used only as interim values until SWPF studies could be performed. Federal OSHA noted that basing APFs on SWPF studies, rather than on WPF studies, was recommended by a number of commenters. The commenters expressed various concerns about the WPF studies and stated that SWPF studies permit investigators to control a number of variables (e.g., particle size, contaminant concentration, environmental conditions) that cannot be controlled in WPF studies.

A study of the fitting characteristics of eighteen filtering facepiece respirators was published by NIOSH researchers.¹ Without fit-testing, the 5th percentile SWPF for all models combined was 2.9 with individual model values ranging from 1.3 to 48.0. Passing a fit test generally resulted in an increase in protection; however the report concluded that it may be of more benefit to the user to wear a respirator model with good-fitting characteristics without fit-testing than to wear a respirator model with poor-fitting characteristics after passing a fit-test. Several commenters mentioned that NIOSH had eliminated the fit test portion of its certification procedures. They believed that as a result of this NIOSH action, one could not be sure if a filtering facepiece respirator achieves an adequate face-seal and provides the expected protection. During the federal OSHA public hearing, NIOSH indicated that it would establish a new respirator certification testing procedure, stating such changes would result in additional certification tests to assure or assess the overall performance of every respirator model, and thus assure that every model is capable of providing a level of protection consistent with the class APF. Federal OSHA supported NIOSH's plans to add performance testing to its respirator certification procedures, stating federal OSHA agrees with Tim Roberts that performance testing will assist in identifying respirators with poor fitting characteristics that may not provide protection consistent with the respirator's APF.

The efficacy of user seal check procedures provided by filtering facepiece manufacturers also was questioned by several commenters. The Respiratory Protection Standard requires that an employee perform a user seal check each time the respirator is put on. During the rulemaking, several commenters referred to the use of fit check cups to perform user seal checks. These devices are designed to assist the respirator user in performing a positive seal check by covering the surface of a filtering facepiece respirator; however they are not routinely used because they are not convenient. Federal OSHA did not find merit in the comments that fit check cups are necessary to perform user seal checks with filtering facepieces. Federal OSHA argued previously in *National Cottonseed Products Associations v. Brock*, 825 F.2d 482 (D.C. Cir. 1987) that filtering facepieces used to protect employees against exposure to cotton dust should have an APF of 5 based on the difficulty of fit testing, particularly fit checking on a daily basis. Federal OSHA states that new developments in seal check techniques and procedures allowed federal OSHA to reassess filtering facepieces and find that these respirators can be reliably fit tested and fit checked. Federal OSHA states that the WPF studies provide further support for this conclusion, and in fact, every WPF study of filtering facepieces in the federal OSHA APF database involved using the new and refined methods.

The Final Rule does not provide a description of the new developments in seal check techniques and procedures. The following is a manufacturer's recommended procedure for performing a user seal check on a filtering facepiece respirator:

Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 3. If air leaks at the respirator edges, work the straps back along the sides of your head.

¹ C. Coffey, R. Lawrence, D Campbell, Z Ahuang, C. Calvert, P. Jensen, *Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators*, Journal of Occupational and Environmental Hygiene, 1:262-271, April 2004.

*If you CANNOT achieve proper seal, DO NOT enter the isolation or treatment area. See your supervisor.*²

In summary, federal OSHA concludes the following in regards to the APF for half-mask respirators: 1) the APF rulemaking relied upon the best data available, 2) the extensive quantitative analyses of the data bases clearly indicate that both filtering facepieces and elastomeric respirators are capable of achieving an APF of 10, 3) an APF of 10 is an underestimate of the true protection provided by both types of respirators, and 4) the APF of 10 provides employees who use respirators with an extra margin of safety against airborne contaminants.

The Board staff concludes that the APF rulemaking provides credible evidence that federal OSHA relied upon the best available data to determine an APF of 10 for filtering facepieces; however federal OSHA and NIOSH acknowledge that the data is incomplete in that it does not include several models of filtering facepiece respirators. Furthermore, WPF and SWPF study results indicate that several models of filtering facepieces may not provide a WPF of 10. The Board staff believes that the Petitioner presents credible evidence that challenges the assumption that the database of WPFs, which federal OSHA developed and analyzed, represents a random sample of WPFs from all workers who use filtering facepiece respirators.

In conclusion, Board staff agrees with the Division that the Petitioner's request should be considered by an advisory committee.

CONCLUSION AND ORDER

The Occupational Safety and Health Standards Board has considered the petition of Mr. Tim Roberts, to make recommended changes to Sections 1529, 1532, 1532.1, and 1535 of the Construction Safety Orders; Sections 5144, 5190, 5198, 5200, 5202, 5207, 5208, 5210, 5211, 5212, 5213, 5214, 5217, 5218, and 5220 of the General Industry Safety Orders; and Section 8358 of the Ship Building, Ship Repairing, and Ship Breaking Safety Orders in regards to Assigned Protection Factors for Respirators. The Board has also considered the recommendations of the Division and Board staff. The Petition is hereby granted to the extent that the Division convene an advisory committee to consider whether a NIOSH certified filtering facepiece respirator can be expected to provide an employee with a WPF of 10 when the employer implements a respiratory protection program in compliance with the Respiratory Protection Standard. If warranted, the Division should propose an amended APF for filtering facepiece respirators for the Board's consideration.

² Health Care Particulate Respirator and Surgical Mask, 3M Models 1860/1860S, User Instructions, 2002, available at: <http://multimedia.mmm.com/mws/mediawebsserver.dyn?6666660Zjcf6lVs6EVs666iLYCOrrrrQ->