

The few discrepancies were small, and could be attributed, for example, to rounding off values. The 95th percentiles in the NIOSH study were based on a formula using the geometric mean and geometric standard deviation, and assumed that the distribution was log normal. For comparison, the reviewers calculated the 50th and 95th percentiles based on the raw data alone (*i.e.*, assuming no distribution). Using this approach, the LLNL reviewers noted that, for many respirator models, the 50th percentile differed markedly from the geometric mean. They also saw differences between the 95th percentile calculated using a log normal distribution and the corresponding percentile determined directly from the data. LLNL reviewers stated that the NIOSH study demonstrated the advantages of SWPF studies for half-mask respirators. Their results confirm the quality of this important SWPF study of filtering facepiece and elastomeric half-mask respirators.

3. ORC Study of PAPRs and SARs

In 1997, ORC and a group of its member companies sponsored a study of 11 powered air-purifying and supplied-air respirators (PAPRs and SARs) to evaluate the protection that these respirators afforded to workers in the pharmaceutical industry. The study, "Simulated Workplace Protection Factor Study of Powered Air Purifying and Supplied Air Respirators" (Ex. 3-4-1) was completed in 1998 by researchers at LLNL. OSHA requested Dr. Gerry Wood of LANL to evaluate ORC's LLNL study. He evaluated the study using the data received from ORC, as well as information on the study published in the American Industrial Hygiene Association Journal (Exs. 3-1, 3-4-2).

The raw data files from the study consisted of instantaneous (0.1 second) photometer aerosol measurements obtained before, during, and after 12 exercise periods (including four periods of normal breathing) performed by each study participant. The instantaneous penetration results for the 144 tests were plotted against time. Wood examined patterns of aerosol penetration into the respirator that occurred throughout testing, noting that certain exercises often exhibited penetration spikes. He found that running in place produced the most penetration spikes. However, he also noted other respirator/subject combinations result in spikes. Wood indicated that such non-random distributions of readings was not surprising, as different movements during an exercise should affect instantaneous penetrations differently.

Wood calculated 95% confidence limits for the average and maximum penetration values during each exercise. In doing so, he assumed that pre-test and post-test background, and chamber aerosol measurements were distributed normally, since no movement variables were present. He then calculated aerosol penetration. Wood found that the photometer reading averages and standard deviations that he analyzed for all 144 data sets were in agreement with the LLNL figures, and that rounding off figures accounted for any minor differences in average penetrations that he calculated.

In summary, Dr. Wood believed that the quality of the data, experimental protocol, measurements and data, and calculations applied to the data in the ORC-LLNL study were excellent. He agreed with the authors' conclusions that SWPF studies are useful for comparing respirators, and that the study protocol was reproducible.

D. OSHA's Overall Summary Conclusions

Prior to this current rulemaking, OSHA explored several procedures to evaluate and compare respirator performance across models, studies, agents, and testing protocols. The Agency thoroughly reviewed the available data on respirator performance to determine the current concepts, and possible methodologies, for deriving APFs. To evaluate the data, OSHA had to make several decisions.

For example, while OSHA was aware that particle size can affect concentration values, the Agency was unable to quantify this factor based on available information. Consequently, OSHA did not attempt to adjust for differences in particle size in the analyses. Furthermore, the Agency had to decide how to address sampling results that were below the limit of detection (LOD). Accordingly, whenever sampling results were below the limit of detection, OSHA set the C_i at a percentage of the LOD reported in the study. When the study reported extremely low C_i results as a percentage of the LOD, the Agency used the values provided by the authors.

OSHA was concerned that the analyses be those best able to account for parameter uncertainty, and be a measure of respirator effectiveness that is valid over a plausible range of concentrations for each of the agents against which the respirator is to be used. As discussed above, the Agency contracted with Drs. Nicas and Brown to independently evaluate the raw WPF data. As a result of these analyses, OSHA preliminarily agrees with Drs.

Rappaport and Kupper, who indicated that, while some modeling may be useful, concerns remain regarding the lack of model validation (Ex. 1-182-1). Furthermore, OSHA finds merit in Thomas Nelson's comment that a simple analysis of the entire data may sufficiently cover the relevant sources of variation in these data (Ex. 1-174). Databases of the information used by the Agency in its analyses have been placed in the docket for review by interested parties (Exs. 5-3, 5-4, 5-5).

The Agency also recognizes that WPF and SWPF studies have their strengths and weaknesses. SWPF studies can control for a number of variables, thus providing less variable results across respirators classes than WPF studies. Also, SWPF studies can test respirators safely at the limits of their effectiveness. However, WPF studies evaluate respirators during use in the workplace. Therefore, the Agency believes that WPF or SWPF studies provide complementary information.

OSHA developed the proposed APFs using a multi-faceted approach. The Agency reviewed the various analyses of respirator authorities, available WPF and SWPF studies, and other APF literature. For example, OSHA reviewed Brown's analyses and noted no difference in performance between filtering facepiece and elastomeric half-mask APRs, and that few data pairs from the combined data sets analysis failed to achieve a WPF of 10. In addition, the data from WPF and SWPF studies, as well as a qualitative review of the available APF literature, supported an APF of 10 for all half-mask APRs. Therefore, OSHA is proposing an APF of 10 for half-mask APRs. The Agency used a similar approach in developing the remaining proposed APFs.

In conclusion, the APFs proposed by OSHA in this rulemaking represent the Agency's evaluation of all the available data and research literature; *i.e.*, a composite evaluation of all the relevant quantitative and qualitative information. The Agency seeks comment on this approach, as well as the proposed APFs developed using this approach.

E. Summaries of Studies

Researchers often determine the protection afforded by a respirator by conducting Workplace Protection Factor (WPF) studies and Simulated Workplace Protection Factor (SWPF) studies. A WPF study measures the effectiveness of respirators under workplace conditions. Workers participating in a WPF study wear respirators while performing their usual job tasks. The WPF is a measure of the reduction in exposure achieved while using respiratory protection and