

possible deterioration). The memo further stated that respirators will provide less protection than they are capable of, when used improperly (e.g., donning and doffing the respirators while still in containment; disconnecting the air hose prior to leaving the exposure area). In addition, these respirators are used in extreme conditions during construction activities (e.g., substantial and, sometimes rapid, deterioration caused by high-speed "bounceback" of the abrasive blasting material; very high levels of exposure). The impact of "bounceback" on the integrity of the respirator was not evaluated in the LLNL SWPF study since the study challenge agent was a liquid, not a particulate (which is typically the type of contaminant found in workplaces). Also, because these respirators may, at times, be used near the limits of their protective capability, workers wearing these respirators in abrasive blasting operations could receive acute exposures if the respirators do not perform properly. Therefore, performance consonant with the elevated APF can only be assured when the respirators are properly used.

As a result of the above, OSHA adopted a modified enforcement policy for these two respirators. This policy was limited to the Lead in Construction Standard (29 CFR 1926.62) and applied only to the Bullard Models 77 and 88. Also, the interim APF of 1,000 was pending until a final APF for this class of respirators could be determined through this rulemaking. Since OSHA believes that proper use of these respirators is imperative, the policy made it clear that the Agency would be very strict in assuring that these respirators are used in accordance with the manufacturer's specifications and the requirements of 1926.62.

*Clemco Apollo Models 20 and 60 and 3M Whitecap II.* With the assistance of the Industrial Safety Equipment Association (ISEA), other respirator manufacturers of Type-CE, continuous-flow, abrasive blasting respirators covered by the Lead in Construction Standard were contacted. By participating in a similar study, these manufacturers were provided with an equal opportunity to obtain the same relief afforded to Bullard. The Clemco Apollo Models 20 and 60 and the 3M Whitecap II were tested under conditions similar to the Bullard Model 77 and 88 study. Based on the results of the studies, OSHA granted the respirators the interim APF of 1,000, and developed the same enforcement policy for Clemco (Ex. 3-7-4; memo to Regional Administrators dated 03/31/

97) and 3M (Ex. 3-9-3; memo to Regional Administrators dated 12/08/98). Again, the interim APF was contingent on the final APF for these respirators being determined through this rulemaking.

#### 9. SWPF Studies—N95 Air-Purifying Respirators

*NIOSH N95 Chamber Studies.* In 1999, NIOSH conducted a chamber study of N95 respirators and statistically analyzed the respirators' performance (Ex. 4-14). The study involved twenty-five subjects meeting the criteria of the LANL respirator panel. Twenty-one respirators were tested and included twenty filtering-facepiece and one elastomeric half-mask. Each test involved a sequence of six sedentary-type exercises: Normal breathing, deep breathing, moving the head side to side, moving the head up and down, reading the rainbow passage out loud, and normal breathing. Each exercise took about 80 seconds. For all tests, the subjects donned the respirator and conducted a user seal check in accordance with the manufacturer's instructions. After each test, the test operator returned the respirator to its original pre-test configuration (e.g., strap was loosened). The investigators used a PortaCount Plus, a condensation nucleus type of particle detector, to determine the protection factor by measuring both the challenge aerosol (i.e., ambient aerosol) and the aerosol penetrating the respirator.

The total penetration of an aerosol into a respirator includes the penetration through the filter media in addition to that resulting from face seal leakage. To determine face seal leakage, the study authors subtracted estimated filter media penetration from the total observed penetration. Filter media penetration was ascertained by separate testing performed on the filter media after human subject testing. Testing was conducted at an airflow rate of 31.4 Lpm, as determined from a volume-weighted average cycle having a peak flow rate of 40 Lpm. The same penetration for a given media was subtracted from the total penetration for all subjects using a respirator with that media. Calculating face seal leakage in this manner assumes all subjects have the same constant, volumetric flow rate through the respirator. The authors also summarized total penetration and face seal leakage penetrations. The 95th percentiles presented by NIOSH were based on a formula using the geometric mean and geometric standard deviation, and assumes the distribution to be log normal.

*LLNL Study of Four N95 Filtering Facepiece Respirators.* At OSHA's request, researchers at LLNL conducted chamber testing on four of the same commercial N95 filtering facepiece half-mask respirators used in the NIOSH study (Ex. 4-14). The four N95 filtering facepieces selected by OSHA for study were: 3M Model 8210, 3M Model 8511, Wilson Model 9501, and MSA Affinity Ultra (formerly Uvex/Pro Tech Model 4010). Six subjects (three male, three female) with six different face dimensions (according to lip length) used each filtering facepiece. These subjects represented six different boxes on the Los Alamos National Laboratory half-mask test panel (Boxes 4, 5, 7, 8, 9, and 10). Subjects used the manufacturer's instructions prior to donning the respirator. Each subject tested each respirator 4 times, for a total of 16 tests per subject and 96 tests overall. The investigators probed the respirators in the area of the nose, using the TSI fit-test probe kit, and measured penetration values with a TSI PortaCount Model 8020. They used ambient room aerosol as the challenge atmosphere and monitored it continuously during testing with a second PortaCount. They used room aerosol at concentrations greater than 2,000 particles/cc. Subjects removed the filtering facepiece at the conclusion of each test and, after approximately 2 minutes, redonned the same unit. The test operator restored the respirator to pre-test configuration (e.g., straps were loosened) after each donning. Each test consisted of nine exercises: normal breathing, deep breathing, side-to-side head movement, up and down head movement, reading the rainbow passage, normal breathing, scooping rocks between buckets, stacking 30-pound concrete blocks and normal breathing. Subjects performed each exercise for 80 seconds, with a 20-second instrument purge cycle and 60 seconds of data collection per exercise.

For each model of respirator, the investigators used the size that showed the least penetration when the subject performed a 60-second reading of the rainbow passage. This was a change from using the penetration measured during normal breathing (as done in the original NIOSH tests), and was chosen because reading is frequently found to be an exercise that permits high penetration. A 60-second normal breathing fit test was performed in addition to the reading fit test. Multiple fit tests (both reading and normal breathing) were performed, if necessary, to select a model size. Once fitted, each