

to another study. He concluded that it is not possible to know to what extent the outcome of a study is attributable to characteristics of the respirator used.

Brown believed that the variability identified in this analysis was probably due to uncontrolled parameters in the workplace test situations, such as aerosol particle size distributions and densities, and work activities. Based on the data from these studies, he found that WPF tends to increase as Co increases (equivalently, penetration, or PEN., tends to decrease). He believed that the probability of a Co dependence for WPFs seemed to be established by his analyses.

C. Analyses of SWPF Studies

1. Bullard Models 77 and 88, Clemco Apollo Models 20 and 60, and 3M Whitecap II

In the mid-1980s, SWPF studies provided OSHA with information on the effects of temperature, relative humidity, airflow, and facial hair on respirator performance (LANL, 1988; Ex. 1-64-101, LLNL, 1986; Ex. 1-64-94). More recent SWPF studies provided additional information on the performance of the following abrasive blasting respirators: the Bullard Models 77 and 88 (Ex. 3-8-3), the Clemco Apollo Models 20 and 60 (Ex. 3-7-3), and the 3M Whitecap II (Ex. 3-9-2).

OSHA contracted with Mr. Harry Ettinger to review and comment on the study principles and protocols described in the five reports (Bullard, Clemco, 3M Whitecap, the LLNL study, and the LANL study). His report (Ex. 3-3) contained the following observations and conclusions.

Mr. Ettinger noted that while the reports do not satisfy the typical criteria for defining peer-reviewed publications, this was not a serious problem because the studies were conducted in national laboratories by knowledgeable and experienced investigators. Furthermore, the review procedures generally used by these national laboratories most likely provide a sufficient peer-review process. He noted that none of the reports provided sufficient detail to permit a statistical re-analysis of the data by OSHA. In addition, he observed that the studies of the Bullard, Clemco, and 3M respirators reported considerably higher fit factors than the 1986 and 1988 national laboratory studies. However, he believed that it was not appropriate to compare the results of recent studies with the older studies, but he noted that older respirators may not perform as well as newer designs.

Mr. Ettinger also noted that the tests of the Bullard, Clemco, and 3M

respirators satisfied the established criteria of fit factors that exhibited only brief negative pressure spikes. He believed these results indicated that if these devices are used and maintained properly, they appear to have fit factors of at least 20,000. He believed that, using a safety factor of 20, a protection factor of 1,000 is attainable, assuming that the testing protocol is adequate.

Ettinger stated that he could not define clearly a relationship between the older and more recent study results. For example, he suggested that the additional exercises in the more recent study (ORC, 2001; Ex. 3-4-2) did not adequately represent normal or extreme work situations. Ettinger cautioned against assuming that all blasting helmets would achieve the high fit factors measured in the recent studies because performance is device specific, and indicated that older respirator designs may need to be reevaluated. Furthermore, he believed that quality control, human factors, minimum flow rate, and the sturdiness of respirator construction are important variables that should be evaluated in the testing protocol.

2. NIOSH N95 Study

In 1999, NIOSH conducted a chamber study of 21 N95 respirators (20 filtering facepiece, and 1 elastomeric, respirators) and statistically analyzed the respirators' performance (Ex. 4-14). At the request of OSHA, Drs. Johnson, Foote, and Bierman of LLNL undertook a review of this study to assist the Agency in evaluating APFs of half-mask respirators (Ex. 3-2). OSHA provided the raw data files from the study to LLNL for independent evaluation.

The NIOSH investigators used ambient (*i.e.*, room) aerosol as the challenge agent, and a PortaCount to measure respirator penetration. Use of ambient aerosol does not require aerosol generation equipment, thereby circumventing use of a possibly hazardous chemical. However, if this technique generates a low ambient particle concentration it is difficult to detect the reduced number of particles that penetrate the respirator; this effect results in an artificially low protection factor. In addition, an ambient aerosol that is varying in concentration during testing can cause error in the penetration measurements. Study participants can also produce aerosols ranging from 0.1 to 3 particles/cc through their breathing (*i.e.*, "breathing" background). Whenever the amount of challenge agent that penetrates the respirator is low (*i.e.*, on the order of particles/cc or less), the PortaCount cannot distinguish between particles in

the breathing background and the challenge aerosol penetrating the respirator. The LLNL researchers believed that the breathing background can limit fit factor measurements to 1,000 and less when the challenge concentration is below 2,000 particles/cc (Ex. 4-15). They concluded that challenge aerosol concentrations can be better controlled in chamber studies than under this protocol.

When calculating face seal leakage, the NIOSH authors assumed that all study participants have the same constant volumetric flow rate through the respirator. Using a filtration model developed by Rubow (Ex. 3-7-3), the LLNL reviewers determined media penetration that was approximately 5% less than the media penetration calculated by the NIOSH authors using the constant flow rate assumption. Since the method used by the NIOSH authors results in only a 5% error, and gives a conservative estimate of the filter penetration, the LLNL reviewers believed that the constant flow rate assumption is reasonable. The LLNL reviewers also discussed other considerations, including fluctuations in peak flows under various exercise conditions, and the correction factor for filter media penetration used by the NIOSH authors.

Investigating the possible effect of breathing background on the PortaCount fit factor measurement, the LLNL reviewers applied an estimated worst-case scenario to the data. The scenario consisted of the following two assumptions: (1) A challenge aerosol concentration of 3,000 particles/cc, and (2) a breathing background of 5 particles/cc. Applying these assumptions to the NIOSH data, the LLNL reviewers recalculated total penetrations, and adjusted the results for breathing background. They found that, when compared to the NIOSH results, 14 of the 21 respirators had more tests passing the 0.01 penetration criteria than before. The LLNL reviewers also calculated the 50th and 95th percentiles for the penetration data, both with and without applying the breathing background assumption. In view of their results, they believed that the original NIOSH analysis and findings result in a conservative estimate of the respirators' performance.

The LLNL reviewers also used the NIOSH raw data to reproduce values, geometric standard deviations, and the 95th percentile for total penetration, filter penetration, and face seal leakage. They then compared these results to total penetration and face seal leakage penetrations summarized in the NIOSH study (Exs. 4-1, Table 2; 4-14, Table I).