

use, and other provisions. However, OSHA reserved the sections of the final standard related to APFs and maximum use concentration (MUC) pending further rulemaking (see 63 FR 1182 and 1203). The Agency stated that, until a future rulemaking on APFs is completed:

[Employers must] take the best available information into account in selecting respirators. As it did under the previous [Respiratory Protection] standard, OSHA itself will continue to refer to the [APFs in the 1987 NIOSH RDL] in cases where it has not made a different determination in a substance specific standard. (see 63 FR 1163)

The Agency subsequently established a separate docket (*i.e.*, H049C) for the APF rulemaking. This docket includes copies of material related to APFs that it previously placed in the docket (H049) for the revised Respiratory Protection Standard. The APF rulemaking docket also contains other APF-related materials, studies, and data that OSHA obtained after it promulgated the final Respiratory Protection Standard in 1998.

History of Assigned Protection Factors

In 1965, the Bureau of Mines published "Respirator Approval Schedule 21B," which contained the term "protection factor" as part of its approval process for half-mask respirators (for protection up to 10 times the TLV) and full facepiece respirators (for protection up to 100 times the TLV). The Bureau of Mines based these protection factors on quantitative fit tests, using dioctyl phthalate (DOP), that were conducted on six male test subjects performing simulated work exercises.

The Atomic Energy Commission (AEC) published proposed protection factors for respirators in 1967, but later withdrew them because quantitative fit testing studies were available for some, but not all, types of respirators. To address this shortcoming, the AEC subsequently sponsored respirator studies at LASL, starting in 1969.

ANSI standard Z88.2-1969, which OSHA adopted by reference in 1971, did not contain APFs for respirator selection. Nevertheless, this ANSI standard recommended that "due consideration be given to potential inward leakage in selecting devices," and contained a list of the various respirators grouped according to the quantity of leakage into the facepiece expected during routine use.

In 1972, NIOSH and the Bureau of Mines published new approval schedules for respiratory protection under 30 CFR Part 11. However, these new approval schedules did not include

fit testing provisions as part of the respirator certification process.

NIOSH sponsored additional respirator studies at LASL, beginning in 1971, that used quantitative test systems to measure the overall performance of respirators. Dr. Edwin C. Hyatt of LASL included a table of protection factors for, single-use dust respirators; quarter-mask, half-mask, and full facepiece air-purifying respirators; and SCBAs in a 1976 report titled "Respirator Protection Factors" (Ex. 2). The protection factors were based on data from DOP and sodium chloride quantitative fit test studies performed on these respirators at LASL between 1970 and 1973. The table also contained recommended protection factors for respirators that had no performance test data. Dr. Hyatt based these recommended protection factors on the judgment and experience of LASL researchers, as well as extrapolations from available facepiece leakage data for similar respirators. For example, he assumed that performance data for SCBAs operated in the pressure demand mode could be used to represent other (non-tested) respirators that maintain positive pressure in the facepiece, hood, helmet, or suit during inhalation. In addition, he recommended in his report that NIOSH continue testing the performance of respirators that lacked adequate fit test data. Relative to this, staff members at LASL (from 1974 to 1978) used a representative 35-person test panel to conduct quantitative fit tests on all air-purifying particulate respirators approved by the Bureau of Mines and NIOSH.

In August 1975, the Joint NIOSH-OSHA Standards Completion Program published the RDL (Ex. 25-4, Appendix F, Docket No. H049). The RDL contained a table of protection factors that were based on quantitative fit testing performed at LASL and elsewhere, as well as the expert judgment of the RDL authors. The 1978 NIOSH update of the RDL contained the following protection factors:

- 5 for single-use respirators;
- 10 for half-mask respirators with DFM or HEPA filters;
- 50 for full facepiece air-purifying respirators with HEPA filters or chemical cartridges;
- 1,000 for PAPRs with HEPA filters;
- 1,000 for half-mask SARs operated in the pressure demand mode;
- 2,000 for full facepiece SARs operated in the pressure demand mode; and
- 10,000 for full facepiece SCBAs operated in the pressure demand mode.

ANSI's respiratory protection Subcommittee decided to revise Z88.2-1969 in the late 1970s. During its

deliberations, the Subcommittee conducted an extensive discussion regarding the role of respirator protection factors in an effective respiratory protection program. As a result, the Subcommittee decided to add an APF table to the revised standard. In May 1980, ANSI published the revision as Z88.2-1980 (Ex. 10, Docket No. H049) and it contained the first ANSI Z88.2 respiratory protection factor table. The ANSI Subcommittee based the table on Hyatt's protection factors, which it updated using results from fit testing studies performed at LANL and elsewhere since 1973. For example, the protection factor for full facepiece air-purifying particulate respirators was 100 when qualitatively fit tested, or 1,000 when equipped with high efficiency filters and quantitatively fit tested. The table consistently gave higher protection factors to tight-fitting facepiece respirators when employers performed quantitative fit testing rather than qualitative fit testing. The ANSI Subcommittee concluded that PAPRs (with any respiratory inlet covering), atmosphere-supplied respirators (in continuous flow or pressure demand mode), and pressure demand SCBAs required no fit testing because they operated in a positive pressure mode. Accordingly, it gave these respirators high protection factors, limited only by IDLH values. The Subcommittee assigned protection factors of 10,000 and over to respirators used in IDLH atmospheres.

In response to a complaint to NIOSH that the PAPRs used in a plant did not appear to provide the expected protection factor of 1,000, Myers and Peach of NIOSH conducted a WPF study during silica bagging operations. Myers and Peach tested half-mask and full facepiece PAPRs and found protection factors that ranged from 16 to 215. They published the results of the study in 1983 (Ex. 1-64-46). The results of this study led NIOSH and other researchers, as well as respirator manufacturers, to perform additional WPF studies on PAPRs and other respirators.

NIOSH revised its RDL in 1987 (Ex. 1-54-437Q). While the revision retained many of the provisions of the 1978 RDL, it recognized the problems involved in developing APFs. The 1987 RDL also revised the APFs for some respirators, based on NIOSH's WPF studies. For example, the APFs were lowered for the following respirator classes: PAPRs with a loose-fitting hood or helmet to 25; PAPRs with a tight-fitting facepiece and a HEPA filter to 50; supplied-air continuous flow hoods or helmets to 25; and supplied-air continuous flow tight-fitting facepiece respirators to 50.