

is the ratio of the concentration of the contaminant found in the workplace air to the concentration found inside the respirator facepiece. Similarly, a SWPF study measures the ratio of a contaminant's concentration both outside and inside the facepiece. However, researchers obtain these measurements in test chambers, which allows them to control some important variables (e.g., outside concentration of the challenge agent). Rather than performing the actual job tasks found in a particular work setting, the study participants perform a series of exercises in the test chamber that simulate the actions of workers in general.

In developing the proposed APFs listed in Table 1 of the proposed amendments to the standards (Section XII). OSHA reviewed data from properly conducted WPF studies and SWPF studies. In addition, the Agency reviewed published APF tables. These data formed the basis for OSHA's proposed APFs. OSHA also reviewed other types of studies, such as Effective Protection Factors (EPF) and Program Protection Factor (PPF) studies, along with respirator performance studies that lacked raw data. A review of those studies can be found in the Docket (Exs. 3–10, 3–11). However, EPF and PPF studies account for aspects of respirator use other than effectiveness of the respirator while it is being worn, while studies that lack raw data give little information for in-depth statistical analysis. Therefore, OSHA relied on WPF and SWPF studies, since they attempt to account for actual use conditions and focus on the performance characteristics of the respirator only.

1. WPF Studies—Filtering Facepiece and Elastomeric Half-Mask Respirators

Study 1B. C.E. Coulton, H.E. Mullins, and J.O. Bidwell gave a presentation at the May 1994 American Industrial Hygiene Conference and Exposition (AIHCE) on worker protection afforded by the same respirator in two different environments and against two different contaminants (Ex. 1–64–13). At the first site, the authors determined exposure to cadmium dust for 18 workers in a plastic colorant manufacturing facility. They determined exposure to lead fume for 18 workers during ship breaking and recycling at the second site. At the colorant facility, cadmium-containing pigments were weighed, mixed with plastic resin, and fed into extruders for production of concentrated colorant. Samples were obtained from workers in the weighing, mixing, and extruding areas. Workers at the ship breaking

facility used torches to cut an aircraft carrier into large sections that were then cut into smaller pieces on shore. Burners and firemen, on the ship and on shore, were sampled for lead. Work rate at the colorant facility was judged to be low, while the work rate of the ship breaking workers was assessed as being moderate. The respirator used in the study was a 3M 6000 series elastomeric half-mask equipped with either 3M 2040 or 3M 2047 HEPA filters (the 2047 HEPA filter has some activated charcoal for removal of nuisance levels of organic vapors). Employees normally wore the study respirator and were provided with training in its proper donning, fitting, and operation. In addition, the employees had to pass a saccharin qualitative fit test prior to study participation; they also had to be clean-shaven. The study was explained to the participants and they were observed on a one-on-one basis throughout the sampling periods.

The inside-the-facepiece sampling train consisted of a 25 mm three-piece cassette with a 0.8 micron pore size mixed cellulose ester filter. Respirators were probed with a Liu probe inserted opposite the mouth and projecting one cm into the facepiece. The sampling cassette was attached directly to the probe, and a cassette heater was utilized to prevent condensation of moisture from exhaled breath. Outside-the-facepiece samples used a 25 mm three-piece cassette with a 0.8 micron pore size mixed cellulose ester filter. The outside sample cassette was also connected to a Liu probe, and this combination was attached in the worker's breathing zone. Inside samples and outside samples were collected at a flow rate of 2 Lpm. Respirators were donned and doffed, and sampling trains started and stopped, in a clean area. Field blanks were used for contamination evaluation. Particle size distribution was ascertained with a six-stage single-jet cascade impactor that sampled all day at 1 Lpm.

Samples were analyzed by inductively coupled plasma (ICP) spectroscopy. For both cadmium and lead, the authors presented the range of outside concentrations, inside concentrations, and the associated geometric means and standard deviations. Three sets of WPFs were determined for cadmium and lead, based on three different methods for reporting inside samples that were below the limit of detection (LOD) (i.e., calculating WPF using 70% of the LOD; calculating WPF using the LOD; or eliminating these samples from the WPF calculation database). No field blank adjustments were made (i.e., no

cadmium or lead detected), and no mention is made of adjusting the data for pulmonary retention of particles. In addition, samples were invalidated as a result of equipment and procedural problems, and if the outside filter weights were less than 100 times the limit of detection (or 101 times the field blank value). The authors reported a mean WPF of 353, with a fifth percentile of 34, for the cadmium samples, and a mean WPF of 135, with a fifth percentile of 15, for the lead fume samples. The authors noted a sizable difference in WPFs for cadmium and lead (using the same respirator), and discussed a number of possible reasons for the difference (e.g., differences in particle size, work environment, work rate). The authors concluded that the ANSI Z88.2–1992 recommended APF of 10 for half-facepieces was appropriate.

Study 1C. In a poster presentation at the 1992 AIHCE, C.E. Coulton and H.E. Mullins provided results of a study of several contaminants (Ex. 1–146). Exposure to iron (Fe), manganese (Mn), titanium (Ti), and zinc (Zn) were determined for shipyard workers involved with welding and grinding. The respirators studied were 3M 9920 and 3M 9925 dust/fume/mist disposable respirators.

At the Agency's request, 3M provided the raw data from the study, but the information provided had no discussion of sampling or analytical methodologies. However, in a brief abstract, the authors mention using blank samples and observing participants during sampling (in the context of discarding particular sample sets). Outside- and inside-the-facepiece concentrations, and associated WPFs, were provided for the four analytes: Fe (31 data sets), Mn (32 data sets), Ti (28 data sets), and Zn (32 data sets). Calculated WPFs ranged as follows: 24 to 1010 for Fe, 10.21 to 715 for Mn, 50.38 to 2545 for Ti, and 27.41 to 854.89 for Zn. Tom Nelson (Ex. 135) calculated a geometric mean (GM) of 147, a geometric standard deviation (GSD) of 2.5, and a best estimate fifth percentile of 33 for the 32 sample sets he used in evaluating this study. The information he provided contained no additional discussion of the results or study conclusions.

Study 1D. Workplace performance of an elastomeric half-mask against exposure to lead was reported in 1984 by S.W. Dixon and T.J. Nelson for 11 workers in an unidentified work environment (Ex. 1–64–19). The participants' work rate was judged to be moderate to heavy. Workers viewed a training program and selected from three mask sizes of a Survivair 2000 elastomeric half-mask respirator,