

subject completed four full nine-exercise tests.

The NIOSH penetration results without fit-testing were compared to the LLNL test results. In general, the investigators found good agreement between the two studies, with the range of penetrations being similar in both studies. However, two differences were noted. For one model, (referred to by the researchers as Model D), the OSHA/LLNL study result indicated slightly more penetration than was observed in the NIOSH study. While the minimum penetration for Model D was 2 in both studies, the maximum penetration was 460 in the OSHA/LLNL study compared to 370 in the NIOSH study. However, both studies showed this respirator to be in the low performance range of penetrations. The researchers believed that this could be attributed to a poor-fitting individual that participated in the larger NIOSH study, but whose fit factor attributes were not represented by any participants in the smaller OSHA/LLNL study. They also noted that the design features of Model D, such as its folded shape and the plastic nose clip, may explain this respirator's poor performance. Furthermore, while this respirator was available in three sizes, it was very difficult to determine which size provided the best fit for several of the subjects.

The LLNL penetration result for another respirator, referred to by the researchers as Model A, was slightly better than the NIOSH result for the same respirator. The LLNL researchers believed that the lower penetration they measured for Model A was possibly due to the difference in model size/fit selection criteria between the NIOSH tests and the LLNL tests (discussed above). Again, they felt that another possible reason could have been a poor-fitting individual in the larger NIOSH study that was not represented by the smaller OSHA/LLNL study.

The LLNL researchers further investigated the apparent difference between the LLNL and NIOSH results for Model A. They found that eliminating subjects with poorly-fitting

respirators significantly affects results. For example, a subject was started in the LLNL/OSHA test but was not tested because the investigators were unable to maintain a proper fit on the individual when using Model A (*i.e.*, it fell completely off the nose of the subject upon donning). If tested, this subject or another less obvious subject who experienced poor fit, could have skewed the results of the LLNL/OSHA N95 evaluation significantly. The LLNL researchers believed that this latter analysis illustrates the potential influence of a single outlier on the overall results of a study. The advantages of controlled SWPF testing are apparent in this example.

10. SWPF Studies—PAPRs and SARs

ORC Study on Respirators Used in the Pharmaceutical Industry. Before the publication of the final respiratory protection standard, Organization Resources Counselors, Inc. (ORC) raised an issue that had been the subject of discussions between ORC and OSHA for several years. In 1997, ORC and a group of its member companies sponsored a study of certain models of powered air-purifying and supplied-air respirators to evaluate the ability of these respirators to protect workers from exposures in the pharmaceutical industries. The study, "Simulated Workplace Protection Factor Study of Powered Air Purifying and Supplied Air Respirators," (Ex. 3-4-1) was completed in 1998, and the initial results, along with detailed experimental data, were presented to OSHA.

The experimental protocol used in the study was developed by the Organization Resources Counselors' respirator task force, LLNL investigators, participating respirator manufacturers, and representatives from NIOSH and OSHA. The study included a simulated workplace exercise protocol consisting of 12 exercises: normal breathing, twisting the head from side-to-side, moving the head up and down, touching toes, raising arms above the head, twisting at the waist, running in place, normal breathing, hand scooping of

pebbles, normal breathing, building a concrete block wall, and normal breathing. Two exercises, hand scooping of pebbles and building a concrete block wall, were included to simulate tasks in the pharmaceutical industry. Seventeen subjects participated in the evaluation of five powered air-purifying respirators (PAPRs) and six supplied-air respirators (SARs). Twelve tests were conducted for each respirator, with the study being performed in the LLNL respirator test facility.

Input from OSHA resulted in two modifications to the protocol. It was decided that at least one of the three units for each respirator model tested would be purchased from the open market with the others being supplied directly from the manufacturer. A second change resulted from the Agency's interest in evaluating intra-personal variability in the performance of respirators. This was accomplished by testing one PAPR model and one SAR model during six wearings by a single individual. No significant difference in respirator performance was noted as a result of these modifications, and the overall results are presented below.

The results of the ORC study indicated that although simulated workplace protection factors (SWPFs) greater than one million were recorded during some of these tests, a reporting limit of 250,000 was established as the highest value in which reliable facepiece leakage could be detected (limit of quantification). The median SWPFs for all respirators, except one SAR, were at or above the reporting limit of 250,000. Lower fifth percentiles were above 100,000, with the exception of the one SAR. APFs were established for each of the 11 respirators by dividing the lower 5th percentile by a safety factor of 25. APFs ranged from 6,000–10,000 for PAPRs (including one loose-fitting PAPR), and 3,000–10,000 for SARs, with the exception of one device. This SAR had lower 5th percentile of less than 20 and an APF of 1. Results are presented in the table below.

TABLE 4.—SUMMARY OF SIMULATED WORKPLACE PROTECTION FACTOR RESULTS

Device	Range of SWPFs	Median SWPF	5th percentile SWPF
PAPR 1	140,000→250,000	>250,000	>250,000
PAPR 2	11,000→250,000	>250,000	170,000–210,000
PAPR 3	11,000→250,000	>250,000	>250,000
PAPR 4	94,000→250,000	>250,000	246,000→250,000
PAPR 5	240→250,000	>250,000	150,000–230,000
SAR 1	68,000→250,000	>250,000	>250,000
SAR 2	13,000→250,000	>250,000	170,000–220,000
SAR 3	9,700→250,000	>250,000	86,000–114,000
SAR 4	5,500→250,000	>250,000	150,000–240,000
SAR 5	5→250,000	GM=1217	13–18