

ensure that employees receive the optimum level of protection afforded by that standard.

C. Review of the Proposed Standard by the Advisory Committee for Construction Safety and Health (ACCSH)

The proposed provisions would replace the existing respirator-selection requirements specified by the Respiratory Protection Standard for the construction industry (29 CFR 1926.103). Accordingly, OSHA's regulation governing the Advisory Committee on Construction Safety and Health (ACCSH) at 29 CFR 1912.3 requires OSHA to consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees. On December 5, 2002, OSHA briefed the ACCSH membership on the proposed provisions and responded to their questions. On March 27, 2003, the APF proposal was distributed to the ACCSH membership for their review prior to their next regular meeting on May 22, 2003. OSHA staff discussed the APF proposal and answered questions from the ACCSH members during their meeting on May 22, 2003. The ACCSH then recommended that OSHA proceed with publishing the proposal.

IV. Methodology for Developing Assigned Protection Factors

This section contains an overview of the analyses performed for OSHA and summaries of the studies used in these analyses. OSHA entered the complete analyses and studies into Docket H049C as Exhibits 3, 4, and 5 and Exhibit 1-156 (Dr. Nicas' report). Studies and information supporting the APF for each class of respirator are discussed in Section VII of this document. The analyses discussed below assisted OSHA in determining its proposed approach to deriving APFs. Commenters expressed appreciation for the approach suggested by Dr. Nicas, but nearly all did not support implementation of his methods. However, his recommendations provided guidance to the Agency regarding the types of studies and data needed for determining APFs. Dr. Brown's complex statistical analyses demonstrated the widespread variability inherent in current workplace protection factor studies. However, he found in his final analysis that the performance of filtering facepiece and elastomeric half-mask respirators could not be differentiated, thereby supporting grouping of these two types of respirator under one APF.

A. Dr. Nicas' Proposal and Response From Commenters

During the June 1995 APF hearings, OSHA devoted a full day to a panel discussion on the uncertainties associated with sample statistics and their use for deriving APFs. Based on this discussion, OSHA contracted with Dr. Mark Nicas to develop a statistical method for deriving APFs. Nicas used two approaches to account for within-wearer and between-wearer variabilities. For penetration data collected from a specific cohort of respirator wearers, he used a one-factor lognormal analysis of variance. He used a two-factor lognormal analysis of variance to perform a meta-analysis of the data from studies of different cohorts of respirator wearers. Using these approaches, Nicas proposed assigning two different protection factors; he recommended one for chronic toxicants (*i.e.*, substances regulated by an 8-hour PEL), and the other for acute toxicants (*i.e.*, substances regulated by a STEL). Nicas also made recommendations regarding sampling data management and inclusion of studies in statistical analyses of respirator performance.

OSHA reopened the rulemaking record on November 7, 1995 (60 FR 56127) to request comment on Dr. Nicas' report titled "The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors" (Ex. 1-156). OSHA received 12 comments on the report. While some commenters expressed general support for Nicas' approach (*e.g.*, Ex. 1-182-4, American College of Occupational and Environmental Medicine), others had serious reservations about establishing APFs using this approach. The issues raised by these commenters are described below.

1. Lack of Valid and Reliable WPF Data

Two commenters stated that the available WPF data were of insufficient quality to permit a sophisticated statistical analysis. The 3M Company (3M) commended OSHA for "attempting to use science to evaluate workplace studies for determining Assigned Protection Factors," but stated that insufficient valid data were available for such an evaluation, and that the data that were available were too variable (Ex. 1-182-5). In addition, Organization Resource Counselors, Inc. (ORC) stated: "The use of existing, often flawed, workplace protection factor studies, is not a solution to the problem. * * * A reliance on sophisticated statistics in an attempt to compensate for a lack of reliable scientific data on respirator

performance is both bad science and bad policy" (Ex. 1-182-10).

2. Inappropriate Use of ANOVA Model

Three commenters believed that using Nicas' lognormal ANOVA model to analyze existing data was inappropriate (Exs. 1-174, 1-182-5, 1-182-1). Two of these commenters advocated using a simple analysis of the aggregate data instead (Exs. 1-174, 1-182-5). Thomas Nelson (Ex. 1-174) and 3M (1-182-5) expressed concern that the ANOVA model focuses primarily on within-wearer and between-wearer variability, while ignoring the potential variability contributed by other sources such as work site, respirator model, filter, and contaminant. Nelson stated: "A simple analysis of the entire data (*i.e.*, geometric mean, estimates of percentiles and confidence intervals) includes these and other possible sources of variation and the within-person variability in the model." Two other commenters, Drs. Rappaport and Kupper [contractors for the Industrial Safety Equipment Association (ISEA)] believed that using an ANOVA model provided some benefits; however, they had concerns regarding the assumption of log-normality of penetration values, the lack of validation of the model, and errors that appeared in some of the equations. Therefore, they regarded "implementation of Dr. Nicas' ideas as being problematic at this time," and encouraged the industry to develop improved methods and data for deriving APFs (Ex. 1-182-1).

3. ANOVA Model Fails To Account for Differences Between WPF Studies

Five commenters stated that the proposed analysis fails to account for important differences between studies that could affect WPF values. Thomas Nelson and 3M believed that the ANOVA model does not account for other sources of variability (Exs. 1-174, 1-182-5). NIOSH stated that Nicas' report did not address the effect of the test subjects' work rates and other activities on a respirator's performance (Ex. 1-182-3), and did not account for employee training and program surveillance (Ex. 1-182-9). The Chemical Manufacturers Association (CMA) also commented on factors not considered in the Nicas report, "including differences in training, experience, work site, work rate and sample collection" (Ex. 1-182-7). ORC noted: "The results of a WPF study are based on at least the following components: quality of the respirator chosen; quality of the training program; quality of the fit testing and selection program; nature of the work and ability