DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. H049C]

RIN 1218–AA05

Assigned Protection Factors

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: In this final rule, OSHA is revising its existing Respiratory Protection Standard to add definitions and requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs). The revisions also supersede the respirator selection provisions of existing substance-specific standards with these new APFs (except for the respirator selection provisions of the 1,3-Butadiene Standard).

The Agency developed the final APFs after thoroughly reviewing the available literature, including chamber-simulation studies and workplace protection factor studies, comments submitted to the record, and hearing testimony. The final APFs provide employers with critical information to use when selecting respirators for employees exposed to atmospheric contaminants found in general industry, construction, shipyards, longshoring, and marine terminal workplaces. Proper respirator selection using APFs is an important component of an effective respiratory protection program. Accordingly, OSHA concludes that the final APFs are necessary to protect employees who must use respirators to protect them from airborne contaminants.

DATES: The final rule becomes effective November 22, 2006.

ADDRESSES: In compliance with 28 U.S.C. 2212(a), the Agency designates Joseph M. Woodward, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of this rulemaking.

FOR FURTHER INFORMATION CONTACT: For technical inquiries regarding this final rule, contact Mr. John E. Steelnack, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693–2289 or fax (202) 693–1678. For general inquiries regarding this final standard contact Kevin Ropp, OSHA Office of Public Affairs, Room N–3647, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1999). Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1888). For an electronic copy of this notice, as well as news releases and other relevant documents, go to OSHA's Web site (*http://www.osha.gov*), and select ''**Federal Register**,'' ''Date of Publication,'' and then ''2006''.

SUPPLEMENTARY INFORMATION:

I. General

A. Table of Contents

The following Table of Contents identifies the major preamble sections of this final rule and the order in which they are presented:

B. Glossary

This glossary specifies the terms represented by acronyms, and provides definitions of other terms, used frequently in the preamble to the final rule. This glossary does not change the legal requirements in this final rule, nor is it intended to impose new regulatory requirements on the regulated community.

1. Acronyms

ACGIH: American Conference of Governmental Industrial Hygienists
AIHA: American Industrial Hygiene Association
ANSI: American National Standards Institute
APF: Assigned Protection Factor
APR: Air-purifying respirator
Ci: Concentration measured inside the respirator facepiece
Co: Concentration measured outside the respirator
DOP: Dioctylphthalate (see definition below)
DFM: Dust, fume, and mist filter
EPF: Effective Protection Factor (see definition below under ''Protection factor study'')
HEPA: High efficiency particulate air filter (see definition below)
IDLH: Immediately dangerous to life or health (see definition below)
LANL: Los Alamos National Laboratory
LASL: Los Alamos Scientific Laboratory
LLNL: Lawrence Livermore National Laboratory
MSHA: Mine Safety and Health Administration
MUC: Maximum Use Concentration
NFPA: National Fire Protection Association
NIOSH: National Institute for Occupational Safety and Health
NRC: Nuclear Regulatory Commission
OSHA: Occupational Health and Safety Administration
OSH Act: The Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657, 665).
PAPR: Powered air-purifying respirator (see definition below)

PEL: Permissible Exposure Limit
PPF: Program Protection Factor (see definition below under ''Protection factor study'')
QLFT: Qualitative fit test (see definition below)
QNFT: Quantitative fit test (see definition below)
RDL: Respirator Decision Logic (see definition below)
REL: Recommended Exposure Limit (see definition below)
SAR: Supplied-air (or airline) respirator (see definition below)
SCBA: Self-contained breathing apparatus (see definition below)
WPF: Workplace Protection Factor (see definition below under ''Protection factor study'')
TLV: Threshold Limit Value (see definition below)
SWPF: Simulated Workplace Protection Factor (see definition below under ''Protection factor study'')

2. Definitions

Terms followed by an asterisk (*) refer to definitions that can be found in paragraph (b) (''Definitions'') of OSHA's Respiratory Protection Standard (29 CFR 1910.134).

Air-purifying respirator:* A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Atmosphere-supplying respirator:* A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes SARs and SCBA units.

Canister or cartridge:* A container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Continuous flow respirator: An atmosphere-supplying respirator that provides a continuous flow of breathable air to the respirator facepiece.

Demand respirator:* An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Dioctylphthalate (DOP): An aerosolized agent used for quantitative fit testing.

Elastomeric: A respirator facepiece made of a natural or synthetic elastic material such as natural rubber, silicone, or EPDM rubber.

Filter or air-purifying element:* A component used in respirators to remove solid or liquid aerosols from the inspired air.

Filtering facepiece (or dust mask):* A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor:* A quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test:* The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Helmet:* A rigid respiratory inlet covering that also provides head protection against impact and penetration.

High-efficiency particulate air filter (HEPA):* A filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR part 84 particulate filters are the N100, R100, and P100 filters.

Hood:* A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health (IDLH):* An atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Loose-fitting facepiece:* A respiratory inlet covering that is designed to form a partial seal with the face.

Negative pressure respirator (tight-fitting):* A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Permissible Exposure Limit (PEL): An occupational exposure limit specified by OSHA.

Positive pressure respirator:* A respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR):* An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator:* A positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Protection factor study: A study that determines the protection provided by a respirator during use. This determination generally is accomplished by measuring the ratio of the concentration of an airborne contaminant (e.g., hazardous substance) outside the respirator (Co) to the concentration inside the respirator (Ci) (i.e., Co/Ci). Therefore, as the ratio between Co and Ci increases, the protection factor increases, indicating an increase in the level of protection provided to employees by the respirator. Four types of protection factor studies are:

Effective Protection Factor (EPF) study: A study, conducted in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator when used intermittently for only some fraction of the total workplace exposure time (i.e., sampling is conducted during periods when respirators are worn and not worn). EPFs are not directly comparable to WPF values because the determinations include both the time spent in contaminated atmospheres with and without respiratory protection; therefore, EPFs usually underestimate the protection afforded by a respirator that is used continuously in the workplace.

Program Protection Factor (PPF) study: A study that estimates the protection provided by a respirator within a specific respirator program. Like the EPF, it is focused not only on the respirator's performance, but also the effectiveness of the complete respirator program. PPFs are affected by all factors of the program, including respirator selection and maintenance, user training and motivation, work activities, and program administration.

Workplace Protection Factor (WPF) study: A study, conducted under actual conditions of use in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator, when the respirator is worn correctly and used as part of a comprehensive respirator program that is in compliance with OSHA's Respiratory Protection Standard at 29 CFR 1910.134. Measurements of Co and Ci are obtained only while the respirator is being worn during performance of normal work tasks (i.e., samples are not collected when the respirator is not being worn). As the degree of protection afforded by the respirator increases, the WPF increases.

Simulated Workplace Protection Factor (SWPF) study: A study, conducted in a controlled laboratory setting and in which Co and Ci sampling is performed while the respirator user performs a series of set exercises. The laboratory setting is used to control many of the variables found in workplace studies, while the exercises simulate the work activities of respirator users. This type of study is designed to determine the optimum performance of respirators by reducing the impact of sources of variability through maintenance of tightly controlled study conditions.

Qualitative fit test (QLFT):* A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT):* An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Recommended Exposure Limit (REL): An occupational exposure level recommended by NIOSH.

Respirator Decision Logic (RDL): Respirator selection guidance developed by NIOSH that contains a set of respirator protection factors.

Self-contained breathing apparatus (SCBA):* An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Supplied-air respirator (or airline) respirator (SAR):* An atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Threshold Limit Value (TLV): An occupational exposure level recommended by ACGIH.

Tight-fitting facepiece:* A respiratory inlet covering that forms a complete seal with the face.

II. Events Leading to the Final Standard

A. Regulatory History of APFs

Congress established the Occupational Safety and Health Administration (OSHA) in 1970, and gave it the responsibility for promulgating standards to protect the health and safety of American workers. As directed by the OSH Act, the Agency adopted existing Federal standards and national consensus standards developed by various organizations such as the NFPA and ANSI. The ANSI standard Z88.2–1969, ''Practices for Respiratory Protection,'' was the basis of the first six sections (permissible practice, minimal respirator program, selection of respirators, air quality, use, maintenance and care) of OSHA's Respiratory Protection Standard (29 CFR 1910.134) adopted in 1971. The seventh section was a direct, complete incorporation of ANSI Standard K13.1–1969, ''Identification of Gas Mask Canisters.''

The Agency promulgated an initial respiratory protection standard for the construction industry (29 CFR 1926.103) in April 1971. On February 9, 1979, OSHA formally applied 29 CFR 1910.134 to the construction industry (44 FR 8577). Federal agencies that preceded OSHA developed the original maritime respiratory protection standards in the 1960s (e.g., Section 41 of the Longshore and Harbor Worker Compensation Act). The section designations adopted by OSHA for these standards, and their original promulgation dates, are: Shipyards—29 CFR 1915.82, February 20, 1960 (25 FR 1543); Marine Terminals—29 CFR 1917.82, March 27, 1964 (29 FR 4052); and Longshoring—29 CFR 1918.102, February 20, 1960 (25 FR 1565). OSHA incorporated 29 CFR 1910.134 by reference into its Marine Terminal standards (Part 1917) on July 5, 1983 (48 FR 30909). The Agency updated and strengthened its Longshoring and Marine Terminal standards in 1996 and 2000, and these standards now incorporate 29 CFR 1910.134 by reference.

Under the Respiratory Protection Standard that OSHA initially adopted, employers were required to follow the guidance of the Z88.2–1969 ANSI standard to ensure proper selection of respirators. Subsequently, OSHA published an Advance Notice of Proposed Rulemaking (''ANPR'') to revise the Respiratory Protection Standard on May 14, 1982 (47 FR 20803). Part of the impetus for this notice was the Agency's inclusion of new respirator requirements in the comprehensive substance-specific standards promulgated under section (6)(b) of the OSH Act, e.g., fit testing protocols, respirator selection tables with assigned protection factors, use of PAPRs, changing filter elements whenever an employee detected an increase in breathing resistance, and referring employees with breathing difficulties, either at fit testing or during routine respirator use, to a physician trained in pulmonary medicine (see, e.g., 29 CFR 1910.1025 (OSHA's Lead Standard)). The respirator provisions in these substance-specific standards reflected advances in respirator technology and changes in related guidance documents that were state-of-the-art information at the time when OSHA published these substance-specific standards. These standards recognized that effective respirator use depends on a comprehensive respiratory protection program that includes the use of APFs.

In the 1982 ANPR, OSHA sought information on the effectiveness of its current Respiratory Protection Standard, the need to revise the standard, and recommendations regarding what revisions should be made. The 1982 ANPR referenced the ANSI Z88.2–1980 standard on respiratory protection with its table of protection factors, the 1976 report by Ed Hyatt from LASL titled ''Respiratory Protection Factors'' (Ex. 2), and the RDL developed jointly by OSHA and NIOSH, as revised in 1978 (Ex. 9, Docket No. H049). The 1982 ANPR asked for comments on how OSHA should use protection factors. The Agency received 81 responses to this inquiry. The commenters generally supported revising OSHA's Respiratory Protection Standard, and provided recommendations regarding approaches for including a table of protection factors (Ex. 15).

On September 17, 1985, OSHA announced the availability of a preliminary draft of the proposed Respiratory Protection Standard. This preproposal draft standard included a discussion of the public comments received in response to the 1982 ANPR, and OSHA's analysis of revisions needed in the Respiratory Protection Standard to address up-to-date respiratory protection. The Agency received 56 responses from interested parties (Ex. 36), which OSHA carefully reviewed in developing the proposed rule.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and provided notice of an informal public hearing on the proposal (59 FR 58884). The Agency convened the informal public hearing on June 6, 1995. In response to the comments OSHA received on the proposal, the Agency proceeded to develop APFs. On June 15, 1995, as part of the public hearing, OSHA held a one-day panel discussion by respirator experts on APFs. The discussion included measuring respirator performance in WPF and SWPF studies, the variability of data from these studies, and setting APFs for various types of respirators that protect employees across a wide variety of workplaces and exposure conditions.

OSHA also reopened the rulemaking record for the revised Respiratory Protection Standard on November 7, 1995 (60 FR 56127), requesting comments on a study performed for OSHA by Dr. Mark Nicas titled ''The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors'' (Ex. 1–156). This study, which the Agency placed in the rulemaking docket on September 20, 1995, addressed the use of statistical modeling for determining respirator APFs. OSHA received 12 comments on the Nicas report. This report, and the comments received in response to it, convinced OSHA that more information would be necessary before the Agency could resolve the complex issues regarding how to establish APFs, including what methodology to use in analyzing existing protection factor studies. (See Section IV. Methodology for Developing Assigned Protection Factors in the June 6, 2003 NPRM, 68 FR 34044, for a detailed discussion of the Nicas report and the comments OSHA received.)

OSHA published the final, revised Respiratory Protection Standard, 29 CFR 1910.134, on January 8, 1998 (63 FR 1152). The standard contains worksite-specific requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator use, and other provisions. However, OSHA reserved the sections of the final standard related to APFs and MUCs 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. (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 previously were 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.

On June 6, 2003, the Agency published in the **Federal Register** an NPRM titled ''Assigned Protection Factors; Proposed Rule'' (68 FR 34036) that contained proposed definitions for APFs and MUCs, a proposed Table 1 with APFs for the various respirator classes, and proposed revisions to the APF provisions and tables in OSHA's substance-specific standards. The NPRM announced that OSHA would be holding an informal public hearing in Washington, DC on the proposal. The public hearings were held over three days, from January 28–30, 2004. OSHA received extensive pre-hearing comments (Exs. 9–1 through 9–43 and 10–1 through 10–60), written hearing testimony (Exs. 16–1 through 16–25), post-hearing comments (Exs. 17–1 through 17–12), and post-hearing briefs (Exs. 18–1 through 18–9 and 19–1 through 19–8). Transcripts of the public hearings also were made and added to the APF Docket (Exs. 16–23–1, 16–23–2, and 16–23–3). It is from these public comments, exhibits, hearing transcript, and post-hearing submissions that OSHA has prepared these final APF and MUC provisions and revisions to substance-specific standards.

B. Non-Regulatory History of APFs

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 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, which the AEC used to determine APFs, were available for some, but not all, types of respirators. To address this shortcoming, the AEC sponsored respirator performance 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 expected quantity of leakage into the facepiece during routine use.

In 1972, NIOSH and the Bureau of Mines published new approval schedules for respiratory protection under 30 CFR 11. However, these new approval schedules did not include provisions for determining facepiece leakage 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. In a 1976 report titled ''Respirator Protection Factors'', 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 (Ex. 2). Hyatt based these protection factors on data from DOP and sodium chloride quantitative fit test studies performed at LASL on these respirators between 1970 and 1973. The table also contained recommended protection factors for respirators that had no performance test data. 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, Hyatt 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, Hyatt recommended in his report that NIOSH continue testing the performance of respirators that lacked adequate fit test data. To increase the database, Hyatt used a representative 35-person test panel to conduct quantitative fit tests from 1974 to 1978 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. In 1978, NIOSH updated the RDL specifying 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 (''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 which contained the first ANSI Z88.2 respirator protection factor table (Ex. 10, Docket H049). 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

HEPA 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 either a continuous flow or pressure-demand mode), and pressure-demand SCBAs required no fit testing because they operated in a positive-pressure mode. ANSI assigned high protection factors to these respirators, but limited their use to concentrations below the IDLH values. Pressure-demand SCBAs and combination continuous flow or pressure-demand airline respirators with escape provisions for use in IDLH atmospheres were assigned protection factors of 10,000 plus.

In response to a complaint to NIOSH that the PAPRs used in a workplace 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 under these conditions, and found protection factors that ranged from 16 to 215. They published the results of their 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) to address advances in respirator technology and testing. The revision retained many of the provisions of the 1978 RDL, but also lowered the APFs for other 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 (reduced to 25); PAPRs with a tight-fitting facepiece and a HEPA filter (lowered to 50); supplied-air continuous flow hoods or helmets (decreased to 25); and supplied-air continuous flow tight-fitting facepiece respirators (reduced to 50).

In August 1992, ANSI again revised its Z88.2 Respiratory Protection Standard (Ex. 1–50). The ANSI Z88.2–1992 standard contained a revised APF table, based on the Z88.2 Subcommittee's review of available protection factor studies. In a report describing the revised standard (Ex. 1–64–423), Nelson, Wilmes, and daRoza described the rationale used by the ANSI Subcommittee in setting APFs:

> If WPF studies were available, they formed the basis for the [APF] number assigned. If no such studies were available, then laboratory studies, design analogies, and other information [were] used to decide what value to place in the table. In all cases where the assigned protection factor changed when compared to the 1980 standard, the assigned number is lower in the 1992 standard.

In addition, the 1992 ANSI Z.88.2 standard abandoned ANSI's 1980 practice of giving increased protection factors to some respirators when quantitative fit testing was performed.

Thomas Nelson, the co-chair of the ANSI Z88.2–1992 Subcommittee, published a second report entitled ''The Assigned Protection Factor According to ANSI'' (Ex. 135) four years after the Z88.2 Subcommittee completed the revised 1992 standard. In the report, Nelson reviewed the reasoning used by the ANSI Subcommittee in setting the 1992 ANSI APFs. Nelson noted that the Z88.2 Subcommittee gave an APF of 10 to all half mask air-purifying respirators, including quarter mask, elastomeric, and disposable respirators. The Subcommittee also recommended that full facepiece air-purifying respirators retain an APF of 100 (from the 1980 ANSI standard) because no new data were available to justify another value. Nelson noted that the Z88.2 Subcommittee approved the RDL's reduction to an APF of 25 for loose-fitting facepieces and PAPRs with helmets or hoods based on their performance in WPF studies. For half mask PAPRs, the ANSI Subcommittee set an APF of 50 based on a WPF study by Lenhart (Ex. 1–64–42). The ANSI Subcommittee had no WPF data available for full facepiece PAPRs, so Nelson indicated that the Subcommittee selected an APF of 1,000 to be consistent with the APF for PAPRs with helmets or hoods. The Subcommittee, in turn, based its APF of 1,000 for PAPRs with helmets or hoods on design similarities (i.e., same facepiece designs, operation at the same airflow rates) between these respirators and airline respirators. Nelson noted that the results from a subsequent WPF report by Keys (Ex. 1–64–40) on PAPRs with helmets or hoods were consistent with an APF of 1,000. According to Nelson, the Subcommittee used WPF studies by Myers (Exs. 1–64–47 and 1–64–48), Gosselink (Ex. 1–64–23), and Que Hee and Lawrence (Ex. 1–64–60) to set an APF of 25 for PAPRs with loose-fitting facepieces. Nelson stated that two WPF studies, conducted by Gaboury and Burd (Ex. 1–64–24) and Stokes (Ex. 1–64–66) subsequent to publication of ANSI Z88.2–1992, supported the APF of 25 selected by the Subcommittee for PAPRs with loose-fitting facepieces.

Nelson also stated in his report that the ANSI Subcommittee had no new information on atmosphere-supplying respirators. Therefore, the APFs for these respirators were based on analogies with other similarly designed respirators (Ex. 135). The ANSI Subcommittee based the APF of 50 for half mask continuous flow atmosphere-supplying respirators, and the APF of 25 for loose-fitting continuous flow atmosphere-supplying respirators, on the similarities between these respirators and PAPRs with the same airflow rates. Nelson noted that the ANSI Subcommittee set the APF of 1,000 for full facepiece continuous flow atmosphere-supplying respirators consistent with the APF for SARs with helmets or hoods using the results of two earlier studies: a WPF study by Johnson (Ex. 1–64–36) and a SWPF study by Skaggs (Ex. 1–38–3). The Subcommittee used the design analogy between PAPRs and continuous flow supplied-air respirators to select the APF of 50 for half mask pressure-demand SARs and an APF of 1,000 for full facepiece pressure-demand SARs. Nelson stated, ''The committee believed that setting a higher APF because of the pressure-demand feature was not warranted, but rather that the total airflow was critical'' (Ex. 135).

Nelson noted in the report that the Subcommittee selected no APF for SCBAs. In explaining the committee's decision, he stated that ''the performance of this type of respirator may not be as good as previously measured in quantitative fit test chambers.'' Nelson also observed that the ANSI Z88.2–1992 standard justified this approach in a footnote to the APF table. The footnote states:

> A limited number of recent simulated workplace studies concluded that all users may not achieve protection factors of 10,000. Based on [these] limited data, a definitive assigned protection factor could not be listed for positive pressure SCBAs. For emergency planning purposes where hazardous concentrations can be estimated, an assigned protection factor of no higher than 10,000 should be used.

A new ANSI Z88.2 Subcommittee recently finished revising the ANSI Z88.2–1992 standard, in accordance with the ANSI policy specifying that each standard receive a periodic review. This revised ANSI Z88.2 standard is currently under appeal to the ANSI Board.

C. Need for APFs

When OSHA published the final Respiratory Protection Standard in January 1998, it noted that the revised standard was to ''serve as a 'building block' standard with respect to future standards that may contain respiratory protection requirements'' (63 FR 1265).

OSHA's final Respiratory Protection Standard established the minimum elements of a comprehensive program that are necessary to ensure effective performance of a respirator. The only parts missing from this building block standard are the APF and MUC provisions that are being finalized in this rulemaking. In the standard the Agency recommended that employers in the interim ''take the best information into account in selecting respirators. As it did under the previous standard, OSHA itself will continue to refer to the NIOSH APFs in cases where it has not made specific compliance interpretations'' (63 FR 1203).

In October 2004, NIOSH published its Respirator Selection Logic (RSL), an update of the 1987 RDL. The APF tables in the new RSL have not changed from those in the 1987 RDL. However, NIOSH stated in the forward to the 2004 RSL: ''[w]hen the OSHA standard on APFs is finalized NIOSH intends to consider revisions to this RSL.'' (Ex. 20–4.)

The ANSI Z88.2–1992 APF table also has been a source for interim APFs while OSHA completed its APF rulemaking. However, the ANSI Z88.2–1992 respiratory protection standard was withdrawn by ANSI in 2003. While a revised ANSI Z88.2 standard has been written, the final ANSI standard has yet to be published since it is currently under appeal. Therefore, no ANSI respiratory protection standard with recommended APFs is available at this time. The draft APF table from the ANSI Z88.2 revision was submitted to the OSHA rulemaking docket (Ex.13–7–2), and was the subject of discussion during the public hearings on APFs. OSHA considered the draft ANSI table during its deliberations in this rulemaking.

Throughout the Respiratory Protection Standard rulemaking, OSHA has emphasized that the APF and MUC definitions and the APF table are an integral part of the overall standard. A careful review of the submitted comments and information supports the Agency's conclusion that this final standard is necessary to guide employers in selecting the appropriate class of respirator needed to reduce hazardous exposures to acceptable levels. The final APF for a class of respirators specifies the workplace level of protection that a class of respirator should provide under an effective respiratory protection program. In addition, the APFs can be utilized by employers to determine a respirator's MUC for a particular chemical exposure situation.

The final APFs must be used in conjunction with the existing provisions of the Respiratory Protection Standard. Integration of the final APF and MUC provisions into the reserved provisions of paragraph (d) completes that standard. With the addition of these provisions, appropriate implementation of the Respiratory Protection Standard by employers in their workplaces should afford each affected employee the maximum level of respiratory protection.

III. Methodology for Developing APFs for Respirators

A. Introduction

In the proposed rule for Assigned Protection Factors (APFs), OSHA raised a number of issues or questions about its proposed methodology for deriving APFs (68 FR 34112–34113). OSHA asked for information on: (1) The evidence-based method used by OSHA in developing the proposed APFs; (2) any additional studies that may be useful in determining APFs that were not already identified by OSHA in the proposal; and, (3) statistical analyses, treatments, or approaches, other than those described in the proposal, available for differentiating between, or comparing, the respirator performance data. The vast majority of the comments in response to the NPRM addressed the use of WPF studies for establishing the APF for filtering facepiece half mask respirators. OSHA also received comments on the methodology and data it used for determining the filtering facepiece APF, and was provided with new studies on these respirators for consideration. OSHA's quantitative analyses for establishing the APFs for other classes of higher performing respirators drew little comment, and no new studies on these respirators were submitted. This section, therefore, focuses on methodology and new information relative to the APF for half mask air-purifying respirators.

More specifically, Part C of this section contains a discussion of the comments about OSHA's proposed methodology for determining APFs for filtering facepiece half mask respirators, including comments on data analysis and study selection. In addition, OSHA is providing an overview of Dr. Kenny Crump's statistical analyses (Ex. 20–1) of the updated half mask database (Ex. 20–2). Comments about alternative approaches are discussed in Part D (''Methodology, Data, and Studies on Filtering Facepieces and Elastomerics''). The Agency's overall conclusions on methodology, and summaries of new studies submitted during the public comment process, are presented under Part E. Discussion of the comments and opinions regarding the APF for half mask respirators and the establishment of the APFs for higher performing respirators is included in Section VI, Summary and Explanation of the Final Standard.

B. Background

The Occupational Safety and Health Act of 1970 (''OSH Act''), 29 U.S.C. 651–678, enacted to ensure safe and healthy working conditions for employees, empowers OSHA to promulgate standards and provides overall guidance on how these standards are to be developed. It states:

> (5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, *shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence,* that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. *Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate.* In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be *the latest available scientific data in the field,* the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. 29 U.S.C. 655(b)(5) [emphasis added].

A reviewing court will uphold standards set under this section when they are supported by substantial evidence in the record considered as a whole (29 U.S.C. 655(f)). In searching for the ''best available evidence'' upon which to base its rulemaking, OSHA is required to ''identify the relevant factual evidence, * * * to state candidly any assumptions on which it relies, and to present its reasons for rejecting any significant contrary evidence or argument.'' *Public Citizen Health Research Group* v. *Tyson*, 796 F.2d 1479, 1495 (D.C. Cir. 1986).

OSHA has retained the multifaceted approach it used in the proposal to determine the APFs for classes of respirators. That is, the Agency reviewed all of the available literature, including the various analyses by respirator authorities, as well as quantitative analyses of data from WPF and SWPF studies. During revision of the overall Respiratory Protection Standard, the Agency used a similar approach when reviewing protection factor studies related to the effectiveness and necessity of a comprehensive respiratory protection program.

The Agency did not use Effective Protection Factor (EPF) and Program Protection Factor (PPF) studies in its APF analyses since these measure deficiencies in respirator program practices. More specifically, EPFs are not directly comparable to WPF values because the determinations include the time spent in contaminated atmospheres both with and without respiratory protection. PPFs are affected by any deficient elements of a respirator program, including inadequate respirator selection and maintenance, poor user training and motivation, work activities, and inadequate program administration. Therefore, OSHA relied on WPF and SWPF studies, since they focus on the performance characteristics of the respirator only.

During the APF rulemaking, OSHA reviewed the extensive literature on APFs and developed selection criteria for including studies and data in its quantitative analysis of respirator performance. This procedure ensured that only carefully designed and executed WPF and SWPF studies were included in the analysis. The Agency then used these studies to compile the NPRM's original database. The database was comprised of 917 data points from 16 WPF studies for half mask respirators (Matrix 1) and 443 data points from 13 studies for PAPRs and SARs (Matrix 2), conducted in a variety of American workplaces. OSHA made the studies, its selection criteria, the data, and its analyses available to the public electronically and through the rulemaking docket. In addition, the Agency encouraged the public to access this information and to reanalyze the data using methods of their choice. The Agency also sought submissions from the public of any additional studies for inclusion in its database. Four additional WPF studies of half masks were submitted during the public comment period following publication of the NPRM. Dr. Kenny Crump updated the Matrix 1 half mask database with these additional studies (Ex. 20–2) and reanalyzed the resulting 1,339 data points for half mask respirators (Ex. 20–1).

Dr. Crump also performed a second quantitative analysis in which the 1,339 accepted data points (original NPRM database updated with data from the four new studies) for half mask respirators were combined with 403 data points from 12 studies that the Agency originally excluded from the analysis. This second analysis corroborated the original findings to the extent practicable. The results of both of these analyses provide compelling support of OSHA's conclusions regarding the appropriate APF for half mask respirators. The Agency believes that the database it constructed represents the best available data on APFs, and that its conclusions are based on substantial evidence. *See Texas Independent Ginners' Association* v. *Marshall*, 630 F.2d 398, 413 n. 48 (5th Cir. 1980), citing *Industrial Union Dept., AFL–CIO–CIC* v. *American petroleum Institute*, 448 U.S. 607, 661 (1980).

In past rulemakings, OSHA's conclusions as to the best available evidence have been upheld as based on substantial evidence when it has relied on a body of reputable scientific evidence. *See ASARCO* v. *Occupational Safety and Health Administration*, 746 F.2d 483, 494 (9th Cir. 1984). OSHA need not accept all data presented to it as long it considers the data and rejects it on reasonable grounds. *See id.* Furthermore, each study relied upon by the Agency need not be a model of textbook scientific inquiry, and OSHA need not find one definitive study supporting its decision. *Public Citizen Health Research Group*, 796 F.2d at 1489, 1495. Rather, the Agency is justified in adopting a conclusion when the cumulative evidence is compelling. *Id.* at 1489, 1491, 1495. OSHA's conclusions are strongest when it has relied on multiple data sources that support each other, as it has in this rulemaking.

C. Methodology, Data, and Studies on Filtering Facepieces and Elastomerics

1. Comments on the Methodology

OSHA developed the proposed APFs through a multi-faceted approach. As it stated in the preamble to the proposal, "The Agency reviewed the various analyses of respirator authorities, available WPF and SWPF studies, and other APF literature." It later concluded that "the APFs proposed by OSHA in this rulemaking represent the Agency's evaluation of all available data and research literature i.e., a composite evaluation of all relevant quantitative and qualitative information" (68 FR 34050). OSHA then asked the public if this method was appropriate to determine APFs. The methodology was supported by a number of commenters, including NIOSH (Ex. 9–13), the Department of the Army (Ex. 9–42), ALCOA (Ex. 10–31), and others (e.g., Exs. 9–1, 9–4, 9–14, 9–16, 9–22, 10–2, 10–17, 10–18, and 10–59). NIOSH stated:

> NIOSH agrees that the APF values resulting from this multi-faceted approach are reasonable indications of the level of protection that should be expected for each class of respirators. * * *
>
> The available data are not ideal because there can be considerable model-to-model variation and only a few models in each class have been evaluated. Given that lack of complete data, the approach taken by OSHA is the most appropriate currently possible. (Ex. 9–13.)

The United States Army Center for Health Promotion and Preventive Medicine commented:

> The method of APF development used by OSHA is appropriate. OSHA reviewed available data, both published and unpublished; utilized technical reviews and summaries from subject matter experts outside-OSHA; weighed study findings and conclusions based on study shortfalls, as then state-of-the-art technical bias and procedural omissions; and used a conservative approach to maintain confidence that minimal risk of respirator selection and use errors will exist in worker protection from proposed APF use. (Ex. 9–42–1.)

Nevertheless, some commenters did not agree with OSHA's approach. These participants included several labor organizations (Exs. 9–27, 9–29, 9–34, 9–40, and 10–37), trade associations (Exs. 9–24 and 10–27), and individuals (e.g., Exs. 9–17, 9–25, 9–33, 9–41, 10–33, and 10–42). Criticisms of OSHA's approach focused on the Agency's selection of WPF studies for its determination of the proposed APFs. Reasons given to support these criticisms included: The differences between the studies do not permit comparison of the studies; the study conditions are not representative of typical workplaces; the study data are too old; the data do not cover all configurations of filtering facepieces available; and, the analytical method employed by some studies was too sensitive.

A few commenters (Exs. 10–34 and 10–47) recommended that certain criteria should be met before a WPF study is deemed acceptable for analysis. These criteria include: Exposures to small particle sizes; work time of at least four hours; moderate to heavy work rate; and, high temperature and humidity. Still others believed that OSHA should develop and perform SWPFs on a representative subset of all filtering facepieces or all configurations of filtering facepiece respirators and all respirator models, and establish APFs for all classes of respirators based on the SWPF study results (Exs. 9–41 and 10–27). A more detailed discussion of data issues is presented below.

2. Comments on Data and Study Problems

Selection bias in WPF studies. Several commenters stated that the authors of WPF studies "cherry-picked" either the workplaces in which the studies were conducted or the individual tasks that were performed by workers chosen for monitoring (Pascarella, Tr. at 464; Faulkner, Tr. at 549 and 564–565). ''Cherry-picking'' is a common term for ''selection bias.'' Selection bias is a matter of concern when either workplace study participants or job tasks are selected for inclusion in the study in a manner that skews the results of the study away from the true value.

Selection bias is a matter of concern for all scientific studies, not just WPF studies, and peer reviewers typically evaluate its effects before a study is accepted for publication in a peer-reviewed journal. Most of the studies included in OSHA's analysis of WPF studies were either published in peer-reviewed journals or were presented at the AIHCE, and met the criteria for respirator research studies accepted by the industrial hygiene community. The half mask database consists of 16 studies performed in a variety of workplaces over a range of years (from 1976 to 2004) by many different researchers. Therefore, it is highly improbable that these studies were subject to selection bias. OSHA could find no instance of selection bias either in its review of the scientific studies or its analysis of the data. Finally, OSHA repeatedly asked commenters who raised concerns about ''cherry-picking'' for specific studies in which selection bias occurred. In no case did the commenters provide any details to support their allegations.

Observer effect in WPF studies. Several commenters (Shine, Tr. at 644 and Macaluso, Tr. at 652) stated that data from the WPF studies considered by OSHA were the result of a condition known as the ''observer effect.'' The observer effect occurs when the act of observing or monitoring test subjects causes their responses to differ from their usual (nonobserved) responses. In some of the WPF studies used by OSHA, the researchers stated that during the study, they were present to monitor the test equipment to ensure that the sampling equipment functioned properly, thereby increasing the usefulness of the results. In other WPF studies, the researchers did not indicate their presence during the study.

The mere presence of an observer does not, in and of itself, presume that there will be an observer effect. For example, if the observer is a researcher who is monitoring the test equipment instead of a supervisor who is monitoring the workers' practices, the workers are unlikely to change their practices.

Although the Agency repeatedly asked the commenters who raised this concern to identify specific studies in which the observer effect may have been involved, they could not do so (i.e., in no case did the commenters provide any example to support their allegations). In its own analysis of the WPF studies, the Agency was also unable to find any evidence of an observer bias.

Representativeness of the data. A number of commenters expressed concern that the study data analyzed by OSHA were not representative of conditions found in the construction industry (Ex. 9–29, Building Construction Trades Department), or of workplace conditions in general (e.g., Exs. 9–34, International Union Operating Engineers; 9–35, Melissa Rich; 9–40, United Steel Workers of America; and 10–60, Paul Hewett). The bulk of these concerns are represented in the comments of Melissa Rich, a Department of Energy respirator program manager, who stated:

> The selection of the test sites for the cited APF proposed rulemaking WPF studies are not representative of the worksite for American workers. Many test sites chosen for these studies were selected on availability only. Moreover, key study attributes such as hot humid conditions, long work hours, and heavy workload were the exception, not the norm for most of the cited studies. Most test sites had ambient concentrations less than the OSHA half mask respirator maximum use limit (i.e., ten times the PEL).
>
> * * * * *
>
> The various particle sizes, a critical issue in a WPF, cited in many of the APF proposed rule Workplace Protection Factor studies are so large that they do not penetrate the faceseal. Many respiratory protection studies have indicated that particles larger than two microns are less likely to penetrate the most important attribute of a respirator, the faceseal. Most of the APF proposed rule Workplace Protection Factor studies have a particle size greater than two microns. (Ex. 9–35.)

The studies analyzed by OSHA consisted of a varied cross-section of workplaces and conditions. For example, workplaces included ship breaking, asbestos removal, aluminum and lead smelters, brass foundries, and aircraft painting and manufacturing. Two of the four new studies analyzed by OSHA involved concrete-block manufacturing. The authors of an aluminum smelter study (Ex. 1–64–24) noted that employees were required to rest in a cool area for 50% of each hour due to high heat, and a steel mill study (Ex. 1–64–50) and a primary lead smelter study (Ex. 1–64–42) both were conducted in the sinter plant and blast furnace areas. The asbestos study (Ex. 1–64–54) was conducted under high humidity conditions. Tasks performed by test subjects included welding and grinding, torch cutting, pouring molten metal, handling concrete blocks, and spray painting. Work rates for these studies, when provided, ranged from low to heavy.

The purpose of a WPF study is to evaluate a respirator's effectiveness under actual workplace use conditions. Consequently, the contaminant concentrations and particle sizes contained in the analyzed studies were generated while the workers performed their normal job duties. With regard to concerns about particle size, Myers et al. (Ex.1–64–51) found particles larger than 10 microns inside the respirator facepiece. The Agency believes that accepting only WPF studies that are conducted at exposure levels close to 10 times the PEL, with particulates of two microns in size or less, would not be representative of the conditions found in the workplace. Studies based on such selective criteria would be more akin to a SWPF, rather than a WPF, study. OSHA has concluded that the data used in its analyses are applicable to other American work settings because a range of work rates and environmental conditions were represented, and many of the tasks performed by the test subjects are performed in a variety of workplaces, including construction. Accordingly, the Agency is not persuaded by comments suggesting that the studies were so narrowly focused that the data cannot be applied to other work settings.

Sensitive analytical method. Several commenters questioned the use of sensitive analytical methods for the analyses of workplace exposures, sometimes accompanied by a recommendation to test respirators under controlled laboratory settings, and at sufficiently high concentrations to obtain inside-the-facepiece measurements (Ci) that can be assessed by less sensitive methods (e.g., Exs. 9–32, 9–35, 10–6, 10–37, and 10–49). The commenters believed that sensitive analytical methods (particularly PIXEA, proton-induced x-ray emission analysis) permit the determination of low Ci concentrations, resulting in high protection factors.

In response to these comments, OSHA reviewed the seven half mask studies that used the PIXEA analytical method (Exs. 1–64–19, 1–64–51, 1–64–52, 1–64–15, 1–64–16, and 1–64–34) and found that six of the studies used the method to measure both the Ci and Co concentrations. The seventh study (Ex. 3–12) used PIXEA to measure the Ci concentration but used atomic absorption (AA) to assess Co concentrations because the respirator filters were overloaded. However, the

Agency does not believe that this study provided inaccurate results. Under conditions of high Co concentrations, the AA method must be used because the PIXEA method would exceed its maximum measurement limits. Therefore, the PIXEA method would be unable to provide accurate Co data. Based on its review of these seven studies, the Agency found that the sensitive analytical method (i.e., PIXEA) allowed the investigators to quantify small amounts of contaminant that penetrate a respirator. This method permitted accurate assessment of Ci concentrations under conditions of low ambient concentrations, thereby permitting the use of actual Ci values in determining WPFs. Less sensitive methods would result in penetration values that are nondetectable or less than the limit of detection (LOD) for the analytic method, thereby requiring the study to discard these data or to correct for nondetected values using unvalidated statistical techniques. On the other hand, the sensitive analytical method was able to quantify low Ci concentrations, thereby enhancing the validity of the subsequent analysis by retaining the actual data and avoiding unvalidated statistical corrections.

Craig Colton of 3M provided the following testimony in support of OSHA's conclusions:

Some commenters also asserted that the use of analytical methods with low detection limits are a reason to invalidate some of the WPF studies. The claim is erroneously made that the analytical sensitivity affects the results from WPF studies. However, the actual amount of contaminant on the Ci sample is not changed by the analytical method.

* * * Because the [Ci levels are] typically very small in a WPF study, the higher sensitivity of [the PIXEA method] is necessary to get the best data.

* * * The WPF protocol from the AIHA Respirator Committee recommended the use of analytical methods with sensitive detection limits. * * * Use of less sensitive analytical methods for * * * [Ci] sample[s] that result in nondetect values are not meaningful for determining true exposure. (Tr. at 413–414.)

In its post-hearing comments, 3M illustrated the value of sensitive analytical methods using the following example:

[C]onsider three filters ''spiked with 1 μg of silicon each and analyzed by three different methods [gravimetric, atomic absorption (AA), and PIXEA]. In the case of gravimetric and AA analyses, it is certain only that the silicon mass on the filter is between 0 μg and 10 [μg] or 0 μg and 5 μg respectively. However, PIXE[A] has sufficient analytical sensitivity to ''find'' the true value of 1 μg. Because the mass of contaminants on a Ci filter is typically very small in a WPF study, the higher sensitivity of PIXE[A] is necessary to get the best data. (Ex. 19–3–1.)

Tom Nelson commented that ''[t]he analytical method must be sensitive for a WPF study. For a half facepiece respirator[,] the detection limit should be at least 1⁄100 of the ambient concentration'' (Ex. 18–9). Later in these comments, Nelson stated, ''The [low-concentration Ci] samples are part of the distribution of WPF samples collected during a study. These represent true measures of performance.''

Based on the evidence in the record, OSHA concludes that using sensitive analytic methods for assessing Ci samples is both necessary and appropriate. Specifically, the Agency sees no scientific basis for excluding WPF studies that used PIXEA, particularly when using the method to determine both Ci and Co. The Agency's review of the record evidence shows that a leading national organization representing industrial hygienists (i.e., the AIHA) recommends using sensitive analytic methods for assessing Ci samples. Furthermore, using sensitive analytic methods improves significantly the validity of data analyses by allowing studies to retain low Ci values, and by reducing substantially the need to use unvalidated techniques to correct low Ci values. Therefore, OSHA concludes that the data from the WPF studies used in its analyses are accurate, and that the availability of data with low Ci values improved the validity of the APFs derived from these analyses.

Large particles. Several commenters (e.g., Exs. 9–33, 9–35, 10–6, 10–37, and 10–41) postulated that larger particles (greater than one or two microns) do not penetrate a respirator's faceseal. They believed that WPF studies having large particles in the Co concentration should be excluded from OSHA's analyses. They reasoned that these large particles were being measured as part of the Co but had no chance of being measured in the Ci, and consequently were inflating the WPF values.

These commenters appear to be ignoring the possibility that half masks (both elastomerics and filtering facepieces) with faceseals that selectively filter large particles still are capable of providing an adequate level of protection. Nevertheless, OSHA notes that in one of the WPF studies used in OSHA's data analyses, Myers et al. found large particles (i.e., 10 microns in diameter) inside the facepiece, indicating that large particles are capable of penetrating a respirator faceseal (Ex. 1–64–51). Consistent with these results, Tom Nelson stated in his comments that ''[t]he particle size of contaminants in the various WPF studies in the docket range from [about] 0.5 [microns] to 14 [microns] MMAD,'' and that ''particles much larger than those that would be predicted from laboratory studies have been found inside the facepiece in WPF studies'' (Ex. 18–9). At the hearing, Nelson presented data showing that large particles enter half mask respirators, probably through breaks in the faceseal; moreover, these data demonstrate that no relationship exists between particle size and the WPF obtained for the respirator (Tr. at 146–148). The 3M Company addressed this point further, stating in its comments:

Laboratory studies have shown that particle losses occur through fixed leaks. A faceseal leak is not accurately represented by a fixed leak, however. To perform these studies[,] assumptions were made regarding leak size, shape, and the particle size penetrating those leaks. These assumptions have been shown to be wrong. Myers has shown that large particles can be found inside the facepiece[,] much larger than could have occurred with the fixed leaks used by several researchers.[] As shown in Figure 1 [of the Myers et al. study], an analysis of particle size and the geometric mean WPF from a number of studies does not show any relationship between particle size and WPF. If the size of the particle played a role in faceseal leaks, a relationship would be evident. (Ex. 9–16.)

Based on the evidence in the record, OSHA concludes that the data in its APF analyses for half masks were the same as particle sizes found in the workplaces represented in the WPF studies. Therefore, eliminating the study data from the Agency's analyses would be unnecessary and inappropriate.

Probe bias. Probe bias refers to the misplacement of the sampling probe when taking measurements inside the respirator facepiece. Some commenters expressed concern that probe bias may have underestimated Ci in the half mask WPF studies analyzed by Dr. Brown (e.g., Exs. 9–17, 9–30, 9–35, and 10–42). These commenters suggested that OSHA reanalyze its database after applying a correction factor to account for probe bias. Tim Roberts provided a specific description of this concern when he testified:

Respirator probe error is an issue. It's been better characterized for elastomeric type respirators than it has for filtering facepiece respirators, and we think that this needs some additional work as well, to characterize what that means when we put probes in different locations in elastomeric facepieces (Tr. at 208).

Later in the hearings, Ching-tsen Bien questioned Craig Colton of 3M on Colton's experiences with probe location while conducting filtering facepiece WPF studies. Colton responded:

> [S]treamlining that you see is similar to that in the elastomeric half-facepieces. You see it streamlining from the leak up to the mouth and nose. And so what Dr. Myers indicated in his sampling bias—not really probe bias, but the sampling bias—was that location becomes important because if your probe is flushed with the facepiece, you can miss the streamlines. So his recommendation was that the probe needs to be ideally on the midline, between the mouth and the nose, and as close to the face as possible. And so that's what we attempt to do as best as you can with the products you end up testing to meet his recommendations. (Tr. at 455–456.)

Colton also noted that, although some of his studies may show probes entering the side of the filtering facepiece, a probe extension was used to place the sampling inlet in the nose-mouth area (Tr. at 455–456). Tom Nelson explained the purpose of the probe location when he commented, ''The sampling probe is placed so that it is close to the nose and mouth. This minimizes sampling bias'' (Ex. 18–9). Warren Myers testified that, in unusual circumstances, the configuration of a half mask (including some elastomerics) requires placing the sampling probe on the side of the mask instead of the centerline between the nose and the mouth; in these cases, a study can control for sampling bias by randomly alternating the location of the probe on the right and left side of the mask (Tr. at 77).

OSHA also reviewed the 13 half mask studies analyzed by Dr. Brown. The authors of nine of these studies specifically state that the probe was located in the area of the nose and mouth. While the remaining four studies do not specify the probe's location, no evidence from this rulemaking indicates that the sampling probes were inappropriately placed. Therefore, the majority of the WPF studies, along with the new studies included in the updated database, located the sampling probe in the nose-mouth area. Of the 1,339 data points in the updated database, approximately 220 of these points (about 16%) are from the four studies in which no information on probe placement was available. OSHA believes the sampling methodology that was used in these studies was consistent with comments indicating that the optimum location for a probe is at the centerline between the nose and the mouth. At this location, the probe will sample any streamlining that occurs between a faceseal leak and the nose-mouth area, thereby detecting the maximum Ci exposure level. In addition, no analysis was submitted indicating that the data from these studies, whether corrected for probe bias or excluded altogether, would have resulted in APFs that differed from the final APFs derived from this rulemaking.

3. Summary and Conclusion

OSHA considered the comments addressing the data and study problems identified by commenters, but does not find that these comments merit rejection of the data or analyses. The studies OSHA analyzed were conducted on employees in actual workplaces who were performing their normal job duties. Consequently, the particle sizes, work rates, work times, and environmental conditions varied among these studies. The Agency has concluded that using data collected under these various conditions presents a more accurate picture of workplace use of these respirators and is a better measure of the protection provided by half mask respirators than data collected only from SWPF or other highly controlled studies.

D. Alternative Approaches

1. Alternatives Based on Non-Compliant Respirator Programs

Several commenters suggested alternative means for ascertaining APFs. While not completely disagreeing with OSHA's approach, Paul Hewett of Exposure Assessment Solutions Incorporated (Ex. 10–60) stated that OSHA should include EPF studies in its APF deliberations. He commented that EPF studies account for actual use conditions in that they factor in the time that the employee does not wear the respirator but is still exposed to atmospheric contaminants. He also believed that determination of an appropriate APF should represent respirator use in hot, strenuous jobs. Therefore, he recommended that ''OSHA should factor in real world conditions and not rely exclusively on WPF and particularly SWPF studies'' (Ex. 10–60.)

OSHA noted in the proposal that the Agency would analyze only WPF and SWPF studies since they address respirator performance exclusively (68 FR 34045). This alternative approach already has been addressed above by the Agency in its discussion of the usefulness of WPF data. The Agency has no data in the record showing that EPF studies would improve, or even complement, its analyses. Therefore, OSHA is not convinced that EPF data would increase the validity of the APFs derived in this final rule. The discussion of an EPF study by Harris et al. (Ex. 27–11; 63 FR 1167) substantiates these conclusions.

Ching-tsen Bien of LAO Consulting, Inc. (Ex. 18–5) wanted OSHA to enter into the record any available independent assessment reports (and applicable check lists) for the year prior to, and for the year of, each WPF study. Bien noted that the reports would have covered applicable program elements, and ensure that OSHA selected studies for its analyses that were in compliance with appropriate respiratory protection standards. He also requested that OSHA enter the ''selection criteria, decision matrix for each study, and the review report for these studies to the H–049C Docket'' (Ex. 18–5.)

As stated in the NPRM at 68 FR 34046, the Agency evaluated all studies used in its analyses for compliance with the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134), as well as for completeness of the data. The Agency also compiled a list of criteria (Ex. 5–5) for evaluating each study. Accordingly, OSHA evaluated each published article or each written study report to determine whether the test subjects were trained properly, fit tested, medically evaluated, and in compliance with the requirements of the OSHA Respiratory Protection Standard. The researchers performing these WPF studies ensured that fit testing was performed on the test subjects, trained them on doffing and donning the respirator, as well as the performance of user seal checks, on the selection of proper-sized respirators, and on the other elements of a complete OSHA-compliant respirator program. These researchers did not rely on the existing workplace respirator program, but instead performed the necessary actions to ensure that the test subjects in their WPF studies met the respirator program requirements.

The WPF studies the Agency evaluated were either WPF studies that had been published previously, or were newly performed studies that were submitted during the rulemaking for inclusion in the OSHA database. OSHA did not perform these studies, and was not involved in the selection of the worksites being tested. Therefore, the Agency could not gather additional information on a worksite's respirator program that was in effect when a WPF study was performed, as Bien requested. Additionally, such information is irrelevant to the results of a WPF study since the researchers had to demonstrate compliance with the required respirator program before OSHA included the study in its database.

2. Alternatives Based on SWPF Studies

The American Chemistry Council (Ex. 10–25) stated that OSHA's APFs should be based on SWPF studies, and that the APFs derived from this rulemaking should be used only as interim values until SWPF studies could be performed. OSHA notes that basing APFs on SWPF studies, rather than on WPF studies, was recommended by a number of commenters including Organizational Resource Counselors Worldwide (ORC) (Ex. 10–27), Paper, Allied-Industrial, Chemical & Energy Workers International Union (PACE) (Ex. 10–37), and others (e.g., Exs. 9–32, 9–41, 10–6, 10–49, 9–33, 9–35, and 18–5). These commenters expressed various concerns about the WPF studies, and stated that SWPF studies permit investigators to control a number of variables (e.g., particle size, contaminant concentration, environmental conditions) that cannot be controlled in WPF studies.

SWPF studies use sensitive analytical methods, such as PIXEA, to obtain measurable Ci information. SWPF studies safely test a respirator in a high-concentration atmosphere (i.e., at the respirator's limit of protection) to generate enough penetration for the analytical method to quantify Ci results. OSHA agrees that SWPF testing permits an investigator to control factors such as particle size, contaminant concentration, temperature, and humidity. Accordingly, the Agency used data generated from all available SWPF studies in determining APFs. However, OSHA concluded that controlled SWPF studies alone are not representative of, nor can they be extrapolated readily to, typical workplaces. Standardized protocols for conducting such testing, or a methodology for extrapolating SWPF results to protection levels expected in the workplace, are not available. ORC stated, ''We advocate development of a protocol based on a combination of laboratory testing and field trials for determining expected respirator performance'' (Ex. 10–27). NIOSH also supported the use of both SWPF and WPF studies, noting, ''NIOSH agrees that the APF values resulting from OSHA's multifaceted approach to analysis of existing data provide reasonable values for the level of protection that should be expected for each class of respirators'' (Tr. at 102). NIOSH continued, ''Given this lack of complete data, the noted model-to-model variation and the imperfection in protection level measurements, the approach taken by OSHA is the best currently possible based upon available data'' (Tr. at 103). The Agency has concluded that its approach in using both WPF and SWPF studies is well supported by the rulemaking record and is appropriate for determining APFs specified in this final rule.

3. Model-Specific APFs

The Organization Resources Counselors Worldwide (Ex. 10–27), the American Chemistry Council (Ex. 10–25), and the Pharmaceutical Research and Manufacturers of America (Ex. 9–24) urged OSHA to develop model-specific APFs. Under this recommendation, each respirator model would undergo testing and be assigned a unique APF. NIOSH did not support this approach. In response to questioning by OSHA, NIOSH stated:

> This morning's expert witnesses and the questions I think clearly identified that there is variability, and because of this variability, we believe that class APFs are more appropriate and consistent with the state of the art today. In order to achieve more precise data, much, much larger data sets, including the numbers of test subjects that would have to be involved to eliminate this variability, seems impractical based upon the state of the art today. So we are for these reasons supporting class APFs, not model-specific APFs. (Tr. at 120.)

OSHA considered the use of SWPF studies in developing model-specific APFs. The Agency's review of the ORC SWPF study of PAPRs and SARs in the proposal (68 FR 34069) stated that ORC had recommended that ''the [ORC SWPF] study methodology should be the basis for determining APFs for all respiratory protective equipment regulated by OSHA'' (68 FR 34070). However, only a few SWPF studies are available that measured the performance of a few PAPRs and SARs. Model-specific SWPF studies for the remaining respirator classes have not been performed. In addition, the respirator protection community has not agreed on a standard protocol for conducting SWPF studies, or how the results relate to APFs. These issues would have to be addressed before it would be possible to use model-specific APFs. Also, insufficient data are available to set model-specific APFs, and developing the methodology and conducting the testing could take years. OSHA believes that completing the APF rulemaking with the information available now is necessary. Delaying this rulemaking to develop model-specific APFs will result in employers not knowing what respirators to select and, consequently, employees will not receive adequate protection. Based on the rulemaking record, the Agency has concluded it will determine an APF for each respirator class using information from existing WPF and SWPF studies.

4. Nicas-Neuhaus Model

Several commenters (Paul Hewett, Ex. 10–60; Bill Kojola, AFL–CIO, Ex. 17–2; and NIOSH, Ex. 17–7–1) asked OSHA to consider a February 2004 article by Nicas and Neuhaus (Ex. 17–7–2) that applies a model for analyzing WPF data to establish APFs. The Nicas-Neuhaus article is based on the variability of WPFs (i.e., the variability between different test subjects, as well as the variability within a test subject resulting from repeated donnings of the respirator). APFs based on this Nicas-Neuhaus model require that WPFs for 95% of all workers be above the APF 95% of the time. However, the established method for deriving APFs used by OSHA, NIOSH, and ANSI sets the APFs at the 95% percentile of the between-subject WPFs. By controlling for within-subject variability, APFs based on the Nicas-Neuhaus model will always be smaller than APFs derived using the established method.

To account for within-subject variability, the Nicas-Neuhaus model requires repeated measurements on each test subject which is not required by the established method. Consequently, most available WPF studies did not include multiple measures on individual test subjects, resulting in an extremely limited database for applying the Nicas-Neuhaus model. Nicas and Neuhaus were able to analyze only seven half mask respirator studies, comprising a total of 310 data pairs. In comparison, the database established and analyzed by OSHA for determining the final APFs contains 1,339 data pairs from 16 half mask respirator studies. Also, OSHA had rejected for its analyses several of the WPF studies used by Nicas and Neuhaus in developing their model because these studies did not meet the Agency's selection criteria.

The Nicas-Neuhaus model is a significant departure from established and accepted practices used by the respirator research community, The Agency has concluded that there are insufficient data to fully evaluate the proposed model, and to incorporate it in setting APFs.

5. Other Alternative Approaches

Sheldon Coleman recommended that OSHA select a panel from AIHA members to review the APF data and OSHA's APF determinations (Ex.10–40). OSHA believes this rulemaking has provided ample opportunity for comment from the public and professional associations. Further analysis would delay the development of the final APFs, and is unnecessary as the rulemaking record is sufficient to determine APFs.

6. Summary and Conclusion

OSHA is relying on science, data, and established quantitative analyses to establish the final APFs for filtering facepiece and elastomeric half mask respirators, and is limiting its statistical analyses to those procedures that use the selected data to the fullest extent possible. Reliance on alternative approaches is not supported by the evidence in the record. The data to use such approaches are not currently available, and require either a different set of data or a standardized testing protocol that requires testing every respirator model. OSHA concludes that the available data and analytic methods used in determining the final APFs are appropriate.

E. Updated Analyses

1. Review of the Original WPF and SWPF Databases

In developing its proposed rule regarding APFs for respirators, OSHA contracted with Dr. Kenneth Brown to investigate possible approaches for evaluating respirator performance data from WPF and SWPF studies. To assist Dr. Brown in this evaluation, the Agency reviewed the available studies and created a database from these studies. In deciding which WPF studies to include in this database, OSHA evaluated studies with respect to compliance with the requirements of its Respiratory Protection Standard (29 CFR 1910.134) and the completeness of the data. In doing so, the Agency excluded WPF studies of gas or vapor contaminants due to the limited number of these studies and the difficulties in conducting and interpreting data from such studies (68 FR 34046). During the rulemaking, OSHA received new WPF data on half mask respirators. No new SWPF data were submitted for half masks, and no new WPF data were submitted for higher-performing respirators.

In the NPRM, Dr. Brown initially divided negative pressure half mask air-purifying respirators (APRs) into five classes. Four classes of filtering facepiece half masks were derived based on whether a respirator had adjustable head straps, an exhalation valve, a double-shell construction, or a foam-ring faceseal. Elastomeric half masks were grouped together in a single fifth class. (See Ex. 5–1 for details on respirator class definitions.) In his analyses, Dr. Brown found no clear evidence of a difference in WPFs across these different classes. In particular, he found that elastomeric half masks performed substantially the same as filtering facepieces. From the original database of 917 WPF measurements for negative pressure half mask APRs, 36 WPF measurements (3.9%) were found to have an APF less than 10, and 96.1% at 10 and above.

2. Updated OSHA Database on APRs

In the NPRM, OSHA asked if any more WPF or SWPF studies should be considered in setting APFs. Data from four additional studies were submitted for OSHA's evaluation during the comment period, and an updated half mask database was compiled using these studies (Ex. 20–2). During the post-hearing comment period, the 3M Company provided OSHA with data from two additional WPF studies of filtering facepiece respirators. One study (Colton and Bidwell, Ex. 9–16–1–1) measured the performance of three different types of filtering facepiece respirators used by 21 workers at a lead-battery manufacturing plant. One respirator (3M 8710) was approved under 30 CFR part 11, and two respirators were N95 particulate respirators (3M 8210 and 3M 8510) approved under 42 CFR part 84. Up to three WPF measurements were made with each worker on each respirator type, for a total of 143 WPF measurements. The data submitted to OSHA from this study are provided in Appendix A of Dr. Crump's report on the reanalysis of the half mask database (Ex. 20–1).

The second set of WPF data provided by 3M Company was from a study by Bidwell and Janssen (Ex. 9–16) on the performance of a ''flat-fold'' filtering facepiece respirator conducted at a concrete-block manufacturing facility. Repeated measurements of WPFs were made on 19 workers, and each sample was analyzed for both silicon and calcium. A total of 73 Co and 73 Ci air samples were collected, for a total of 146 WPF measurements. Eleven of the 146 Ci measurements were non-detectable (all coming from silicon exposures).

The third study added to the database was a WPF study by Colton (Ex. 4–10–4) on the performance of an elastomeric half mask respirator. This study had been submitted earlier to OSHA, but was not included in the NPRM database since it was received too late for inclusion in Dr. Brown's original analysis. The data from this study, conducted in the battery-pasting and assembly areas of a battery manufacturing plant, have now been added to OSHA's updated database. Also, three additional data points from a study by Myers and Zhuang (Exs. 1–64–50 and 3–14) were added to the updated database. These data were collected in a concrete-block facility while elastomeric half mask respirators were worn as protection against calcium and silicon particulates.

The updated OSHA half mask database (Ex. 20–2), summarized in Table III–1, contains 1,339 WPF measurements—760 collected from filtering facepiece respirators, and 579 from elastomeric respirators. The database originally analyzed by Dr. Brown contained 917 WPF measurements—471 from filtering facepieces, and 446 from elastomerics.

TABLE III–1.—SUMMARY OF OSHA WPF DATABASE FOR APRS

Respirator class	Figure 1 No.	Constituent sampled	Author	Exhibit No.	Number samples per study	Number samples per class
Filtering Facepiece Respirators						
1	1	Asbestos	Dixon	1–64–54	26	474
1	2	Fe	Myers	1–64–50, 3–14	21	
1	3	Mn	Wallis	1–64–70	69	
1	4	Al	Colton	1–64–15	23	
1	5	Al	Johnston	1–64–34	13	
1	6	Si	Johnston	1–64–34	15	
1	7	Ti	Johnston	1–64–34	18	
1	8	Pb	Colton & Bidwell	9–16–1–1	143	
1	9	Si	Bidwell & Janssen	9–16	73	

TABLE III–1.—SUMMARY OF OSHA WPF DATABASE FOR APRS—Continued

Respirator class	Figure 1 No.	Constituent sampled	Author	Exhibit No.	Number samples per study	Number samples per class
1	10	Ca	Bidwell & Janssen	9–16	73	
3	11	Pb	Myers	1–64–51, 3–12	19	162
3	12	Zn	Myers	1–64–51, 3–12	20	
3	13	Fe	Colton	1–146	31	
3	14	Mn	Colton	1–146	32	
3	15	Ti	Colton	1–146	28	
3	16	Zn	Colton	1–146	32	
4	17	Pb	Colton	1–64–16	62	124
4	18	Zn	Colton	1–64–16	62	
Elastomeric Respirators						
5	19	Asbestos	Dixon	1–64–54	46	579
5	20	B(a)Pyrene	Gaboury	1–64–24	18	
5	21	Pb	Lenhart	1–64–42	25	
5	22	Pb	Myers	1–64–51, 3–12	46	
5	23	Zn	Myers	1–64–51, 3–12	46	
5	24	Fe	Myers	1–64–50, 3–14	30	
5	25	Cr	Myers	1–64–52, 4–5	35	
5	26	Ti	Myers	1–64–52, 4–5	33	
5	27	Cd	Colton	1–64–13	68	
5	28	Pb	Colton	1–64–13	57	
5	29	Pb	Dixon & Nelson	1–64–19	42	
5	30	Pb	Colton	4–10–4	130	
5	31	Calcium	Myers	1–64–50, 3–14	3	
Grand Total						1339

3. Variability of the APF Data

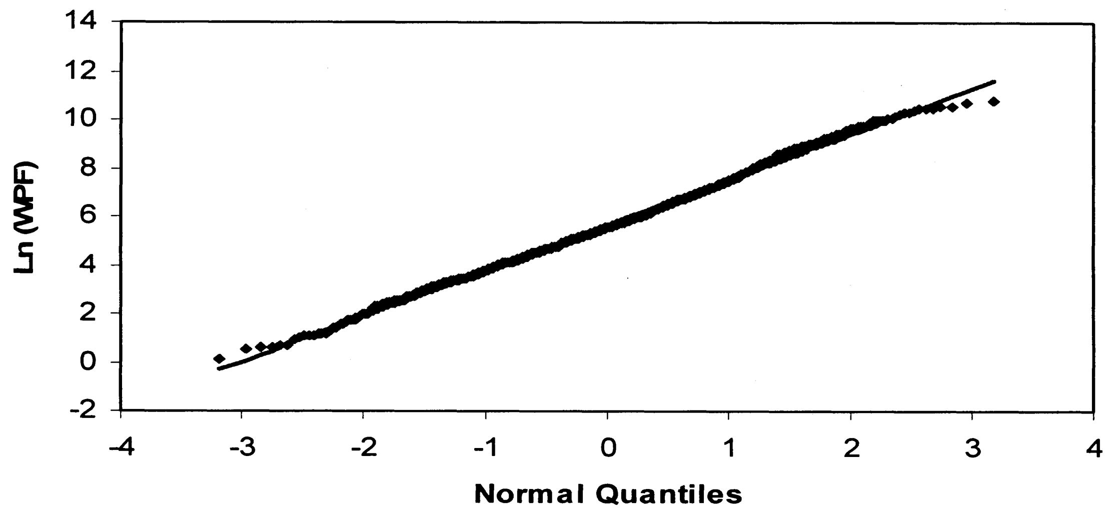
Several commenters (Faulkner, Ex. 9–40 and Kojola, Ex. 9–27) criticized WPF studies because the studies demonstrated what they considered to be a high degree of variability of the data. However, it is inappropriate to describe the variability of the data with terms such as ''high'' or ''low'' because no recognized standard exists by which to characterize variability. The variability of the data should reflect the true variability in respirator fit and performance experienced by workers who wear respirators. It is reasonable to expect variability because respirator performance is determined by many factors, including: Respirator type, the workers' face shapes, work practices and effort levels, and workplace conditions such as temperature and humidity. Thus, the key issue is not whether the data have too much or too little variability, but whether the variability in the data reflects the true variability in respirator performance under actual workplace conditions.

A logarithmic transformation was applied to the WPF data set to adjust for a skewed distribution and extreme outliers, both of which are common with ratio-based data. As Figure III–1 shows, when a logarithmic transformation is applied to OSHA's WPF database, the data closely follow a standard normal distribution. Therefore, OSHA's analysis of the data, which assumes that WPFs are log-normally distributed with a geometric mean of 307 and a geometric standard deviation of 7.1, appropriately accounts for the variability in the WPF data.

Figure III-1

Logarithm of WPFs for Updated Data Base

Versus Quantiles of the Standard Normal Distribution



4. Analysis of Updated Database on APRs

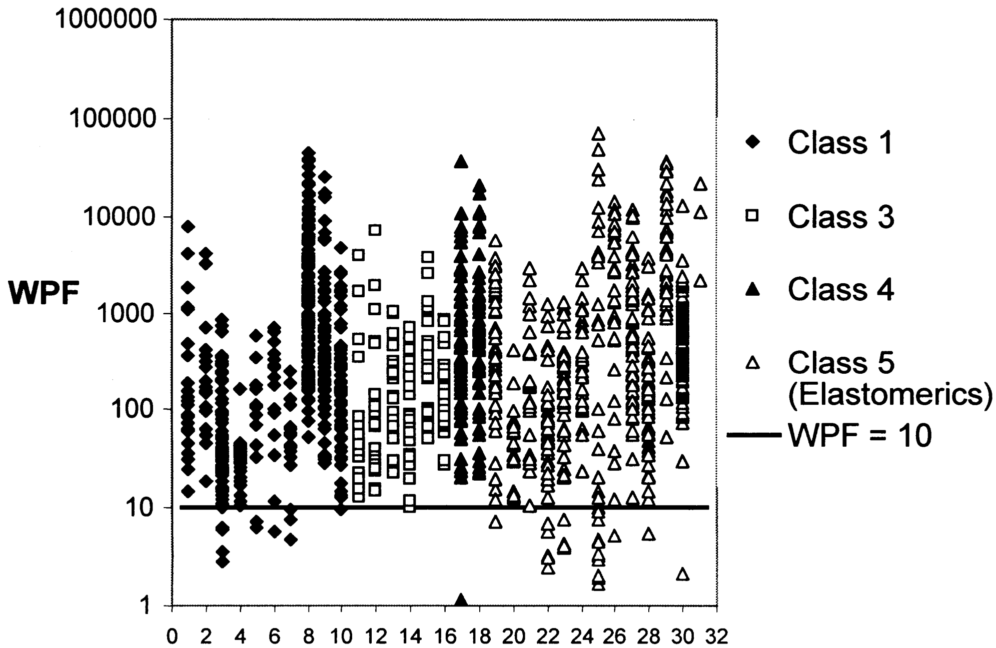
OSHA proposed an APF of 10 for negative pressure half mask APRs, including both filtering facepieces and elastomerics (68 FR 34096). Accordingly, the present analysis focuses on estimating this APF, particularly the percent of WPFs that are less than 10.

Figure III–2 displays the 1,339 WPF values, grouped by respirator class,[1] study, and contaminant. Each column of data points in the figure corresponds to a row number listed in column 2 of Table III–1. This figure shows that more WPFs for elastomerics are less than 10 than was the case for filtering facepieces, even though a much larger proportion of these WPFs are from filtering facepieces.

[1] Includes four of the five classes originally determined in the analysis conducted for OSHA by Dr. Ken Brown; no data were available for Class 2. Dr. Brown characterized disposable half marks according to combinations of the following four design characteristics: (1) Adjustable head straps, (2) presence of an exhalation valve, (3) double shell construction, and (4) foam ring liner. Class 1 has none of the four design characteristics. Class 2 has design characteristics (1) and (3). Class 3 has design characteristics (1) through (3). Class 4 has all four of the design characteristics. Class 5 consists of all elastomeric half masks.

Figure III-2

Graph of WPFs by Study



''Figure 1 Number'' from Table III-1

Figure III–2 also shows that differences exist between WPFs measured in different studies, even among respirators of the same type. For example, both the Colton (Ex. 1–64–15, #4 in Figure 2) and the Colton and Bidwell (Ex. 9–16–1–1, #8 in Figure 2) studies were conducted by some of the same investigators, and both studies used Class 1 filtering facepieces. Nevertheless, all but one of the 23 WPFs in the Colton study (Ex. 1–64–15) are less than 40, while all 143 of the WPFs from the Colton and Bidwell study (Ex. 9–16–1–1) are at least 58 or higher. However, the Colton study evaluated respirators approved under 30 CFR part 11, whereas the Colton and Bidwell study evaluated respirators approved under 42 CFR part 84.

Table III–2 shows the percentages of WPFs less than 10 by respirator class, along with the 90% statistical confidence intervals on these percentages. The exact confidence intervals are based on a binomial distribution for counts. The percentage of WPFs less than 10 is less than 5% for all four classes, and the 90% statistical confidence interval on this percentage excludes 5% for every class except elastomerics. Also, elastomerics had the highest percentage of WPFs less than 10 (4.5%). Over all classes, 38/1339, or 2.8%, of WPFs were less than 10 (90% confidence interval: 2.1%, 3.7%). The upper bound of this two-sided 90% confidence interval, 3.7%, is equivalent to a one-sided 95% upper statistical confidence bound on the true proportion of WPFs less than 10. This bound may be interpreted as follows: assuming the database is representative of workplace WPFs in general (more specifically, that the data approximate a random sample of WPFs from all workers who use respirators), when the true proportion of WPFs less than 10 is 3.7%, the probability of observing 2.8% or less (the observed percentage) would be $1 - 0.95 = 0.05$. Thus, under these assumptions, it is unlikely that the true proportion of WPFs less than 10 is as high as 3.7% (and extremely unlikely to be as high as 5%).

TABLE III–2.—PERCENT OF WPFS LESS THAN 10 BY RESPIRATOR CLASS

	Total n	n < 10	Percent	(90% CI)
Class 1	474	11	2.3	(1.3%, 3.8%)
Class 3	162	0	0.0	(0.0%, 1.8%)
Class 4	124	1	0.8	(0.0%, 3.8%)
Class 1–4 (Filtering Facepieces)	760	12	1.6	(0.9%, 2.5%)
Class 5 (Elastomerics)	579	26	4.5	(3.2%, 6.2%)
Total	1339	38	2.8	(2.1%, 3.7%)

In the earlier database analyzed by Dr. Brown, 3.9% of the WPFs were less than 10. By comparison, among the 422 WPFs added to the database, only 2/422 (0.5%) were less than 10. Thus, the new data indicate a higher level of protection by APRs.

In addition to the 1,339 WPFs in the updated OSHA database, an additional 403 WPFs from 12 studies were coded by OSHA but were not included in either the present database or the one analyzed by Dr. Brown. These data were omitted for various reasons, including too few WPF measurements in a study and problems with the quality of the studies (i.e., study did not meet requirements of OSHA's Respiratory Protection Standard). In addition, as noted earlier, OSHA did not include data from studies in which exposures were predominantly to a gas or vapor. To determine the effect that excluding these data had on the results in Table III–2, the 403 WPFs were added to the updated data base of 1,339 WPFs (for a total of 1,742 WPFs), and the overall fraction of WPFs less than 10 was computed (Table III–3). The percent of WPFs less than 10 was 4.0% (90% confidence interval: 3.2%, 4.8%). Thus, even with no data exclusions, the overall percent of WPFs smaller than 10 is less than 5%, and the 95% statistical upper confidence bound is also less than 5% (i.e., 4.8%).

TABLE III–3.—COMPARISON OF PERCENT OF WPFS LESS THAN 10 IN STUDIES USED AND NOT USED BY OSHA

	Total n	n < 10	Percent	(90% CI)
Used	1339	38	2.8	(2.1%, 3.7%)
Unused	403	31	7.7	(5.6%, 10.2%)
Both Used and Unused	1742	69	4.0	(3.2%, 4.8%)

Consistent with the WPF studies used in its analysis, OSHA adopted the point estimate of the lower 5th percentile of WPF or SWPF data to establish APFs. Table III–4 shows the point estimate of the 5th percentiles of WPFs for different categories of respirators using the updated database. The 5th percentile of WPFs for filtering facepieces as a whole was 18.1, and for elastomerics it was 12.0. In both cases, the point estimate was above the APF of 10 proposed by OSHA. Since several commenters expressed concern about whether sufficient evidence is available to support an APF of 10 for filtering facepieces, OSHA also calculated 90% confidence intervals for each point estimate. (As noted earlier, the lower limit estimate of a two-sided 90% confidence interval is equivalent to a one-sided 95% lower confidence bound.) The lower 95% confidence bounds for the 5th percentile of WPFs exceeded 10 for all classes combined, and, with the exception of elastomerics, for each individual class. The confidence limits for the 5th percentiles were computed using the method for distribution-free confidence intervals of Hahn and Meeker (1991), as implemented in SAS (2001). Therefore, OSHA concludes that sufficient statistical evidence is available to justify an APF of at least 10 for filtering facepieces.

TABLE III–4.—FIFTH PERCENTILES OF WPFS BY RESPIRATOR CLASS

	5th percentile	(90% CI)
Class 1	14.8	(12, 18)
Class 3	19.7	(15, 24)
Class 4	27.0	(22, 49)
Class 1–4 (Filtering Facepieces)	18.1	(15, 22)
Class 5 (Elastomerics)	12.0	(7, 14)
Total	14.7	(13, 18)

5. Comparison of Respirators Approved Under 30 CFR Part 11 Versus 42 CFR Part 84

Several commenters expressed concern that the majority of WPF and SWPF studies were conducted on respirators certified by NIOSH under requirements in 30 CFR 11, instead of the newer NIOSH certification procedure described in 42 CFR 84. While these commenters did not explain the basis of their concern, two major studies were submitted that examined the performance of 42 CFR 84-approved respirators. The 3M study by Colton and Bidwell (Ex. 9–16–1–1) evaluated one respirator approved under 30 CFR 11, and two respirators approved under 42 CFR 84. In this study, WPFs were measured on up to nine different occasions for 21 workers (143 total measurements), 17 of whom used each type of respirator on at least one occasion, with none of them using the same type respirator on more than three occasions. Thus, this study provides an opportunity for comparing the performance of respirators approved under the two standards. Table III–5 shows the performance of these three respirators using three methods: the proportion of samples with Ci non-detects, the distribution of the 30 smallest WPF values among the three respirators, and the geometric mean of WPFs. The two 42 CFR 84-approved respirators performed similarly with each of these methods, and they both performed better than the 30 CFR 11-approved respirator (see Table III–5).

TABLE III–5.—PERFORMANCE OF THE 30 CFR PART 11 RESPIRATOR (3M 8710) AND THE 42 CFR PART 84 RESPIRATORS (3M 8511 AND 3M 8210)

	Inside-the-mask non-detects	Dist. of 30 smallest WPF	WPF geometric means [1]
3M 8710	5/49	15	792
3M 8511	23/47	7	2506
3M 8210	19/47	8	2405

[1] Modeled assuming log-normal distribution with non-detects set at detectin limit.

The geometric means of WPFs of the 42 CFR 84 respirators were similar (2506 and 2405), and were significantly ($p < 0.0001$) higher than the geometric mean of the 30 CFR 11 respirator (792). This comparison was made using a repeated measures analysis that accounted for dependence among different samples collected from the same worker, assumed log-normally distributed WPFs, and set non-detects at the detection limit (which should minimize differences between the two respirator types). All three respirators performed well in this study, with the smallest of the 143 WPFs being 52, well above the APF of 10 proposed by OSHA.

When the 146 WPF measurements from the Bidwell and Janssen study (Ex. 9–16) (that assessed the 3M 9211 respirator approved under 42 CFR 84) are added to the 94 WPFs from the Colton and Bidwell study (Ex. 9–16–1–1), 240 WPFs in the OSHA database are from 42 CFR 84 respirators. None of these WPFs was less than 10 (0/240). This finding, along with the evidence that 42 CFR 84 respirators performed better than 30 CFR 11 respirators in the same study, suggests that the new filtering facepiece respirators certified under 42 CFR 84 may perform better than the respirators relied on by OSHA for its analyses, which consisted mainly of respirators approved under 30 CFR 11. Because the respirators approved under 42 CFR 84 outperformed those respirators approved under 30 CFR 11, which were adequately protective, OSHA is confident current workers will be well protected by the respirators approved under 42 CFR 84.

6. Methodology of Evaluating Overexposure

Another method to assess the appropriateness of an APF is to determine whether an overexposure occurs (Ex. 10–17). The Agency reviewed relevant studies on this subject cited by several commenters (Exs. 9–16, 9–22, and 10–17–1) to determine if such an analysis would provide useful information on filtering facepiece and elastomeric half mask respirators.

Two major studies (Exs. 9–16–1–9 and 4–21) address the likelihood that half mask respirators will not sufficiently reduce occupational exposures to airborne contaminants. In the first of these two studies (Nelson *et al.*, Ex. 9–16–1–9), the authors evaluated the risk of overexposure for selected APFs using Monte Carlo simulation modeling. For a half mask respirator with an APF of 10, the calculations indicated a low risk of being exposed above an occupational exposure limit (OEL), with mean exposures being controlled well below an OEL. In the second article by Drs. Myers and Zhuang (Ex. 4–21), ambient (Co) and in-facepiece exposure monitoring data (Ci) from studies of worker exposures in foundry, aircraft-painting, and steel-manufacturing industries were compared with the OSHA PEL for single-substance exposures. The 5th percentiles of the protection factor (Co/Ci) data from each study were calculated. The authors used a new binomial analysis of likelihood of successes (no overexposure) and failures (overexposures). Their calculations indicate, for both half mask elastomeric and filtering facepiece respirators, that the <5% of workers who fail to achieve an APF of 10 are still being protected.

OSHA considered Nelson's analysis along with the findings of Myers and Zhuang when it conducted its own analysis. Accordingly, the Agency was persuaded to quantify the probability of overexposure by applying the Myers and Zhuang binomial analysis to OSHA's updated database. OSHA's expert, Dr. Gerry Wood, performed the analysis and presented his results in a report (Ex. 20–3) described below. The updated OSHA half mask database (Ex. 20–2) used in this analysis contains 1,339 WPFs from studies with both filtering facepiece half mask respirators (760 WPFs) and elastomeric half mask respirators with cartridge filters (579 WPFs). This database also contains Co and Ci measurements (expressed in $\mu g/m^3$), with asbestos fiber counts converted as follows: 1 fiber/cm^3 = 30 $\mu g/m^3$); these measurements permit binomial analysis of overexposure through calculation of hazard ratios (HR).

The following 8-hour TWA PELs were used to calculate HR = Co/PEL for this study (see Table III–6).

TABLE III–6.—8-HOUR TWA PELS USED TO CALCULATE THE HAZARD RATIOS

Analyte	PEL (mg/m^3)
Benzo(a)pyrene	0.2
Lead	0.05
Zinc	15
Iron	10
Chromium	0.5
Titanium	15
Manganese	5
Aluminum	15
Asbestos	0.003 (0.1 fiber/cm^3)
Silica	10
Cadmium	0.005
Calcium	15

Values for individual WPFs then were plotted against HR as illustrated in the figures of the Myers and Zhuang reference (Ex. 4–21, Figure 1, page 798, and Figure 2, page 799). The same reference lines and labels were used, but the scales were expanded to include all data in the OSHA database.

Figure 1 below shows the plot of all data for both filtering facepieces and elastomerics. The line labeled CD represents WPF = 10; 38 (2.8%) of the 1,339 data points fell below this line and five data points (0.37%) fell within the triangle defined by the letters ABK; Myers and Zhuang (Ex. 4–21) label this triangle as ''Inadequate Protection, Overexposure,'' which corresponds to the region in which Ci exceeds the PEL.

Figure 1. All Half Mask Respirators

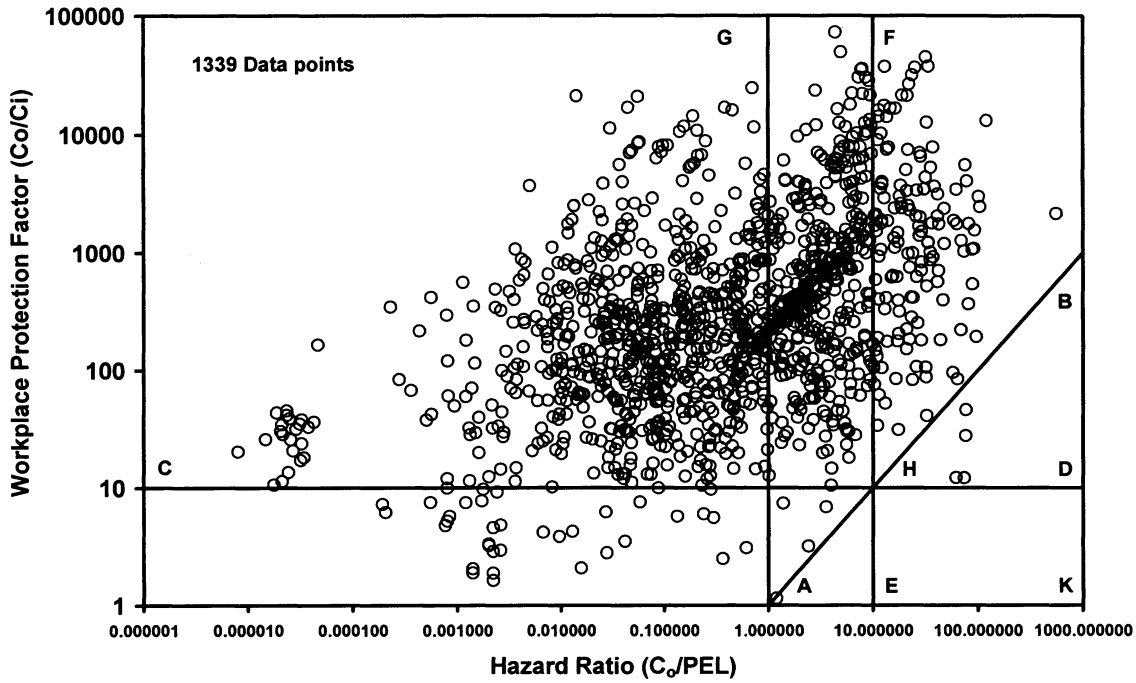
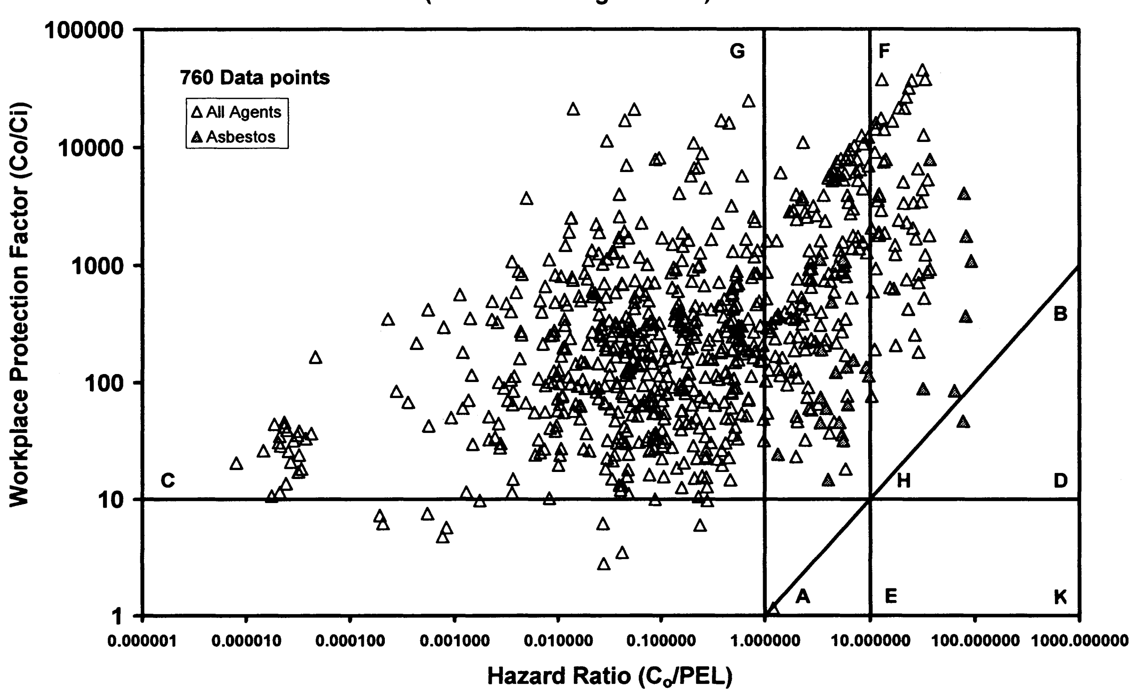


Figure 2 shows the same plot for studies using filtering facepieces only. Twelve data points (1.6%) are below the WPF = 10 line. Two of these twelve data points equal WPF = 10 when rounded off to the nearest whole number. Only 2 (0.26%) of the points are within the ABK overexposure region. The data point in the A corner (from a study by Colton (Ex. 1–64–16, CL4.15.Pb)) represents a Co just above the lead PEL (HR = 1.20) that, with a WPF = 1.15 (almost no protection), gave a Ci = 1.04 * PEL; this value represents an inside-the-mask exposure just barely higher than the PEL. The only other data point in the over-exposure region is from the asbestos (PEL–0.1 fiber/cm^3) study by Dixon (Ex. 1–64–54, CL1.2.Asb) which corresponds to HR = 77, WPF = 47, and a Ci = 1.6 * PEL, (or 0.16 fiber/cm^3).

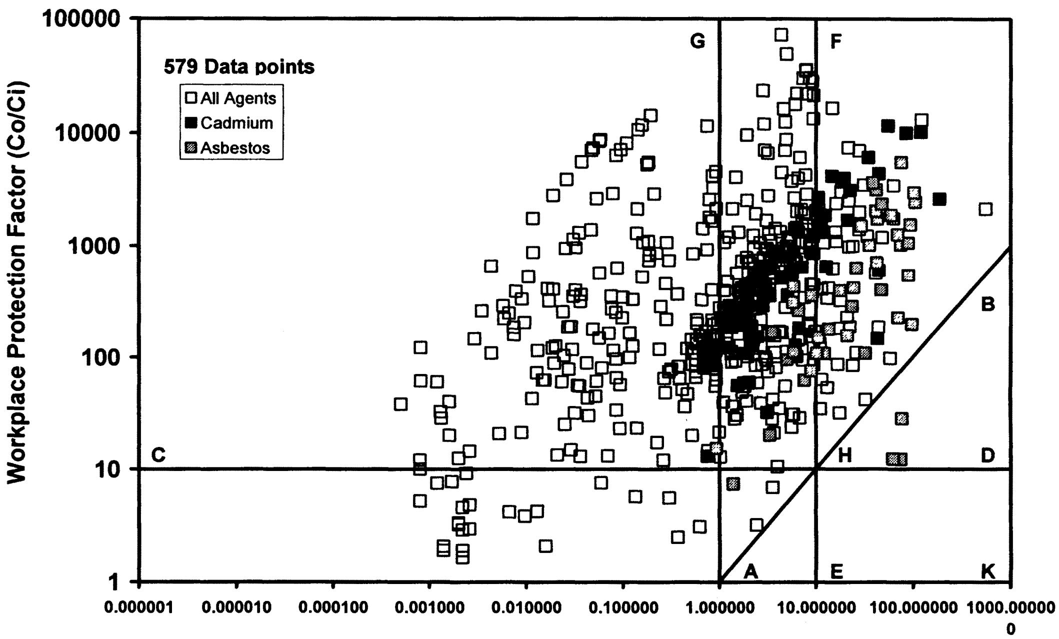
Figure 2. Filtering Facepiece Respirators (PELs since August 1994)



If the MUC is defined as MUC = APF × PEL, and an APF = 10 is assumed, then data points in the triangle labeled AHE represent overexposures. With one data point in this triangle, filtering facepieces are 99.4% effective in protecting employees at an APF = 10 and an MUC = 10 × PEL (i.e., 160 of 161 data points in the AGFE area, with an HR ranging from 1 to 10, are outside the triangle (AHE) that represents diminished protection).

Figure 3 shows the same plot for the elastomerics. Of these 579 data points, 26 (4.5%) fall below WPF = 10. Three data points (0.5%) in the ABK overexposure triangle are from an asbestos study by Dixon (Ex. 1–64–54, CL5.2.Abs). However, no data points of 265 in the AGFE area fall within the AHE triangle, indicating that all of these respirators provided protection at APF = 10 × PEL.

Figure 3. Elastomeric Respirators (PELs since August 1994)



Figures 4 and 5 demonstrate that both filtering facepiece and elastomeric respirators maintain the level of employee protection found in Figures 2 and 3, even when the data are plotted using the higher PELs specified by the older OSHA asbestos standard (pre-August 1994) and cadmium standard (pre-April 1993). The combined data for both Figures 4 and 5 show that filtering facepieces had only one data point of 160 (with an HR ratio of 1 to 10) in the overexposure area (i.e., the AHE triangle), while none of the 241 data points for elastomeric respirators fell into this area. Therefore, Figures 4 and 5 and Figures 2 and 3 demonstrate that both filtering facepiece and elastomeric respirators afford employees effective protection against two different exposure levels of asbestos and cadmium.

BILLING CODE 4510–26–P

Figure 4. Filtering Facepiece Respirators (PELs before August 1994)

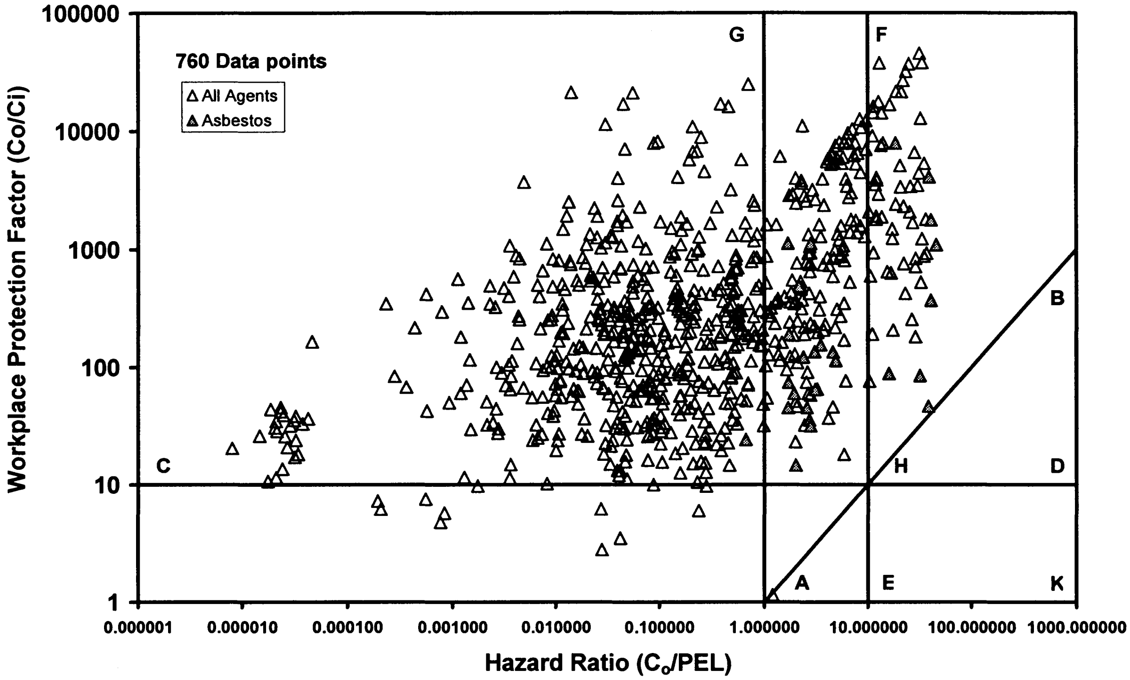
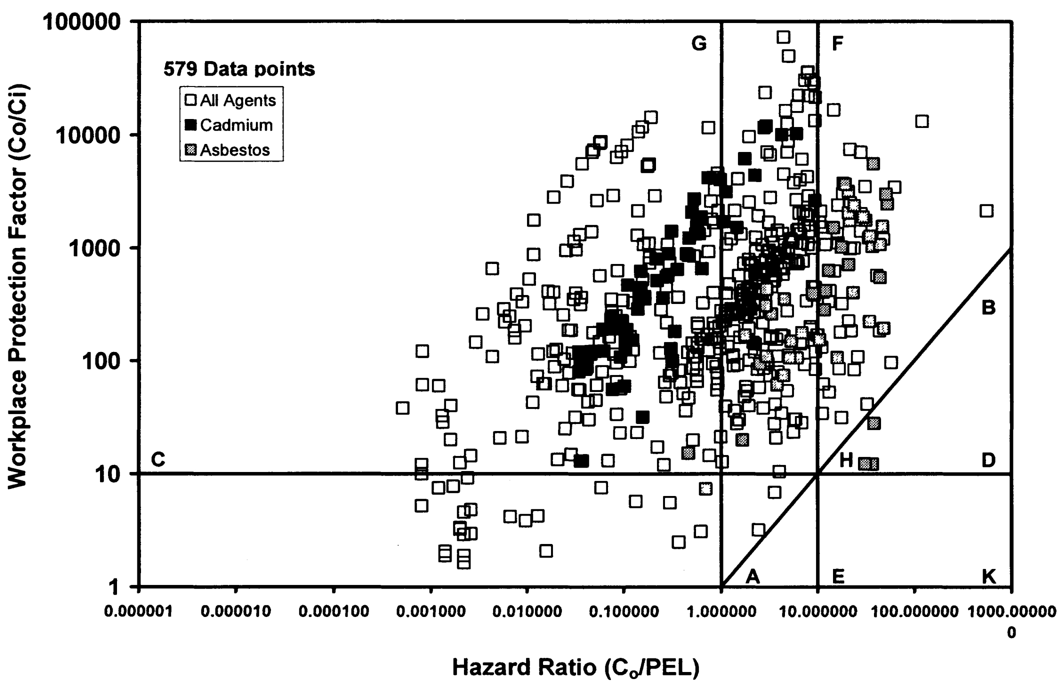


Figure 5. Elastomeric Respirators (PELs before April 1993)



BILLING CODE 4510–26–C

7. Summary of Quantitative Analyses of the Updated Database

First, OSHA's database includes the best available data. As part of the APF rulemaking process, the Agency conducted a metaanalysis of data collected from numerous scientific studies related to APFs. OSHA established criteria that were used to evaluate each study's design and data quality to assure that the database included only the most valid data. The Agency, at each step in the rulemaking process, called on participants to identify additional studies to augment the dataset or to discuss alternative methods of analysis. In response, a number of commenters expressed these concerns about the data analysis: The statistical treatment minimized the true differences between elastomeric and filtering facepieces, and there was too much variability in the data. In all cases, concerns raised by commenters about the composition of the dataset used in the metaanalysis, or the statistical methods used to conduct the analyses, were unsubstantiated by evidence submitted to the record despite repeated requests by OSHA for either specific examples or additional evidence.

Second, the best available data support an APF of 10 for half mask elastomerics and filtering facepieces. The final APF half mask database consists of 1,339 data points from 16 different studies, which represents a data increase of 46% over the 917 data points initially available for analysis in the proposal. The full data set indicates: (a) The precise APF for filtering facepieces is 18.1, with a 90% confidence interval between 15 and 22; (b) the precise APF for elastomerics is 12.0, with a 90% confidence interval between 7 and 14; and (c) that a greater percentage of elastomerics failed to achieve an APF of 10 (4.5%) than filtering facepieces (1.6%). In both cases, fewer than 5% of the respirators failed to achieve an APF of 10, which is the maximum failure rate historically allowed by both OSHA and other standards-setting bodies.

Third, OSHA substantiated its previous analysis by adding to its updated database 403 data points that were excluded originally because they did not meet OSHA's selection criteria and reanalyzing the database. This additional analysis also supports an APF of 10 for both types of respirators, with the results being highly similar to the analysis based on the best-available data.

Fourth, new studies submitted during the rulemaking allowed OSHA to compare the performance of similar respirators that were certified under both NIOSH's old (30 CFR 11) and new (42 CFR 84) certification standards. The 42 CFR 84 respirators achieved a WPF that was better than the 30 CFR 11 respirators. This finding is significant because the majority of the WPF studies, and the only studies in OSHA's original data set, were conducted on respirators certified under 30 CFR 11. Thus, the improved performance of 42 CFR 84 respirators indicates that these respirators are likely to be even more protective of worker health than an APF of 10 as provided for in the final rule.

OSHA also addressed the issue of overexposure among workers. In doing so, it reviewed the respirator literature and performed an analysis of overexposure risk using filtering facepiece or elastomeric respirators. Based on this risk analysis, OSHA concluded that workers participating in effective respirator programs had an extremely low risk of overexposure.

In conclusion, the extensive quantitative analyses of the databases clearly indicate that both filtering facepieces and elastomeric respirators are capable of achieving an APF of 10. The results demonstrate that no statistical justification exists for assigning an APF of less than 10 to either of these two types of respirators. Finally, the results show that an APF of 10 is an underestimate of the true protection provided by both types of respirators. Therefore, the final APF of 10 determined by this rulemaking provides employees who use respirators with an extra margin of safety against airborne contaminants.

F. Summary of Studies Submitted During the Rulemaking

1. Additional Studies Used in the Updated Analyses

OSHA found the studies discussed in this section to be of sufficient quality for inclusion in its APF analyses.

Bidwell and Janssen study (Exs. 9–16–1–1 and 9–16). J. O. Bidwell and L. Janssen of 3M gave a presentation at the May 2003 American Industrial Hygiene Conference and Exposition (AIHCE) on a workplace protection factor study they performed in a concrete-block manufacturing plant with workers using a NIOSH-approved N95 flatfold filtering facepiece respirator. The filtering facepiece respirator tested was the 3M Particulate Respirator 9211, approved by NIOSH under the 42 CFR 84 respirator certification standards. The authors measured silicon and calcium exposures to 19 workers in the bagging and block-handling areas of the plant. In the bagging area, workers placed bags over cement-dust chutes for filling, and then transferred the bags to pallets. In the other areas of the plant sampled by the authors, workers handled concrete blocks, swept and shoveled dust and block pieces into containers, and cleaned out mullers with chipping tools. The workers were informed of the purpose and procedures of, and their role in, the study, and were provided with instructions on proper donning, fitting, and user seal check procedures, as well as respirator operation. In addition, the workers had to pass a Bitrex® qualitative fit test that followed the fit test protocol described in OSHA's Respiratory Protection Standard prior to study participation. They also had to be clean shaven. They were observed by the authors in the workplace 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 polycarbonate filter with porous plastic back-up pads for collecting the inside samples. For sampling purposes, a Liu probe was inserted opposite the mouth near the midline of the respirator. It projected one centimeter into the facepiece. The sampling cassette was attached directly to the probe, and a cassette heater was used 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 also was 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 two liters per minute. Respirators were donned and doffed, and sampling trains started and stopped, in a clean area. Field blanks were used to evaluate for sample-handling contamination, and manufacturer blanks were collected to determine background contamination on the filters.

The inside samples were analyzed using proton-induced X-ray emission analysis (PIXEA), and the outside samples were analyzed by inductively coupled plasma (ICP) spectroscopy. For both calcium and silicon, the authors presented the range of Co, Ci, and the associated geometric means and standard deviations. Three sets of WPF results were determined: One for calcium, a second for silicon, and a harmonic mean for the combined calcium and silicon samples. Silicon was not detected on eleven of the Ci samples. However, by using 70% of the limit of detection as the inside mass, the authors were able to include these samples in the statistical analysis. No field-blank adjustments were made (i.e., no calcium or silicon detected), and no mention is made of adjusting the data for pulmonary retention of particles. In addition, three sample sets were invalidated as a result of equipment and procedural problems. The authors reported a mean WPF of 152, with a 5th percentile of 13, for the calcium samples; a mean WPF of 394, with a 5th percentile of 34, for the silicon samples; and a harmonic mean of the calcium and silicon samples of 206, with a 5th percentile of 20. The authors noted a difference in the WPFs measured for calcium and silicon (using the same respirator), and discussed a number of possible reasons for the difference (e.g., random sampling and analytical errors, possible non-uniformity of the challenge aerosol over time). The authors concluded, ''The estimated WPF for this respirator model based on this study exceeds the APF of 10 assigned to this respirator class by ANSI Z88.2–1992 and proposed by OSHA.'' They also stated, ''The respirator provided an adequate level of protection and reliably provided workplace protection factors of at least 10 when properly fitted, worn, and used'' (Ex. 9–16, page 40).

Colton and Bidwell study (Ex. 4–10–4). C. Colton and J. Bidwell of 3M made a presentation on May 25, 1995 at the AIHCE comparing the workplace performance of two different types of HEPA filters on an elastomeric half mask respirator in a battery manufacturing plant. The HEPA filters and the respirator model tested were approved under the 30 CFR 11 respirator certification standards. The half facepiece respirator tested was the 3M 7000, available in three sizes. The HEPA filters tested were the 3M 7255 high-efficiency (mechanical) filter and the 3M 2040 high efficiency (electret) filter. The authors measured lead exposures for 19 workers in the battery-pasting and assembly areas of the plant because these areas had the highest lead exposures. The workers were informed of the purpose and procedures of, and their role in, the study, and were provided with instructions on proper donning and fitting procedures, as well as respirator operation. In addition, the workers had to pass a saccharin qualitative fit test performed using the fit test protocol described in OSHA's Lead Standard. Workers had to be clean shaven. They were observed in the workplace by the authors on a one-on-one basis throughout the sampling periods.

For sampling purposes, a Liu probe was inserted opposite the mouth near the midline of the respirator. It projected one centimeter into the facepiece. The sampling cassette was attached directly to the probe, and a cassette heater was used to prevent condensation of moisture from exhaled breath. A Liu probe was also attached to the outside sample to ensure that particle loss for the outside samples would be similar to that with the inside samples. Inside samples and outside samples were collected at a flow rate of two liters per minute, and sampling times ranged from 56 to 200 minutes. Up to four samples were collected per day on each worker, each worker was sampled for two days, field blanks were used, and care was taken to avoid handling contamination. The filter for the first day was assigned randomly, with a worker using one filter type on the first day and the second filter type on the second day.

The inside- and outside-the-facepiece samples were analyzed for lead by ICP spectroscopy. The authors presented the range of outside and inside lead concentrations, and the associated geometric means and standard deviations. Two sets of WPF results were determined: One for the 3M 2040 filter and a second for the 3M 7255. A total of 140 samples were collected—one sample was eliminated due to low mass loading, 10 samples were lost due to equipment problems, and 85 samples had inside-sample mass values that were non-detectable. Of the remaining 44 samples, one outlier was identified in the electret filter data set, leaving 22 sets for the 3M 2040 filter and 21 sets for the 3M 7255 filter. No field blank adjustments were reported (i.e., no lead was detected on the field blanks). The authors reported a mean WPF of 562 and a 5th percentile of 71 for the 3M 2040 filter-respirator combination, and a mean WPF of 1006 and a 5th percentile of 80 for the 3M 7255 filter-respirator combination.

When no lead was detected for the inside samples, the WPF results were recalculated using the detection limit to represent the mass for these samples. From these recalculations, the authors identified one outlier in the electret filter data set and two outliers in the mechanical filter data set. They then calculated geometric means, geometric standard deviations, and 5th percentile WPFs for the 67 samples for the 3M 2040 filter and for the 59 samples for the 3M 7255 filter. The authors reported a mean WPF of 420 and a 5th percentile of 101 for the 3M 2040 filter-respirator combination, and a mean WPF of 549 and a 5th percentile of 138 for the 3M 7255 filter-respirator combination.

The authors concluded that the performance differences between the two filter types were not statistically significant. Both filters provided 5th percentile protection factors above 10. No WPFs were less than 30. Under these workplace conditions, no difference was found in the level of protection provided by the electrostatic HEPA filter compared to a mechanical HEPA filter.

Colton and Bidwell study (Ex. 9–16). C. Colton and J. Bidwell of 3M presented a research paper at the May 1999 AIHCE on a WPF study they performed in a battery manufacturing plant with workers using three NIOSH-approved filtering facepiece respirators. The filtering facepiece respirators tested were the 3M 8210 and 3M 8511, approved by NIOSH under the 42 CFR 84 respirator certification standards, and the 3M 8710 filtering facepiece, approved by NIOSH under the 30 CFR 11 respirator certification standards. The authors measured lead exposures for 21 workers in the battery-manufacturing and assembly areas of the plant. The worker job classifications tested were stackers, heat sealers, burners, and assemblers. The workers were informed of the purpose and procedures of, and their role in, the study, and were provided with instructions on proper donning, fitting, and user seal check procedures, as well as respirator operation. In addition, the workers had to pass a Bitrex® qualitative fit test with all three respirators, and they had to be clean shaven. They were observed in the workplace by the authors on a one-on-one basis throughout the sampling periods.

The sampling probe was a Liu probe that was inserted opposite the mouth near the midline of the respirator. It projected one centimeter into the facepiece. The sampling cassette was attached directly to the probe, and a cassette heater was used to prevent condensation of moisture from exhaled breath. Inside and outside samples were collected at a flow rate of two liters per minute for 79 to 159 minutes. Three samples were collected per day for each worker. Field blanks were used, and care was taken to avoid handling contamination.

The inside samples were analyzed for lead using PIXEA. Outside samples were analyzed by ICP spectroscopy. The authors presented the range of outside and inside sample lead concentrations, and the associated geometric means and standard deviations for each respirator model tested. Three sets of WPF results were determined: One for the 3M 8710, a second for the 3M 8210, and a third for the 3M 8511. Lead was not detected on five of the inside samples for the 3M 8710, 19 for the 3M 8210, and 23 for the 3M 8511. No field blank adjustments were reported (i.e., no lead was detected on the field blanks). The authors reported a mean WPF of 730, with a 5th percentile of 105, for the 3M 8710 respirator; a mean WPF of 955, with a 5th percentile of 73, for the 3M 8210; and a mean WPF of 673, with a 5th percentile WPF of 169, for the 3M 8511 using test samples with detectable lead levels. When no lead was detected on the inside samples, the WPF results were calculated by using 70% of the limit of detection as the mass for inside samples. The authors reported a mean WPF of 804, with a 5th percentile of 111, for the 3M 8710 respirator; a mean WPF of 2210, with a 5th percentile of 133, for the 3M 8210; and a mean WPF of 1970, with a 5th percentile WPF of 223, for the 3M 8511.

The authors stated, ''All respirator models provided an equivalent level of protection,'' and that ''[a]ll the respirators tested reliably provided workplace protection factors of 10 when properly fitted, worn, and used.'' No reported WPFs were less than 51, and no difference in workplace protection was found between workers using 30 CFR part 11-approved respirators and workers using 42 CFR 84-approved respirators. The authors concluded that, using the 5th percentile WPFs as an indicator of performance, the APFs should not differ between these respirators.

2. Additional Studies Not Used in the Updated Analyses

The Agency received a number of comments on the relationship between fit testing and APFs. OSHA regulations require that when a respirator user cannot pass a fit test with a particular respirator model, it cannot be used. OSHA does not believe that it is appropriate to assign a lower protection factor to a respirator (e.g., half the APF) when the respirator doesn't fit. However, a number of fit test studies, and one study on farm worker exposures to bioaerosols, were submitted to the record for the Agency to evaluate in terms of APFs. OSHA has evaluated these studies and determined that they do not meet the criteria that data must meet to be included in the database. These criteria have been described above.

NIOSH agreed (Tr. at 102) that the APF values resulting from OSHA's multifaceted approach provide reasonable values for the level of protection expected for each respirator class. Proposed Table 1 (''Assigned Protection Factors'') represents the state of the art for each class or respirator. However, NIOSH stated that designating a specific APF for a respirator class will not ensure that a respirator will perform as expected. The protection afforded by a respirator is contingent on: The respirator user adhering to the respirator program requirements of OSHA's Respiratory Protection Standard; the use of NIOSH-certified respirators in their approved configuration; and fit testing for each employee that ensures selection of a properly fitting respirator. The following studies, which OSHA did not include in its updated analyses, typically violated one or more of these three conditions.

Don-Hee Han study (Ex. 9–13–2). NIOSH (Ex. 9–13) submitted a study by Don-Hee Han (Ex. 9–13–2) of the 3M 8511 cup-shaped filtering facepiece, the MSA Affinity foldable FR 200, and the Willson N95 10FL produced by Dalloz Safety in response to OSHA's request in the NPRM for additional studies that may be useful in determining APFs. The author of the study permitted workers who did not pass a fit test with a minimum fit factor of 100, as required by OSHA's Respiratory Protection Standard, to participate in the study. OSHA reviewed this study and did not add the data set to its quantitative analyses because it was a PPF study that is not directly comparable with WFP studies used by OSHA in its APF determinations. However, the study results confirmed that when a worker's filtering facepiece respirator is fit tested properly, it is capable of achieving a protection factor of at least 10.

Peacock study (Ex. 9–13–4). This fit test research report was submitted to the record by NIOSH. In this study, a liquid-aerosol QNFT (Large Particle QNFT (LPQNFT)) was developed and used to evaluate filter penetration of a regular N95 respirator. Protection factors determined by the LPQNFT were compared to fit factors obtained using the saccharin QLFT. The sensitivity and specificity of the saccharin QLFT were evaluated. The results for the specifity of the LPQNFT indicated that workers who failed the saccharin QLFT also failed the LPQNFT when using a protection factor ≥ 100. The sensitivity was low. Twelve (12) subjects passed both the LPQNFT and the saccharin QLFT (out of 28 subjects), but another 16 subjects failed the saccharin test while passing the LPQNFT. Peacock concluded that the LPQNFT may be subject to particle deposition at leakage sites, as well as conditions inside the facepiece that would lead to sampling bias. OSHA did not rely on these fit test data for setting APFs because, as Peacock noted, further studies should be conducted to identify the cause of these problems.

Lee and Nicas study (Ex. 17–7–3). NIOSH submitted this study of N95 respirators used against *Mycobacterium tuberculosis* (TB). In this study, Lee and Nicas (Ex. 17–7–3) computed risks of TB infection using five medium- or regular-size N95 filtering facepiece respirators. Five NIOSH-approved respirators were selected for evaluation after reviewing manufacturer-provided fit test, comfort, and cost data. After extensive evaluation, the original five brands were rank ordered from highest to lowest fit test pass rates, and the authors calculated the risk of TB transmission. The authors concluded that fit testing is necessary to ensure that respirators perform as expected. However, OSHA did not accept this study for its APF analyses because it is not a WPF or SWPF study, and addresses only fit testing issues.

Coffey, et al. study (Ex. 17–7–4). NIOSH submitted to the record a publication by Coffey et al. (Ex. 17–7–4). In this study, 18 N95 filtering facepiece respirators were evaluated. The authors determined the following measurements from the results: 5th percentile SWPF value; the average SWPF per shift; the h-value; and the assignment error. A SWPF test was used to determine respirator performance, which was assessed using a Portacount Plus with test subjects performing six standard fit test exercises. However, the generally accepted format for a SWPF study involves test subjects performing simulated workplace exercises (e.g., shoveling pebbles, moving blocks, pounding nails).

Using this procedure, the authors found that when properly fit tested, over 80% of the poorly performing respirators achieved a protection factor of more than 10. However, OSHA did not use this study in its APF determinations since this was not a WPF or SWPF study. Nevertheless, the study supports the requirement that APFs apply only when used within the context of a comprehensive respirator program.

Reponen et al. study (Exs. 19–8–3 and 19–8–4). The purpose of this study was to further develop a prototype personal-sampling system for use with N95 filtering facepiece respirators. The study results were calculated from 30–60 minute Co and Ci measurements taken across multiple agricultural settings, tasks, and simulated exposures. The data were combined to calculate dust, microorganism, and cultured microorganism exposures. Descriptions of tasks in several workplaces were provided.

The N95 respirators in this study performed at or above a WPF of 10 when evaluated using dust measurements. However, the dust-exposure measurements counted both dust particles and microorganisms because the optical-particle counter used for this purpose does not differentiate between organic and nonorganic particles. When they calculated WPFs for the microorganism samples alone, the WPFs decreased somewhat. The authors concluded that the geometric mean WPF increased with increasing particle size, and that the WPFs were smaller for biological particles than for dust. The authors speculated that differences in WPFs may result from the measurement effects of particle size or density. They also said that even a small variation in the density of particles can have a pronounced effect on the loss of dust particles through faceseal leaks due to impaction. The authors concluded that their findings deserve further research.

OSHA agrees with the authors that further research is needed to substantiate and explore these findings. Also, the Agency has significant concern regarding the measurement methodology used in this prototype study. For example, it is not clear whether the WPF differences are valid or are simply the result of using different measurement methods. Therefore, the Agency decided not to use this study for developing APFs.

Summary and conclusions for studies not used in the updated database. OSHA reviewed the studies submitted to the APF rulemaking docket and determined that five of them were unsuitable for the database used to develop APFs. OSHA established a set of criteria in the proposal for evaluating new studies for inclusion in the APF database. The studies by Han (Ex. 9–13–4), Peacock (Ex. 9–13–4), Lee and Nicas (Ex. 17–7–3), Coffey *et al.* (Ex 17–7–4), and Reponen *et al.* (Exs. 19–8–3 and 19–8–4) were not used by OSHA in setting the final APFs because these studies did not follow established WPF or SWPF protocols, or required further research to substantiate or explore the results.

IV. Health Effects

American workers use respirators as a means of protection against a multitude of respiratory hazards that include chemical, biological, and radiological agents. Respirators provide protection from hazards that are immediately life-threatening, as well as hazards associated with routine operations for which engineering controls and work practices do not protect employees sufficiently. When respirators fail, or do not provide the degree of protection expected by the user, the user is placed at an increased risk of adverse health effects that result from exposure to the respiratory hazards present. Therefore, it is critical that respirators perform properly to ensure that users are not at an increased risk of experiencing adverse effects caused by exposure to respiratory hazards.

In this final rulemaking, OSHA defined the minimal level of protection a respirator is expected to achieve (i.e., the APFs in Table 1), as well as the MUCs for the respirators. The Agency also is superseding most of the existing APF table requirements in its substance-specific standards. By superceding the APF tables, the Agency estimates that the benefits for the final APFs under the Respiratory Protection Standard will be available as well to employers who must select respirators for employee use under the substance-specific standards. In addition, the Agency believes that harmonizing the APFs of the substance-specific standards with the APFs in the Respiratory Protection Standard will reduce confusion among the regulated community and aids in uniform application of APFs, while maintaining employee protection at levels at least as protective as the existing APF requirements.

V. Summary of the Final Economic Analysis and Regulatory Flexibility Analysis

A. Introduction

OSHA's Final Economic and Regulatory Flexibility Screening Analysis (FEA) addresses issues related to the costs, benefits, technological and economic feasibility, and economic impacts (including small business impacts) of the Agency's Assigned Protection Factors (APF) rule. The Agency has determined that this rule is not an economically significant rule under Executive Order 12866. The economic analysis meets the requirements of both Executive Order 12866 and the Regulatory Flexibility Act (RFA; as amended in 1996). The FEA presents OSHA's full economic analysis and methodology. The Agency entered the complete FEA into the docket as Exhibit 11. The remainder of this section summarizes the results of that analysis.

The purpose of this FEA is to:

- Evaluate the costs employers would incur to meet the requirements of the APF rule;
- Estimate the benefits of the rule;
- Assess the economic feasibility of the rule for affected industries; and
- Determine the impacts of the rule on small entities and the need for a Regulatory Flexibility Analysis.

B. The Rule and Affected Respirator Users

OSHA's APF rule would amend 29 CFR 1910.134(d)(3)(i)(A) of the Respiratory Protection Standard by specifying a set of APFs for each class of respirators. These APFs specify the highest multiple of a contaminant's permissible exposure limit (PEL) at which an employee can use a respirator safely. The APFs would apply to respirator use for protection against overexposure to any substance regulated under 29 CFR 1910.1000. In addition, OSHA rules for specific substances under subpart Z (regulated under the authority of section 6(b)(5) of the OSH Act of 1970, 29 U.S.C. 655) specify APFs for respirators used for protection against these chemicals (hereafter referred to as § 6(b)(5) substances). The rule would supercede most of these protection factors, and harmonize APFs for these substances with those for general respirator use.

OSHA based estimates of the number of employees using respirators and the corresponding number of respirator-using establishments on the NIOSH-BLS survey of respirator use and practices [2] (Ex. 6–3). The NIOSH-BLS survey provides up-to-date use estimates by two-digit industry sector and respirator type for establishments in which employees used respirators during the previous 12 months.[3] As shown in Table V–1, an estimated 291,085 establishments reported respirator use in industries covered by OSHA's regulation. Most of these establishments (208,528 or 71.6 percent) reported use of filtering facepieces. Substantial percentages of establishments also reported the use of half-mask and full facepiece non-powered air-purifying respirators (49.0 and 21.4 percent, respectively). A smaller number of establishments reported use of powered air-purifying respirators (PAPRs) and supplied-air respirators (SARs). Fifteen percent of establishments with respirators (43,154) reported using PAPRs and 19 percent (56,022) reported using SARs. Table V–2 presents estimates of the number of respirator users by two-digit industry sector. An estimated 2.3 million employees used filtering facepiece respirators in the last 12 months, while 1.5 million used half masks, and 0.7 million used full facepiece non-powered air-purifying respirators. Fewer employees reported using PAPRs (0.3 million) and SARs (0.4 million). The industry-specific estimates show substantial respirator use in several industries, including the construction sector, several manufacturing industries (SICs 28, 33, 34, and 37), and Health services (SIC 80).

BILLING CODE 4510–26–P

[2] Preliminary results from the 2001 NIOSH–BLS ''Survey of Respirator Use and Practices'' in press. NIOSH commissioned the survey to be conducted by BLS, who also tabulated the data after completing the survey.

[3] The survey was conducted between August 2001 and January 2002. It asked: ''During the past 12 months, how many of your current employees used respirators at your establishment?'' It excluded voluntary use of respirators from detailed followup respirator use questions (Ex. 6–3).

Table V-1

Estimated Number of Establishments With Respirator Users, by Type

SIC	Title	All Respirator Types	Non-powered Air-Purifying: Filtering Facepiece	Non-powered Air-Purifying: Half-mask	Non-powered Air-Purifying: Full-face	PAPR	Supplied-Air: Total	Supplied-Air: SCBA
07	Agricultural services	7,566	6,466	1,142	33 *	105 *	240 *	164 *
08	Forestry	261	261	208	1 *	4 *	8 *	6 *
09	Fishing, hunting, and trapping	0	0	0	0	0	0	0
13	Oil and gas extraction	1,097	490	1,097	499	220	412	250
15	General building contractors	19,071	15,069	6,729	1,859	1,520	1,213	674
16	Heavy construction, except building	4,718	3,816	2,432	915	757	1,213	355
17	Special trade contractors	40,823	31,380	17,025	10,161	7,136	8,198	2,693
20	Food and kindred products	3,608	1,926	1,433	1,901	428	1,010	720
21	Tobacco products	30	17	13 *	0	20	20	20
22	Textile mill products	720	627	272	201	139	9	0
23	Apparel and other textile products	1,111	943 *	925	14 *	0	0	0
24	Lumber and wood products	1,995	1,326	1,273	353	197	168	106
25	Furniture and fixtures	2,053	1,745	1,469	317	80	83	28
26	Paper and allied products	649	448	329	293	122	193	153
27	Printing and publishing	124	105 *	45	2 *	0	3	0
28	Chemicals and allied products	5,052	3,047	2,896	2,698	910	2,077	1,632
29	Petroleum and coal products	432	64	189	200	99	249	151
30	Rubber and misc. plastics products	3,140	2,094	1,707	1,117	695	938	121
31	Leather and leather products	14 *	12 *	6 *	0	0	340	0
32	Stone, clay, and glass products	3,109	2,089	1,765	495	589	530	119
33	Primary metal industries	1,974	1,533	861	385	491	550	183
34	Fabricated metal products	7,374	4,601	4,988	1,103	1,510	2,456	361
35	Industrial machinery and equipment	7,458	4,425	4,151	1,700	1,093	2,131	441
36	Electronic and other electric equipment	2,731	1,676	1,412	656	341	525	252
37	Transportation equipment	3,788	1,957	2,158	1,656	738	1,225	337
38	Instruments and related products	1,282	711	1,033	736	468	568	155
39	Miscellaneous manufacturing industries	3,140	2,389	2,295	1,442	1,276	439	133
40	Railroad transportation	846	417	803	380	375	503	134
41	Local and interurban passenger transit	809	405	522	87 *	73	86	86
42	Trucking and warehousing	4,090	3,240	793	850	463	751	617
43	United States Postal Service	1,012 **	801 **	196 **	210 **	115 **	186 **	153 **
44	Water transportation	50 *	7 *	50 *	5 *	14 *	55	0
45	Transportation by air	48 *	7 *	48 *	5 *	13	10 *	0
46	Pipelines, except natural gas	252	35 *	180	74	69 *	96 *	91
47	Transportation services	8 *	1 *	7 *	0	2	7	0
48	Communications	100 *	14 *	99 *	11 *	27	18 *	0
49	Electric, gas, and sanitary services	5,085	1,856	2,975	1,486	821	2,737 *	1,956
50	Wholesale trade–durable goods	18,854	10,795	9,641	3,259	2,776	2,926	1,278
51	Wholesale trade–nondurable goods	8,573	4,660	3,619	4,303	2,192	3,045	2,533
52	Building materials and garden supplies	2,386	2,386	1,433	688 *	496	89	66
53	General merchandise stores	687 *	211 *	471 *	190 *	143 *	19 *	19 *
54	Food stores	2,394 *	736 *	1,642 *	662 *	498	67 *	67 *
55	Automotive dealers and service stations	10,243	7,139	6,127	2,271	2,403	3,211 *	1,048 *
56	Apparel and accessory stores	308 *	95 *	211 *	85 *	64	1,442	9
57	Furniture and homefurnishings stores	2,769	2,586	1,710	799 *	576 *	77 *	77 *
58	Eating and drinking places	0	0	0	0	0	0	0
59	Miscellaneous retail	978	679	700 *	282 *	203	27	27
60	Depository institutions	1,372 *	1,349 *	36 *	59 *	6 *	0	0
61	Nondepository institutions	299 *	294 *	8 *	13 *	1	0	0
62	Security and commodity brokers	278 *	274 *	7 *	12 *	1	0	0
63	Insurance carriers	442 *	435 *	62	19 *	2	0	0
64	Insurance agents, brokers, and services	744 *	732 *	19 *	32 *	3	0	0
65	Real estate	1,541	1,031	1,115	67 *	7	0	0
67	Holding and other investment offices	157 *	155 *	4 *	7 *	0	0	0
70	Hotels and other lodging places	1,326	1,326	621	531	7 *	0	0
72	Personal services	9,743	4,779	9,115	1,192	52 *	0	0
73	Business services	13,517	11,574	4,952	4,578	72 *	925	925
75	Auto repair, services, and parking	32,113	26,523	19,568	5,793	5,655	8,778 *	3,263 *
76	Miscellaneous repair services	3,375	3,375	1,199 *	313 *	18 *	4,259	0
78	Motion pictures	17 *	8 *	6 *	2 *	0	2	0
79	Amusement and recreation services	1,612	1,348	1,184	150 *	9 *	0	0
80	Health services	16,486	14,625	1,991	1,307	879	303	260
81	Legal services	61 *	29 *	22 *	6 *	0	3	0
82	Educational services	564	267 *	431	52 *	3 *	0	0
83	Social services	6,668	5,812	2,217 *	579 *	36 *	0	0
84	Museums, botanical, zoological gardens	235	112 *	235	22 *	1 *	16	16
86	Membership organizations	533	252 *	383	49 *	3 *	0	0
87	Engineering and management services	10,292	4,004	7,297	1,800	5,117	254	254
89	Services, n.e.c.	6 *	3 *	2 *	0	0	3	0
	State and local governments	6,893 ***	4,936 ***	3,392 ***	1,479 ***	1,023 ***	1,327 ***	530 ***
	Totals	291,085	208,528	142,947	62,448	43,154	56,022	22,461

Source: Preliminary results from the 2001 NIOSH/BLS Survey of Respirator Use and Practices, in press. Benchmarked to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

* Suppressed industry-level estimates extrapolated from sector totals.

** Estimated based on respirator use patterns in SIC 42.

*** Estimated based on private-sector respirator use patterns.

Table V-2

Estimated Number of Respirator Users, by Respirator Type

SIC	Title	Non-powered Air-Purifying Filtering Facepiece	Non-powered Air-Purifying Half Mask	Non-powered Air-Purifying Full Facepiece	PAPR	Supplied-Air Total[1]	Supplied-Air With SCBA
07	Agricultural services	52,919	6,030 *	1,713 *	139 *	942 *	567 *
08	Forestry	765 *	208 *	23 *	3 *	32 *	20 *
09	Fishing, hunting, and trapping	0	0	0	0	0	0
13	Oil and gas extraction	12,086 *	14,108	1,587 *	6,242	3,071	2,405
15	General building contractors	77,827	36,770	7,752	2,750	6,047	4,744
16	Heavy construction, except building	31,518	30,503	8,747	4,929	8,652	1,933
17	Special trade contractors	259,240	247,483	156,559	49,285	81,803	17,005
20	Food and kindred products	31,317	15,454	13,559	2,465	9,693	7,093
21	Tobacco products	4,232 *	390 *	0	173	412	412
22	Textile mill products	31,996 *	3,198	3,510	3,243	41	0
23	Apparel and other textile products	3,326 *	2,444	213 *	0	0	0
24	Lumber and wood products	17,615 *	8,855	2,869	3,083	1,761	1,096
25	Furniture and fixtures	15,196	7,544	1,916 *	843	530	180
26	Paper and allied products	13,435	16,139	6,313	1,808	6,724	6,222
27	Printing and publishing	1,060 *	341 *	57 *	0	0	0
28	Chemicals and allied products	62,742	88,807	71,534	14,156	46,708	28,306
29	Petroleum and coal products	3,021 *	20,737	20,737	3,448	19,007	12,675
30	Rubber and misc. plastics products	20,523	15,285	5,902	1,729	5,803	1,383
31	Leather and leather products	101 *	8 *	0	0	0	0
32	Stone, clay, and glass products	34,520 *	17,862	5,433	2,595	2,025	705
33	Primary metal industries	42,014	50,150	8,770	6,316	12,168	5,827
34	Fabricated metal products	41,546	38,192	6,824	6,135	11,960	2,335
35	Industrial machinery and equipment	29,381	23,080	9,998	4,313	9,605	2,448
36	Electronic and other electric equipment	20,550	28,259	10,688	2,339	11,422	7,882
37	Transportation equipment	42,965	86,796	18,958	6,520	16,930	3,493
38	Instruments and related products	11,414	13,602	9,192	1,342	4,470	1,296
39	Miscellaneous manufacturing industries	18,431	15,452	2,401	6,554	2,337	555
40	Railroad transportation	NA	NA	NA	NA	NA	NA
41	Local and interurban passenger transit	5,589 *	2,536	203 *	467	587 *	419 *
42	Trucking and warehousing	26,422 *	9,486 *	7,702	4,299	4,879	2,446
44	Water transportation	973 *	20,591 *	143 *	20,591	64 *	0
45	Transportation by air	3,443 *	3,443 *	3,443 *	13	11,282	0
46	Pipelines, except natural gas	40 *	471 *	237 *	160	295	215
47	Transportation services	25 *	214 *	0	2	8 *	0
48	Communications	336 *	2,844 *	49 *	27	18 *	0
49	Electric, gas, and sanitary services	22,784	62,648	35,279	7,147	27,403	13,905
50	Wholesale trade--durable goods	35,783	22,876	16,548 *	4,734	6,936	5,072
51	Wholesale trade--nondurable goods	75,813 *	50,120	13,576	16,524	19,157	4,244
52	Building materials and garden supplies	34,024 *	8,296 *	4,061 *	496	89 *	66 *
53	General merchandise stores	1,008 *	1,008 *	190 *	1,008	19 *	19 *
54	Food stores	2,786 *	2,110 *	802 *	498	921	921
55	Automotive dealers and service stations	66,440	52,361	22,888	16,426	19,415	7,139
56	Apparel and accessory stores	867 *	345 *	85 *	64	1,442 *	9 *
57	Furniture and homefurnishings stores	4,556 *	2,723 *	799 *	1,494	77 *	77 *
58	Eating and drinking places	0	0	0	0	0	0
59	Miscellaneous retail	7,034 *	1,577 *	767 *	203	27 *	27 *
60	Depository institutions	1,933 *	1,790 *	59 *	57	0	0
61	Nondepository institutions	294 *	238 *	13 *	1	0	0
62	Security and commodity brokers	274 *	222 *	12 *	1	0	0
63	Insurance carriers	1,055 *	761 *	19 *	2	0	0
64	Insurance agents, brokers, and services	732 *	593 *	32 *	3	0	0
65	Real estate	5,760 *	10,161	218 *	7	0	0
67	Holding and other investment offices	595 *	165 *	7 *	0	0	0
70	Hotels and other lodging places	72,978 *	4,959	16,012 *	21 *	0	0
72	Personal services	10,771 *	19,239 *	12,074 *	188 *	0	0
73	Business services	78,724	45,461 *	24,576 *	261 *	30,116	29,997
75	Auto repair, services, and parking	115,969	56,952	15,320	12,868	23,583	6,787
76	Miscellaneous repair services	26,018	15,868 *	6,066 *	72 *	4,730	0
78	Motion pictures	859 *	650 *	243 *	0	0	0
79	Amusement and recreation services	14,915	7,217	3,650 *	26 *	0	0
80	Health services	637,932	123,157	64,125	69,893	4,230	3,829
81	Legal services	3,145 *	2,379 *	890 *	0 *	0	0
82	Educational services	29,197 *	2,891	8,259 *	226	0	0
83	Social services	7,868 *	5,128 *	1,813 *	129 *	0	0
84	Museums, botanical, zoological gardens	2,212 *	2,652 *	586 *	4 *	625	624
86	Membership organizations	1,035 *	1,276 *	326 *	9 *	0	0
87	Engineering and management services	69,687 *	42,515 *	19,530 *	6,350	3,354	3,354
89	Services, n.e.c.	715 *	928 *	0	0	0	0
	Totals	2,250,327	1,376,547	655,857	294,682	421,402	187,728

Source: Preliminary results from the 2001 NIOSH-BLS "Survey of Respirator Use and Practices", in press. Benchmarked to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.
* Suppressed industry-level estimates extrapolated from sector totals.
[1] Includes both SCBA and respirators with air supplied by hose.

BILLING CODE 4510–26–C

The standard would have different impacts on employers using respirators to comply with OSHA substance-specific standards than for employers using respirators for other purposes. Therefore, OSHA used findings from the NIOSH–BLS survey of establishments that reported respirator use, by general respirator class, for protection against specific substances (see Table V–3). OSHA applied these numbers to all respirator users and establishments within the industries that make up each sector to derive substance-specific estimates of respirator use. For those § 6(b)(5) substances not reported by NIOSH, OSHA used expert judgments of a consultant with experience in the respirator industry to estimate the percentage of establishments and employees that use respirators for protection against these chemicals (Ex. 6–2) (see Table V–3).

C. Compliance Costs

The standard does not raise issues of technological feasibility because it requires only that employers use respirators already on the market. Further, these respirators are already in use and have proven feasible in a wide variety of industrial settings. However, costs for the APF standard result from requiring some users to switch to more protective respirators than they currently use. When the APF is lower than the baseline (current) APF, respirator users must upgrade to a more protective model. Both the 1992 ANSI Z88.2 Respiratory Protection Standard and the 1987 NIOSH RDL specify APFs for certain classes of respirators. The Agency assumed that employers currently use the ANSI or NIOSH APFs, or the APFs in the OSHA substance-specific standards, as applicable, to select respirators. While the Agency currently refers to the NIOSH RDL as its primary reference for APFs, in the absence of an applicable OSHA standard, this analysis assumes that, in most cases, adhering to the existing ANSI APFs fulfills employers' legal obligation for proper respirator selection under the existing Respiratory Protection Standard. However, in the case of full facepiece negative pressure respirators, the Agency has established that an APF of 50, as opposed to ANSI's APF of 100, is currently acceptable. In this regard, all but one of the substance-specific standards with APFs for full facepiece negative pressure respirators set an APF of 50. In addition, the existing respirator rule and its supporting preamble require that quantitative fit testing of full facepiece negative pressure respirators must achieve a fit factor of 500 when employees use them in atmospheres in excess of 10 times the PEL; this requirement assumes a safety factor of 10. Therefore, based on a fit factor of 500, such respirators are safe to wear in atmospheres up to 50 times the PEL, consistent with similar requirements regarding respirator use found in existing standards for § 6(b)(5) chemicals.

BILLING CODE 4510–26–P

Table V-3A

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments With Respirators	Arsenic		Asbestos		Cadmium		Lead		Cotton Dust [1]		Coke Oven Emissions	
Air-Purifying Respirators													
Agriculture	13,200	1,200	9.1%	1,200	9.1%	1,200	9.1%	1,100	8.3%	2,500	18.9%	1,000	7.6%
Mining	3,500	200	5.7%	400	11.4%	200	5.7%	300	8.6%	100	2.9%	100	2.9%
Construction	60,000	2,900	4.8%	6,000	10.0%	2,600	4.3%	7,900	13.2%	800	1.3%	900	1.5%
Manufacturing	46,200	2,500	5.4%	4,000	8.7%	2,700	5.8%	5,500	11.9%	1,400	3.0%	2,000	4.3%
Transportation and utilities	9,700	900	9.3%	2,200	22.7%	600	6.2%	1,400	14.4%	200	2.1%	200	2.1%
Wholesale trade	28,000	800	2.9%	2,600	9.3%	1,800	6.4%	3,700	13.2%	1,100	3.9%	700	2.5%
Retail trade	16,100	100	0.6%	300	1.9%	200	1.2%	600	3.7%	100	0.6%	0	0.0%
Finance, insurance, and real estate	4,200	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Services	86,600	1,600	1.8%	8,700	10.0%	1,500	1.7%	10,800	12.5%	1,000	1.2%	800	0.9%
Total	267,500	10,200	3.8%	25,400	9.5%	10,800	4.0%	31,300	11.7%	7,200	2.7%	5,700	2.1%
Supplied-Air Respirators													
Agriculture	500	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.05%	0	0.0%
Mining	600	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.00%	0	0.0%
Construction	10,500	1,700	16.2%	1,000	9.5%	1,600	15.2%	2,400	22.9%	0	0.00%	0	0.0%
Manufacturing	12,700	400	3.1%	600	4.7%	600	4.7%	1,100	8.7%	3	0.02%	200	1.6%
Transportation and utilities	3,800	100	2.6%	1,000	26.3%	100	2.6%	300	7.9%	1	0.02%	0	0.0%
Wholesale trade	6,800	0	0.0%	0	0.0%	0	0.0%	700	10.3%	1	0.01%	0	0.0%
Retail trade	2,900	0	0.0%	0	0.0%	0	0.0%	200	6.9%	0	0.00%	0	0.0%
Finance, insurance, and real estate	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Services	9,500	0	0.0%	0	0.0%	0	0.0%	400	4.2%	0	0.00%	0	0.0%
Total	47,300	2,200	4.7%	2,600	5.5%	2,300	4.9%	5,100	10.8%	6	NA	200	0.4%

Source: The 2001 NIOSH-BLS "Survey of Respirator Use and Practices", Bureau of Labor Statistics Press Release, March 20, 2002.

[1] Estimates for supplied-air respirators provided by ERG consultant Jeffrey Stull of International Personal Protection, Inc.

Table V-3B

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments With Respirators [1]	Acrylonitrile		Formaldehyde		DBCP		Ethylene oxide		Vinyl chloride		Butadiene	
Air-Purifying Respirators													
Agriculture	13,200	0	0.00%	66	0.50%	1	0.01%	0	0.00%	0	0.00%	0	0.00%
Mining	3,500	0	0.00%	4	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Construction	60,000	0	0.00%	480	0.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Manufacturing	46,200	92	0.20%	554	1.20%	5	0.01%	231	0.50%	462	1.00%	370	0.80%
Transportation and utilities	9,700	5	0.05%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	0	0.00%
Wholesale trade	28,000	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Retail trade	16,100	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Finance, insurance, and real estate	4,200	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Services	86,600	0	0.00%	0	0.00%	0	0.00%	43	0.05%	0	0.00%	0	0.00%
Total	267,500	97	0.04%	1,105	0.4%	6	0.00%	275	0.1%	463	0.17%	370	0.14%
Supplied-Air Respirators													
Agriculture	500	0	0.00%	0	0.00%	0	0.01%	0	0.01%	0	0.00%	0	0.00%
Mining	600	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Construction	10,500	0	0.00%	5	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Manufacturing	12,700	64	0.50%	102	0.80%	1	0.01%	114	0.90%	152	1.20%	76	0.60%
Transportation and utilities	3,800	1	0.02%	1	0.02%	0	0.00%	1	0.02%	1	0.03%	0	0.01%
Wholesale trade	6,800	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Retail trade	2,900	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Finance, insurance, and real estate	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Services	9,500	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%
Total	47,300	64	0.14%	108	0.2%	1	0.0%	116	0.2%	NA	NA	77	0.16%

Source: Estimates provided by ERG consultant Jeffery Stull of International Personal Protection, Inc.
[1] The 2001 NIOSH-BLS "Survey of Respirator Use and Practices", Bureau of Labor Statistics Press Release, March 20, 2002.

BILLING CODE 4510–26–C

For each respirator type, OSHA compared the new and existing standards and, where these new APFs were lower, identified an incrementally more protective respirator model. To be adequate, the more protective respirator must have an APF greater than the current APF.

1. Number of Users Required To Upgrade Respirator Models

For a given respirator type, the number of users required to shift to a more protective respirator depends on two factors: the total number of users of that type, and the percentage of those users for whom the ambient exposure level is greater than the APF. While survey data are available to estimate the number of users, virtually no information is available in the literature that provides a basis for estimating the percentage of users required to upgrade respirators. The percentage of workers switching respirators would depend on the profile or frequency distribution of users' exposure to contaminants relative to the PEL. For example, the Agency is lowering the APFs for full facepiece respirators used to protect against cotton dust from 100 to 50; accordingly, when workers have ambient exposures that are greater than 50 times the PEL, employers must upgrade the respirator from a full facepiece negative pressure respirator to a more protective respirator (e.g., a PAPR).

Because of the absence of data on this issue, OSHA made several assumptions regarding the requirement to upgrade respirators. First, OSHA assumed that employers use respirators only when their employees have exposures above the PEL. Second, OSHA assumed employers use the most inexpensive respirator permitted, taking into consideration the employees' safety and compliance with regulatory requirements. These assumptions most likely overestimate the cost of compliance because many employers require their employees to use respirators when OSHA does not require such use, or they require respirators with higher APFs than OSHA currently requires. As a result, this analysis assumes shifts in respirators that employers may have implemented already. Two commenters on this issue agreed that these assumptions overestimate the number of employers that would need to change respirators as a result of this rule (see Exs. 9–16 and 13–8). One commenter (Ex. 9–16) noted that ''For about twenty years, 3M has looked for worksites where employers were using respirators at concentrations at the upper end of the APF range. We have not been able to find these worksites.'' This commenter went on to note, as a result ''we believe that the overall compliance costs associated with the proposal, as currently written, will likely be even lower than OSHA has estimated.''

The Agency estimated distributions of exposures above the PELs based on reports from its Integrated Management Information System describing workplace monitoring of § 6(b)(5) toxic substances performed during OSHA health inspections. Of the 9,095 samples reported above the PELs, 68.0 percent reported exposures between one and five times the PEL, 13.1 percent found exposures between five and 10 times the PEL, and 9.5 percent documented exposures between 10 and 25 times the PEL. Exposures for the remaining 9.4 percent of the samples were greater than 25 times the PEL. Based on these data, OSHA modeled the current exposure distribution for each respirator type.

2. Incremental Costs of Upgrading Respirator Models

OSHA also analyzed the costs of upgrading from the current respirator to a more protective alternative. In doing so, OSHA estimated the annualized unit costs for each respirator type, including equipment and accessory costs, and the costs for training and fit testing. One commenter (Ex. 17–9) noted the importance of not just considering the initial costs of a respirator, but all associated costs. OSHA has considered all of these costs, including training, fit testing, program development, and medical evaluation, as this commenter suggested. OSHA then calculated the incremental cost for each combination of upgrades from an existing model to a more protective one, taking into account the effect of replacement before the end of the respirator's useful life. These annualized costs range from $49.98 (for upgrading from a supplied-air, demand mode, full facepiece respirator to a supplied-air, continuous flow, half-mask respirator) to $963.73 (for upgrading from a non-powered, air-purifying full facepiece respirator to a full facepiece PAPR).

In certain instances, workers who use respirators under the substance-specific standards may have to upgrade to a SAR with an auxiliary escape SCBA. Several substance-specific standards currently specify SARs for exposures that exceed 1,000 times the PEL.[4] OSHA believes that workers are unlikely to regularly use respirators at such extreme exposure levels, i.e., they are most likely to use them only in exceptional, possibly emergency-related situations. Furthermore, exposures at levels more than 1,000 times the PEL would generally be at or above levels deemed immediately dangerous to life or health (IDLH), so employers already are required by the Respiratory Protection Standard to provide each worker with a respirator that has SCBA capability. For these reasons, this PERFSA estimated no impacts for these situations.[5]

3. Aggregate Compliance Costs

For each respirator type affected by the regulation, OSHA combined the incremental costs of upgrading to a more protective respirator, the estimated share of users forecast to upgrade, and the number of users involved to estimate the compliance costs associated with each respirator type. Table V–4 shows estimated compliance costs for OSHA's APF rule. The rule would require 1,918 users of non-powered air-purifying respirators to upgrade to some respirator more expensive than they are now using at a cost of $1.8 million. The Agency estimates that 22,848 PAPR users would upgrade their respirators at a cost of $2.3 million. A relatively small number of SAR users (5,110) would upgrade to more expensive respirators at a cost of $0.4 million. Industry-specific compliance costs vary according to the number of respirator users and the proportion of these users affected by the rule. Industries with relatively large compliance costs include SIC 17, Special trade contractors ($0.8 million), and SIC 80, Health services ($0.8 million).

As discussed previously, the Agency believes the actual costs of the standard almost certainly are overestimated. The cost analysis assumes all respirator wearers have levels of exposures that require the particular respirator they are using. Under this assumption, 15,000 employees would be allowed to safely shift to a less expensive respirator, which could lead to cost savings for the employer. Such potential cost savings are not accounted for in this cost analysis.

In many cases, employers use respirators when respirators are not required by OSHA, or use respirators more protective than required by OSHA. As a result, OSHA's cost analysis overestimates the number of employees who are affected by the standard, and therefore overestimates costs associated with the standard.

D. Benefits

The benefits that would accrue to respirator users and their employers take several forms. The standard would benefit workers by reducing their exposures to respiratory hazards. Improved respirator selection would augment previous improvements to the Respiratory Protection Standard, such as better fit-test procedures and improved training, contributing substantially to greater worker protection. Estimates of benefits are difficult to calculate because of uncertainties regarding the existing state of employer respirator-selection practices and the number of covered work-related illnesses. At the time of the 1998 revisions to the Respiratory Protection Standard, the Agency estimated that the standard would avert between 843 and 9,282 work-related injuries and illnesses annually, with a best estimate (expected value) of 4,046 averted illnesses and injuries annually (63 FR 1173). In addition, OSHA estimated that the standard would prevent between 351 and 1,626 deaths annually from cancer and many other chronic diseases, including cardiovascular disease, with a best estimate (expected value) of 932 averted deaths from these causes. The APFs in this rulemaking will help ensure that these benefits are achieved, as well as provide an additional degree of protection. These APFs also will reduce employee exposures to several § 6(b)(5) chemicals covered by standards with outdated APF criteria, thereby reducing exposures to chemicals such as asbestos, lead, cotton dust, and arsenic.[6] While the Agency did not quantify these benefits, it estimates that 29,655 employees would have a higher degree of respiratory protection under this APF standard. Of these employees, an estimated 8,384 have exposure to lead, 7,287 to asbestos, and 3,747 to cotton dust, all substances with substantial health risks.

BILLING CODE 4510–26–P

[4] These standards regulate cotton dust, coke oven emissions, acrylonitrile, arsenic, DBCP, ethylene oxide, and lead.

[5] Paragraph (d)(2) of the Respiratory Protection Standard requires employers to provide either a pressure demand SCBA or a pressure demand SAR with auxiliary SCBA to any employee who works in IDLH atmospheres.

[6] In the 1998 rulemaking revising the Respiratory Protection Standard, the Final Economic Analysis noted that the standard would not directly affect the benefits for the estimated 5% of employees who use respirators under OSHA's substance-specific health standards (except to the extent that uniformity of provisions improve compliance). Therefore, the Agency likely over-estimated the benefits of that rulemaking since the standard did not affect directly the type of respirator used by those employees (63 FR 1173). Conversely, this rule directly addresses the APF provisions of the substance-specific standards; therefore, this rule would affect directly the respirators used by employees covered by these standards.

Table V-4

Summary of Costs by Respirator Class

SIC	Industry	Non-powered Air-Purifying Respirators: Users [1]	Non-powered Air-Purifying Respirators: No. Upgrading	Non-powered Air-Purifying Respirators: Cost	Powered Air-Purifying Respirators: Users [1]	Powered Air-Purifying Respirators: No. Upgrading	Powered Air-Purifying Respirators: Cost	Supplied-Air Respirators: Users [1,2]	Supplied-Air Respirators: No. Upgrading	Supplied-Air Respirators: Cost	Total Cost
07	Agricultural services	60,662	46	$43,030	139	7	$657	467	2	$81	$43,768
08	Forestry	996	0	$0	3	0	$0	16	0	$0	$0
09	Fishing, hunting, and trapping	0	0	$0	0	0	$0	0	0	$0	$0
13	Oil and gas extraction	27,781	6	$6,016	6,848	415	$50,887	666	12	$1,399	$58,302
15	General building contractors	122,350	15	$13,713	4,355	288	$30,519	5,846	80	$9,067	$53,300
16	Heavy construction, except building	70,768	17	$15,472	7,342	380	$38,426	6,719	90	$9,445	$63,344
17	Special trade contractors	663,282	296	$276,942	102,625	3,933	$428,165	86,591	1,007	$87,432	$792,539
20	Food and kindred products	60,330	58	$54,509	4,105	107	$12,643	2,600	60	$6,620	$73,772
21	Tobacco products	4,621	0	$0	271	0	$0	121	3	$125	$125
22	Textile mill products	38,704	15	$14,112	5,071	36	$4,153	164	4	$190	$18,455
23	Apparel and other textile products	5,984	0	$0	0	0	$0	0	0	$0	$0
24	Lumber and wood products	29,339	12	$11,535	3,178	102	$12,283	792	11	$535	$24,353
25	Furniture and fixtures	24,657	8	$7,703	844	15	$1,847	521	5	$387	$9,937
26	Paper and allied products	35,888	27	$25,382	2,086	73	$7,507	2,662	57	$2,853	$35,742
27	Printing and publishing	1,458	0	$0	0	0	$0	3	0	$0	$0
28	Chemicals and allied products	223,083	307	$287,588	18,791	238	$25,243	27,066	443	$22,139	$334,970
29	Petroleum and coal products	44,494	89	$83,367	5,207	35	$4,099	6,333	147	$8,052	$95,518
30	Rubber and misc. plastics products	41,711	25	$23,728	4,437	43	$5,152	6,253	84	$8,583	$37,463
31	Leather and leather products	108	0	$0	0	0	$0	340	11	$1,651	$1,651
32	Stone, clay, and glass products	57,815	23	$21,844	4,123	131	$13,691	1,648	5	$248	$35,783
33	Primary metal industries	100,933	38	$35,257	7,163	270	$27,951	7,061	80	$6,326	$69,534
34	Fabricated metal products	86,562	29	$27,435	8,885	152	$15,766	12,536	93	$8,955	$52,156
35	Industrial machinery and equipment	62,459	43	$40,196	5,501	38	$4,362	8,549	51	$4,156	$48,714
36	Electronic and other electric equipment	59,497	46	$42,968	2,967	99	$11,927	5,419	109	$6,441	$61,337
37	Transportation equipment	148,719	81	$76,217	9,511	125	$14,084	18,614	241	$24,308	$114,609
38	Instruments and related products	34,208	39	$36,953	2,412	17	$2,073	4,737	50	$3,320	$42,345
39	Miscellaneous manufacturing industries	36,285	10	$9,653	10,640	539	$64,860	2,161	22	$1,915	$76,427
40	Railroad transportation	NA	NA	$0	NA	NA	$1,064	NA	NA	$518	$1,581
41	Local and interurban passenger transit	8,327	0	$0	1,086	86	$8,330	168	2	$124	$8,453
42	Trucking and warehousing	43,611	22	$21,069	6,492	326	$39,424	5,832	104	$9,349	$69,843
44	Water transportation	21,707	0	$0	21,490	2,368	$290,046	64	1	$197	$290,243
45	Transportation by air	10,328	10	$9,417	17	0	$0	12,008	225	$11,267	$20,684
46	Pipelines, except natural gas	747	0	$0	237	3	$312	80	1	$58	$369
47	Transportation services	240	0	$0	2	0	$0	8	0	$0	$0
48	Communications	3,229	0	$0	37	0	$0	18	0	$0	$0
49	Electric, gas, and sanitary services	120,711	103	$96,504	7,545	65	$7,532	14,630	249	$15,425	$119,461
50	Wholesale trade--durable goods	75,206	92	$86,246	5,430	52	$6,040	5,217	107	$8,545	$100,831
51	Wholesale trade--nondurable goods	139,508	76	$70,757	16,524	1,788	$164,785	15,428	38	$4,140	$239,682
52	Building materials and garden supplies	46,382	4	$3,347	852	19	$1,842	89	3	$494	$5,683
53	General merchandise stores	2,206	0	$0	1,111	32	$2,935	0	0	$0	$2,935
54	Food stores	5,698	0	$0	854	19	$1,848	0	0	$0	$1,848
55	Automotive dealers and service stations	141,690	20	$18,860	21,635	177	$19,874	17,645	435	$21,720	$60,454
56	Apparel and accessory stores	1,297	0	$0	110	1	$105	1,442	56	$8,561	$8,667
57	Furniture and homefurnishings stores	8,078	0	$0	2,989	71	$7,253	0	0	$0	$7,253
58	Eating and drinking places	0	0	$0	0	0	$0	0	0	$0	$0
59	Miscellaneous retail	9,378	0	$0	349	7	$699	0	0	$0	$699
60	Depository institutions	3,782	0	$0	57	0	$0	0	0	$0	$0
61	Nondepository institutions	545	0	$0	1	0	$0	0	0	$0	$0
62	Security and commodity brokers	508	0	$0	1	0	$0	0	0	$0	$0
63	Insurance carriers	1,835	0	$0	2	0	$0	0	0	$0	$0
64	Insurance agents, brokers, and service	1,357	0	$0	3	0	$0	0	0	$0	$0
65	Real estate	16,139	0	$0	7	0	$0	0	0	$0	$0
67	Holding and other investment offices	766	0	$0	0	0	$0	0	0	$0	$0
70	Hotels and other lodging places	93,949	26	$24,531	21	0	$0	0	0	$0	$24,531
72	Personal services	42,084	20	$18,497	188	0	$0	0	0	$0	$18,497
73	Business services	148,761	40	$37,651	261	0	$0	119	3	$132	$37,783
75	Auto repair, services, and parking	188,241	25	$23,471	28,435	1,308	$141,436	27,832	815	$91,407	$256,314
76	Miscellaneous repair services	47,952	10	$9,293	464	0	$0	4,730	179	$25,988	$35,281
78	Motion pictures	1,752	0	$0	0	0	$0	2	0	$0	$0
79	Amusement and recreation services	25,782	6	$5,592	26	0	$0	0	0	$0	$5,592
80	Health services	825,213	105	$98,238	78,349	8,094	$740,937	1,355	14	$691	$839,865
81	Legal services	6,414	1	$1,363	0	0	$0	3	0	$0	$1,363
82	Educational services	40,347	14	$12,652	226	0	$0	0	0	$0	$12,652
83	Social services	14,809	3	$2,778	129	0	$0	0	0	$0	$2,778
84	Museums, botanical, zoological gardens	5,450	0	$0	4	0	$0	2	0	$0	$0
86	Membership organizations	2,638	0	$0	9	0	$0	0	0	$0	$0
87	Engineering and management services	131,731	32	$29,919	12,085	734	$67,171	1,114	28	$1,399	$98,488
89	Services, n.e.c.	1,643	0	$0	0	0	$0	3	0	$0	$0
	Totals	4,282,731	1,840	$1,723,804	423,531	22,191	$2,277,927	315,672	4,925	$414,245	$4,415,976

Source: OSHA estimates based preliminary results from the 2001 NIOSH-BLS "Survey of Respirator Use and Practices," in press.
[1] Includes employees who use more than one type of respirator. Total may exceed total number of users for respirator class.
[2] Excludes employees using SCBAs exclusively.

BILLING CODE 4510–26–C

In addition to health benefits, OSHA believes other benefits result from the harmonization of APF specifications, thereby making compliance with the respirator rule easier for employers. Employers also benefit from greater administrative ease in proper respirator selection. Employers would no longer have to consult several sources and several OSHA standards to determine the best choice of respirator, but could make their choices based on a single, easily found regulation. Some employers who now hire consultants to aid in choosing the proper respirator should be able to make this choice on their own with the aid of this rule. In addition to having only one set of numbers (i.e., APFs) to assist them with respirator selection for nearly all substances, some employers may be able to streamline their respirator stock by using one respirator class to meet their respirator needs instead of several respirator classes. The increased ease of compliance would also yield additional health benefits to employees using respirators.

Alternatively, these APFs would clarify when employers can safely place employees in respirators that impose less stress on the cardiovascular system (e.g., filtering facepiece respirators). Many of these alternative respirators may have the additional benefit of being less expensive to purchase and operate. As previously discussed, OSHA estimates that over 15,000 employees currently use respirators that fall in this group (i.e., shift to a less expensive respirator).

One commenter (Ex. 9–16) agreed that the standard would have significant benefits, saying:

> 3M concurs with OSHA's conclusion that significant health benefits will accrue to workers as a result of this rulemaking. 3M believes that the majority of these benefits will be the result of simplification of the respirator selection process for employers. This will in turn lead to greater compliance with OSHA's various standards regarding exposure to toxic and harmful substances. * * *
>
> In addition to these benefits from increased compliance, 3M also concurs with OSHA's determination that the simplification and clarification of the APF tables will result in lessening of cardiovascular stress, as well as other potential stresses, because of the ability to select a filtering facepiece respirator.

E. Economic Feasibility

OSHA is required to set standards that are feasible. To demonstrate that a standard is feasible, the courts have held that OSHA must ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry'' (*United Steelworkers of America, AFL–CIO–CLC* v. *Marshall* (the ''Lead'' decision), 647 F.2d 1189 (DC Cir. 1980)).

OSHA conducted its analysis of economic feasibility on an establishment basis. Accordingly, for each affected industry, the Agency compared estimates of per-establishment annualized compliance costs with per-establishment estimates of revenues and per-establishment estimates of profits. It used two worst-case assumptions regarding the ability of employers to pass the costs of compliance through to their customers: The no-cost-pass-through assumption, and the full-cost-pass-through assumption. Based on the results of these comparisons, which define the universe of potential impacts of the APFs, OSHA then assessed the economic feasibility for all affected establishments, i.e., those covered by this rule.

The Agency assumed that establishments falling within the scope of the standard would have the same average sales and profits as other establishments in their industries. OSHA believes this assumption is reasonable because no evidence is available showing that the financial characteristics of those firms with employees who use respirators are different from firms that do not use respirators. In the absence of such evidence, OSHA relied on the best available financial data (those from the Bureau of the Census (Ex. 6–4) and Robert Morris Associates (Ex. 6–5)), used a commonly accepted methodology to calculate industry averages, and based its analysis of the significance of the projected economic impacts and the feasibility of compliance on these data.

The analysis of the potential impacts of this standard on before-tax profits and sales shown in Table V–5 is a ''screening analysis,'' so called because it simply measures costs as a percentage of pre-tax profits and sales under the worst-case assumptions discussed above, but does not predict impacts on these before-tax profits or sales. OSHA used the screening analysis to determine whether the compliance costs potentially associated with the standard could lead to significant impacts on all affected establishments. The actual impact of the standard on the profit and sales of establishments in a specific industry would depend on the price elasticity of demand for the products or services of these establishments.

Table V–5 shows the economic impacts of these costs. For each industry, OSHA constructed the average compliance cost per affected establishment and compared it to average revenues and average profits.[7] These costs are quite small, i.e., less than 0.005 percent of revenues; the one major exception is SIC 44 (Water transportation), for which OSHA estimated the costs impacts to be 0.16 percent of revenues. When the Agency compared average compliance costs with profits, the costs also are small, i.e., less than 0.17 percent; again, the major exception was SIC 44, which had an estimated impact of 2.12 percent of profits.[8] Based on the very small impacts for establishments in all industries shown in Table V–5, OSHA concludes that the APF standard is economically feasible, in the sense of being unlikely to close or alter the competitive structure of the affected industries, for the affected establishments.

BILLING CODE 4510–26–P

[7] OSHA defines ''affected establishment'' as any facility that uses respirators, as represented in the NIOSH–BLS survey data.

[8] For some industries, such as SIC 44, data from the NIOSH–BLS survey were suppressed due to low response rates. In these cases, the Agency, for the purposes of assessing economic feasibility, imputed broader sector-level data from the survey to form an estimate of respirator use. This procedure may result in overestimating the impact of the standard (proposal) in some industries. See the full FEA (Ex. 11) for further details.

Table V-5

Costs as a Percentage of Affected Establishment Revenues and Profits
(Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Establish-ments	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Establishments		Average Compliance Costs to Affected Establishments	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$46,797,618	111,841	$418.4	6.02%	$25,183	7,566	6.8%	$5.78	0.001%	0.02%
08	Forestry	$2,533,391	2,689	$942.1	10.30%	$97,040	261	9.7%	$0.00	0.000%	0.00%
09	Fishing, hunting, and trapping	$2,066,630	2,443	$845.9	5.80%	$49,099	0	0.0%	NA	NA	NA
13	Oil and gas extraction	$118,956,993	17,957	$6,624.5	8.65%	$573,023	1,097	6.1%	$53.14	0.001%	0.01%
15	General building contractors	$354,383,931	197,940	$1,790.4	4.00%	$71,614	19,071	9.6%	$2.79	0.000%	0.00%
16	Heavy construction, except building	$129,200,925	37,918	$3,407.4	4.00%	$136,295	4,718	12.4%	$13.43	0.000%	0.01%
17	Special trade contractors	$351,559,520	433,522	$810.9	4.00%	$32,438	40,823	9.4%	$19.41	0.002%	0.06%
20	Food and kindred products	$488,381,169	22,317	$21,883.8	3.46%	$757,938	3,608	16.2%	$20.45	0.000%	0.00%
21	Tobacco products	$36,626,849	185	$197,983.0	4.02%	$7,953,335	30	16.2%	$4.18	0.000%	0.00%
22	Textile mill products	$81,180,135	6,464	$12,558.8	2.77%	$347,644	720	11.1%	$25.63	0.000%	0.01%
23	Apparel and other textile products	$81,000,847	24,460	$3,311.6	2.56%	$84,716	1,111	4.5%	$0.00	0.000%	0.00%
24	Lumber and wood products	$111,381,076	37,716	$2,953.2	3.90%	$115,143	1,995	5.3%	$12.21	0.000%	0.01%
25	Furniture and fixtures	$61,269,677	12,388	$4,945.9	3.51%	$173,603	2,053	16.6%	$4.84	0.000%	0.00%
26	Paper and allied products	$163,517,039	6,863	$23,825.9	4.50%	$1,072,385	649	9.5%	$55.10	0.000%	0.01%
27	Printing and publishing	$209,740,895	63,986	$3,277.9	3.80%	$124,545	124	0.2%	$0.00	0.000%	0.00%
28	Chemicals and allied products	$406,616,253	13,691	$29,699.5	4.49%	$1,332,353	5,052	36.9%	$66.30	0.000%	0.00%
29	Petroleum and coal products	$178,393,963	2,459	$72,547.4	2.99%	$2,168,714	432	17.6%	$221.09	0.000%	0.01%
30	Rubber and misc. plastics products	$160,224,448	17,343	$9,238.6	4.02%	$371,834	3,140	18.1%	$11.93	0.000%	0.00%
31	Leather and leather products	$10,125,106	1,922	$5,268.0	2.20%	$115,725	14	0.7%	$119.63	0.002%	0.10%
32	Stone, clay, and glass products	$87,857,611	17,167	$5,117.8	4.93%	$252,139	3,109	18.1%	$11.51	0.000%	0.00%
33	Primary metal industries	$189,655,505	6,992	$27,124.6	4.52%	$1,225,408	1,974	28.2%	$35.23	0.000%	0.00%
34	Fabricated metal products	$231,787,815	39,399	$5,883.1	4.55%	$267,453	7,374	18.7%	$7.07	0.000%	0.00%
35	Industrial machinery and equipment	$410,878,326	57,563	$7,137.9	4.05%	$288,782	7,458	13.0%	$6.53	0.000%	0.00%
36	Electronic and other electric equipment	$349,240,947	18,619	$18,757.2	5.59%	$1,048,780	2,731	14.7%	$22.46	0.000%	0.00%
37	Transportation equipment	$522,250,748	13,210	$39,534.5	3.74%	$1,479,823	3,788	28.7%	$30.26	0.000%	0.00%
38	Instruments and related products	$158,693,978	12,385	$12,813.4	5.06%	$648,479	1,282	10.4%	$33.03	0.000%	0.01%
39	Miscellaneous manufacturing industries	$52,171,899	18,711	$2,788.3	3.80%	$106,073	3,140	16.8%	$24.34	0.001%	0.02%
40	Railroad transportation	NA	NA	NA	11.08%	NA	NA	NA	NA	NA	NA
41	Local and interurban passenger transit	$18,741,822	20,067	$934.0	4.51%	$42,101	809	4.0%	$10.45	0.001%	0.02%
42	Trucking and warehousing	$197,132,918	135,874	$1,450.9	3.91%	$56,783	4,090	3.0%	$17.08	0.001%	0.03%
44	Water transportation	$34,059,390	9,392	$3,626.4	7.48%	$271,426	50	0.5%	$5,755.39	0.159%	2.12%
45	Transportation by air	$175,932,797	13,694	$12,847.4	3.62%	$465,132	48	0.4%	$427.74	0.003%	0.09%
46	Pipelines, except natural gas	$7,830,792	971	$8,064.7	6.55%	$528,055	252	25.9%	$1.47	0.000%	0.00%
47	Transportation services	$39,490,484	52,884	$746.7	3.39%	$25,322	8	0.0%	$0.00	0.000%	0.00%
48	Communications	$343,904,510	46,030	$7,471.3	5.58%	$416,833	100	0.2%	$0.00	0.000%	0.00%
49	Electric, gas, and sanitary services	$446,859,099	22,716	$19,671.6	10.37%	$2,040,874	5,085	22.4%	$23.49	0.000%	0.00%
50	Wholesale trade--durable goods	$2,290,609,326	341,942	$6,698.8	2.54%	$170,449	18,854	5.5%	$5.35	0.000%	0.00%
51	Wholesale trade--nondurable goods	$1,931,943,829	189,025	$10,220.6	4.46%	$456,162	8,573	4.5%	$27.96	0.000%	0.01%
52	Building materials and garden supplies	$152,492,069	70,064	$2,176.5	2.37%	$51,621	2,386	3.4%	$2.38	0.000%	0.00%
53	General merchandise stores	$334,801,710	36,481	$9,177.4	2.70%	$248,028	687	1.9%	$4.27	0.000%	0.00%
54	Food stores	$424,619,077	179,120	$2,370.6	1.41%	$33,443	2,394	1.3%	$0.77	0.000%	0.00%
55	Automotive dealers and service stations	$787,955,460	202,525	$3,890.7	1.45%	$56,246	10,243	5.1%	$5.90	0.000%	0.01%
56	Apparel and accessory stores	$117,838,184	126,658	$930.4	1.85%	$17,181	308	0.2%	$28.16	0.003%	0.16%
57	Furniture and homefurnishings stores	$138,532,297	117,939	$1,174.6	2.28%	$26,812	2,769	2.3%	$2.62	0.000%	0.01%
58	Eating and drinking places	$249,718,654	484,719	$515.2	3.00%	$15,447	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$372,192,817	374,786	$993.1	2.49%	$24,711	978	0.3%	$0.71	0.000%	0.00%
60	Depository institutions	$626,235,388	115,268	$5,432.9	10.80%	$586,749	1,372	1.2%	$0.00	0.000%	0.00%
61	Nondepository institutions	$208,902,233	53,365	$3,914.6	15.05%	$589,102	299	0.6%	$0.00	0.000%	0.00%
62	Security and commodity brokers	$267,894,402	50,032	$5,354.5	13.32%	$712,970	278	0.6%	$0.00	0.000%	0.00%
63	Insurance carriers	$977,328,464	41,776	$23,394.5	6.82%	$1,596,288	442	1.1%	$0.00	0.000%	0.00%
64	Insurance agents, brokers, and service	$76,085,799	132,265	$575.3	6.83%	$39,261	744	0.6%	$0.00	0.000%	0.00%
65	Real estate	$191,986,451	257,248	$746.3	13.31%	$99,329	1,541	0.6%	$0.00	0.000%	0.00%
67	Holding and other investment offices	$119,637,007	28,175	$4,246.2	24.01%	$1,019,487	157	0.6%	$0.00	0.000%	0.00%
70	Hotels and other lodging places	$103,075,607	59,897	$1,720.9	6.96%	$119,782	1,326	2.2%	$18.50	0.001%	0.02%
72	Personal services	$53,965,771	208,546	$258.8	5.86%	$15,151	9,743	4.7%	$1.90	0.001%	0.01%
73	Business services	$538,701,000	410,246	$1,313.1	4.79%	$62,857	13,517	3.3%	$2.80	0.000%	0.00%
75	Auto repair, services, and parking	$102,979,805	194,877	$528.4	4.39%	$23,214	32,113	16.5%	$7.98	0.002%	0.03%
76	Miscellaneous repair services	$39,030,526	68,439	$570.3	5.44%	$31,000	3,375	4.9%	$10.45	0.002%	0.03%
78	Motion pictures	$72,351,766	46,844	$1,544.5	5.14%	$79,355	17	0.0%	$0.00	0.000%	0.00%
79	Amusement and recreation services	$94,816,288	99,642	$951.6	4.28%	$40,728	1,612	1.6%	$3.47	0.000%	0.01%
80	Health services	$824,840,187	505,878	$1,630.5	6.17%	$100,610	16,486	3.3%	$50.94	0.003%	0.05%
81	Legal services	$124,335,948	170,271	$730.2	17.50%	$127,789	61	0.0%	$22.44	0.003%	0.02%
82	Educational services	$136,669,596	50,146	$2,725.4	8.14%	$221,895	564	1.1%	$22.44	0.001%	0.01%
83	Social services	$95,229,314	165,519	$575.3	4.44%	$25,535	6,668	4.0%	$0.42	0.000%	0.00%
84	Museums, botanical, zoological gardens	$6,636,189	5,466	$1,214.1	21.45%	$260,421	235	4.3%	$0.00	0.000%	0.00%
86	Membership organizations	$111,881,925	249,022	$449.3	7.21%	$32,400	533	0.2%	$0.00	0.000%	0.00%
87	Engineering and management services	$332,197,903	301,160	$1,103.1	6.39%	$70,494	10,292	3.4%	$9.57	0.001%	0.01%
89	Services, n.e.c.	$20,335,429	17,650	$1,152.1	6.80%	$78,346	6	0.0%	$0.00	0.000%	0.00%
	Totals	$18,186,265,527	6,854,769	$2,653.1	NA	NA	282,334	4.1%	$15.64	0.001%	0.01%

Source: OSHA Office of Regulatory Analysis. See full FEA (Ex. 11).

BILLING CODE 4510–26–C

F. Economic Impacts to Small Entities

OSHA also estimated the economic impacts of the rule on affected entities with fewer than 20 employees, and for affected small entities as defined by the Small Business Administration (SBA). Table V–6 shows the estimated economic impacts for small entities with fewer than 20 employees: average compliance costs by industry are less than 0.005 percent of average revenues, and less than 0.19 percent of profits, in all industries. Table V–7 presents the economic impacts for small entities as a whole, as defined by SBA. For these firms, average compliance costs are less than 0.005 percent of average revenues and less than 0.03 percent of average profits. Thus, the Agency projects no significant impacts from the rule on small entities.

BILLING CODE 4510–26–P

Table V-6

Costs as a Percentage of Revenues and Profits for Affected Small Entities with Fewer than 20 Employees
(Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$28,456,904	105,590	$269.5	6.02%	$16,220	6,562	6.2%	$0.09	0.000%	0.00%
08	Forestry	$1,005,916	2,431	$413.8	10.30%	$42,627	231	9.5%	$0.00	0.000%	0.00%
09	Fishing, hunting, and trapping	$934,691	2,325	$402.0	5.80%	$23,333	0	0.0%	NA	NA	NA
13	Oil and gas extraction	$9,568,821	14,566	$656.9	8.65%	$56,826	680	4.7%	$0.86	0.000%	0.00%
15	General building contractors	$140,742,413	185,921	$757.0	4.00%	$30,280	17,671	9.5%	$1.06	0.000%	0.00%
16	Heavy construction, except building	$25,680,517	29,472	$871.4	4.00%	$34,854	2,561	8.7%	$0.19	0.000%	0.00%
17	Special trade contractors	$156,222,049	395,675	$394.8	4.00%	$15,793	35,056	8.9%	$4.08	0.001%	0.03%
20	Food and kindred products	$13,034,058	11,890	$1,096.2	3.46%	$37,968	552	4.6%	$7.84	0.001%	0.02%
21	Tobacco products	$36,982	60	$616.4	4.02%	$24,761	6	10.6%	$0.00	0.000%	0.00%
22	Textile mill products	$2,804,537	3,128	$896.6	2.77%	$24,820	99	3.2%	$0.00	0.000%	0.00%
23	Apparel and other textile products	$7,444,651	16,288	$457.1	2.56%	$11,693	260	1.6%	$0.00	0.000%	0.00%
24	Lumber and wood products	$15,544,934	29,861	$520.6	3.90%	$20,297	437	1.5%	$2.19	0.000%	0.01%
25	Furniture and fixtures	$4,131,575	8,262	$500.1	3.51%	$17,553	410	5.0%	$2.40	0.000%	0.01%
26	Paper and allied products	$2,406,977	2,152	$1,118.7	4.50%	$50,350	48	2.2%	$0.00	0.000%	0.00%
27	Printing and publishing	$22,196,893	49,512	$448.3	3.80%	$17,034	27	0.1%	$0.00	0.000%	0.00%
28	Chemicals and allied products	$8,762,403	7,118	$1,231.0	4.49%	$55,226	2,040	28.7%	$5.44	0.000%	0.01%
29	Petroleum and coal products	$2,213,850	1,455	$1,521.1	2.99%	$45,472	206	14.2%	$4.80	0.000%	0.01%
30	Rubber and misc. plastics products	$7,183,667	8,170	$879.2	4.02%	$35,388	417	5.1%	$6.22	0.001%	0.02%
31	Leather and leather products	$570,806	1,252	$456.0	2.20%	$10,016	3	0.2%	$0.00	0.000%	0.00%
32	Stone, clay, and glass products	$6,351,359	11,248	$564.7	4.93%	$27,819	718	6.4%	$0.00	0.000%	0.00%
33	Primary metal industries	$2,848,236	2,792	$1,020.3	4.52%	$46,094	301	10.8%	$0.00	0.000%	0.00%
34	Fabricated metal products	$17,077,020	23,326	$732.1	4.55%	$33,282	3,541	15.2%	$0.90	0.000%	0.00%
35	Industrial machinery and equipment	$24,064,335	41,000	$586.9	4.05%	$23,746	4,295	10.5%	$1.38	0.000%	0.01%
36	Electronic and other electric equipment	$8,356,375	9,477	$881.7	5.59%	$49,300	1,185	12.5%	$1.45	0.000%	0.00%
37	Transportation equipment	$5,835,684	7,977	$731.6	3.74%	$27,384	2,087	26.2%	$3.44	0.000%	0.01%
38	Instruments and related products	$5,684,460	7,528	$755.1	5.06%	$38,215	644	8.6%	$3.48	0.000%	0.01%
39	Miscellaneous manufacturing industries	$6,908,160	14,733	$468.9	3.80%	$17,838	1,995	13.5%	$2.77	0.001%	0.02%
40	Railroad transportation	NA	NA	NA	11.08%	NA	NA	NA	NA	NA	NA
41	Local and interurban passenger transit	$3,052,031	14,602	$209.0	4.51%	$9,422	620	4.2%	$0.45	0.000%	0.00%
42	Trucking and warehousing	$42,301,497	115,943	$364.8	3.91%	$14,279	3,662	3.2%	$1.54	0.000%	0.01%
44	Water transportation	$4,501,041	7,826	$575.1	7.48%	$43,045	45	0.6%	$3.61	0.001%	0.01%
45	Transportation by air	$3,397,447	9,026	$376.4	3.62%	$13,628	35	0.4%	$0.00	0.000%	0.00%
46	Pipelines, except natural gas	$64,316	719	$89.4	6.55%	$5,853	123	17.2%	$0.47	0.001%	0.01%
47	Transportation services	$12,815,924	47,586	$269.3	3.39%	$9,133	7	0.0%	$0.00	0.000%	0.00%
48	Communications	$9,283,329	32,887	$282.3	5.58%	$15,749	60	0.2%	$0.00	0.000%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	15,676	$690.5	10.37%	$71,638	2,341	14.9%	$2.01	0.000%	0.00%
50	Wholesale trade–durable goods	$467,174,837	288,051	$1,621.8	2.54%	$41,267	10,893	3.8%	$0.74	0.000%	0.00%
51	Wholesale trade–nondurable goods	$321,562,895	154,839	$2,076.8	4.46%	$92,689	4,841	3.1%	$2.09	0.000%	0.00%
52	Building materials and garden supplies	$37,776,200	59,221	$637.9	2.37%	$15,129	1,927	3.3%	$0.00	0.000%	0.00%
53	General merchandise stores	$3,346,901	20,202	$165.7	2.70%	$4,477	114	0.6%	$0.00	0.000%	0.00%
54	Food stores	$57,468,235	141,437	$406.3	1.41%	$5,732	559	0.4%	$0.00	0.000%	0.00%
55	Automotive dealers and service stations	$149,337,410	171,823	$869.1	1.45%	$12,565	7,528	4.4%	$0.56	0.000%	0.00%
56	Apparel and accessory stores	$18,706,435	110,314	$169.6	1.85%	$3,132	79	0.1%	$0.00	0.000%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	105,329	$431.0	2.28%	$9,837	2,218	2.1%	$0.00	0.000%	0.00%
58	Eating and drinking places	$61,841,796	345,818	$178.8	3.00%	$5,362	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$119,265,615	333,875	$357.2	2.49%	$8,889	578	0.2%	$0.00	0.000%	0.00%
60	Depository institutions	$15,538,559	87,085	$178.4	10.80%	$19,270	988	1.1%	$0.00	0.000%	0.00%
61	Nondepository institutions	$13,454,697	46,988	$286.3	15.05%	$43,092	229	0.5%	$0.00	0.000%	0.00%
62	Security and commodity brokers	$19,644,662	42,577	$461.4	13.32%	$61,437	218	0.5%	$0.00	0.000%	0.00%
63	Insurance carriers	$9,416,333	31,420	$299.7	6.82%	$20,449	347	1.1%	$0.00	0.000%	0.00%
64	Insurance agents, brokers, and service	$33,660,359	123,996	$271.5	6.83%	$18,527	580	0.5%	$0.00	0.000%	0.00%
65	Real estate	$108,609,341	241,034	$450.6	13.31%	$59,972	1,139	0.5%	$0.00	0.000%	0.00%
67	Holding and other investment offices	$35,174,755	25,563	$1,376.0	24.01%	$330,365	125	0.5%	$0.00	0.000%	0.00%
70	Hotels and other lodging places	$12,241,793	44,739	$273.6	6.96%	$19,046	872	1.9%	$0.68	0.000%	0.00%
72	Personal services	$27,470,741	193,520	$142.0	5.86%	$8,311	8,203	4.2%	$0.20	0.000%	0.00%
73	Business services	$108,448,938	341,046	$318.0	4.79%	$15,222	8,479	2.5%	$0.67	0.000%	0.00%
75	Auto repair, services, and parking	$52,027,411	183,534	$283.5	4.39%	$12,453	26,179	14.3%	$0.88	0.000%	0.01%
76	Miscellaneous repair services	$18,035,716	63,732	$283.0	5.44%	$15,383	2,762	4.3%	$6.96	0.002%	0.05%
78	Motion pictures	$13,026,870	41,250	$315.8	5.14%	$16,226	10	0.0%	$0.00	0.000%	0.00%
79	Amusement and recreation services	$26,704,545	82,535	$323.6	4.28%	$13,848	1,206	1.5%	$0.00	0.000%	0.00%
80	Health services	$167,087,490	433,861	$385.1	6.17%	$23,764	12,768	2.9%	$0.19	0.000%	0.00%
81	Legal services	$54,265,197	160,755	$337.6	17.50%	$59,074	42	0.0%	$0.00	0.000%	0.00%
82	Educational services	$8,902,333	35,222	$252.7	8.14%	$20,578	421	1.2%	$0.00	0.000%	0.00%
83	Social services	$22,228,579	133,954	$165.9	4.44%	$7,365	4,955	3.7%	$0.10	0.000%	0.00%
84	Museums, botanical, zoological gardens	$1,283,445	4,594	$279.4	21.45%	$59,921	175	3.8%	$0.00	0.000%	0.00%
86	Membership organizations	$43,669,772	224,283	$194.7	7.21%	$14,041	400	0.2%	$0.00	0.000%	0.00%
87	Engineering and management services	$90,405,763	271,244	$333.3	6.39%	$21,300	6,602	2.4%	$0.17	0.000%	0.00%
89	Services, n.e.c.	$5,728,501	16,488	$347.4	6.80%	$23,625	3	0.0%	$0.00	0.000%	0.00%
	Totals	$2,781,206,926	5,797,803	$479.7	NA	NA	194,364	3.4%	$1.53	0.000%	0.01%

Source: OSHA Office of Regulatory Analysis. See full FEA (Ex.11).

Table V-7

Costs as a Percentage of Revenues and Profits for all Affected Small Entities*
(Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	SBA Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$38,501,047	109,663	$351.1	6.02%	$21,130	6,718	6.1%	$0.13	0.000%	0.00%
08	Forestry	$1,496,747	2,400	$623.6	10.30%	$64,235	233	9.7%	$0.00	0.000%	0.00%
09	Fishing, hunting, and trapping	NA	NA	NA	5.80%	NA	NA	NA	NA	NA	NA
13	Oil and gas extraction	$29,931,841	14,787	$2,024.2	8.65%	$175,093	890	6.0%	$18.51	0.001%	0.01%
15	General building contractors	$234,203,450	195,315	$1,199.1	4.00%	$47,964	17,540	9.0%	$1.11	0.000%	0.00%
16	Heavy construction, except building	$68,664,092	35,618	$1,927.8	4.00%	$77,112	3,314	9.3%	$3.43	0.000%	0.00%
17	Special trade contractors	$270,401,924	426,477	$634.0	4.00%	$25,361	34,756	8.1%	$15.53	0.002%	0.06%
20	Food and kindred products	$104,629,113	15,992	$6,542.6	3.46%	$226,600	1,781	11.1%	$8.03	0.000%	0.00%
21	Tobacco products	$1,255,255	91	$13,794.0	4.02%	$554,130	10	11.1%	$0.00	0.000%	0.00%
22	Textile mill products	$20,377,246	4,845	$4,205.8	2.77%	$116,423	458	9.4%	$2.71	0.000%	0.00%
23	Apparel and other textile products	$38,507,048	22,383	$1,720.4	2.56%	$44,010	841	3.8%	$0.00	0.000%	0.00%
24	Lumber and wood products	$58,343,756	35,076	$1,663.4	3.90%	$64,854	1,278	3.6%	$2.08	0.000%	0.00%
25	Furniture and fixtures	$26,295,821	11,217	$2,344.3	3.51%	$82,285	1,540	13.7%	$1.88	0.000%	0.00%
26	Paper and allied products	$31,334,277	4,057	$7,723.5	4.50%	$347,629	249	6.1%	$7.33	0.000%	0.00%
27	Printing and publishing	$85,620,541	57,018	$1,501.6	3.80%	$57,055	91	0.2%	$0.00	0.000%	0.00%
28	Chemicals and allied products	$59,010,014	8,227	$7,172.7	4.49%	$321,776	1,955	23.8%	$52.28	0.001%	0.02%
29	Petroleum and coal products	$13,950,653	1,047	$13,324.4	2.99%	$398,317	118	11.3%	$52.22	0.000%	0.01%
30	Rubber and misc. plastics products	$58,709,872	13,043	$4,501.3	4.02%	$181,167	1,627	12.5%	$5.14	0.000%	0.00%
31	Leather and leather products	$4,003,751	1,675	$2,390.3	2.20%	$52,509	184	11.0%	$4.34	0.000%	0.01%
32	Stone, clay, and glass products	$34,254,470	11,791	$2,905.1	4.93%	$143,127	1,393	11.8%	$14.13	0.000%	0.01%
33	Primary metal industries	$36,511,582	4,806	$7,597.1	4.52%	$343,213	1,023	21.3%	$18.88	0.000%	0.01%
34	Fabricated metal products	$113,752,781	34,250	$3,321.2	4.55%	$150,988	4,015	11.7%	$3.26	0.000%	0.00%
35	Industrial machinery and equipment	$127,178,710	52,548	$2,420.2	4.05%	$97,917	4,176	7.9%	$3.48	0.000%	0.00%
36	Electronic and other electric equipment	$69,499,940	14,355	$4,841.5	5.59%	$270,705	1,292	9.0%	$5.67	0.000%	0.00%
37	Transportation equipment	$41,544,504	10,653	$3,899.8	3.74%	$145,974	1,984	18.6%	$10.84	0.000%	0.01%
38	Instruments and related products	$33,908,725	10,190	$3,327.6	5.06%	$168,410	787	7.7%	$8.93	0.000%	0.01%
39	Miscellaneous manufacturing industries	$30,627,905	17,837	$1,717.1	3.80%	$65,322	2,267	12.7%	$12.90	0.001%	0.02%
40	Railroad transportation	NA	NA	NA	11.08%	NA	NA	NA	NA	NA	NA
41	Local and interurban passenger transit	$7,690,615	16,537	$465.1	4.51%	$20,964	540	3.3%	$1.40	0.000%	0.01%
42	Trucking and warehousing	$79,888,400	114,623	$697.0	3.91%	$27,278	3,166	2.8%	$2.64	0.000%	0.01%
44	Water transportation	$14,075,608	8,051	$1,748.3	7.48%	$130,855	46	0.6%	$3.73	0.000%	0.00%
45	Transportation by air	$15,156,218	6,386	$2,373.4	3.62%	$85,925	22	0.3%	$0.00	0.000%	0.00%
46	Pipelines, except natural gas	$986,979	39	$25,307.2	6.55%	$1,657,050	5	13.9%	$0.43	0.000%	0.00%
47	Transportation services	$19,513,397	40,529	$481.5	3.39%	$16,327	6	0.0%	$0.00	0.000%	0.00%
48	Communications	$41,125,079	17,482	$2,352.4	5.58%	$131,244	28	0.2%	$0.00	0.000%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	8,938	$1,211.0	10.37%	$125,641	1,323	14.8%	$1.69	0.000%	0.00%
50	Wholesale trade--durable goods	$837,107,306	258,492	$3,238.4	2.54%	$82,401	9,740	3.8%	$7.55	0.000%	0.01%
51	Wholesale trade--nondurable goods	$637,454,650	143,751	$4,434.4	4.46%	$197,917	4,455	3.1%	$41.68	0.001%	0.02%
52	Building materials and garden supplies	$37,776,200	46,450	$813.3	2.37%	$19,289	1,368	2.9%	$0.00	0.000%	0.00%
53	General merchandise stores	$3,346,901	8,796	$380.5	2.70%	$10,283	85	1.0%	$0.00	0.000%	0.00%
54	Food stores	$101,566,550	123,572	$821.9	1.41%	$11,595	852	0.7%	$0.00	0.000%	0.00%
55	Automotive dealers and service stations	$149,337,410	116,015	$1,287.2	1.45%	$18,609	5,043	4.3%	$0.61	0.000%	0.00%
56	Apparel and accessory stores	$18,706,435	50,308	$371.8	1.85%	$6,867	63	0.1%	$0.00	0.000%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	78,842	$575.7	2.28%	$13,142	1,494	1.9%	$0.00	0.000%	0.00%
58	Eating and drinking places	$128,561,814	355,297	$361.8	3.00%	$10,850	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$119,265,615	258,538	$461.3	2.49%	$11,479	488	0.2%	$0.00	0.000%	0.00%
60	Depository institutions	$15,538,559	14,378	$1,080.7	10.80%	$116,718	186	1.3%	$0.00	0.000%	0.00%
61	Nondepository institutions	$13,454,697	21,262	$632.8	15.05%	$95,230	117	0.6%	$0.00	0.000%	0.00%
62	Security and commodity brokers	$19,644,662	27,262	$720.6	13.32%	$95,949	157	0.6%	$0.00	0.000%	0.00%
63	Insurance carriers	$5,850,805	4,967	$1,177.9	6.82%	$80,375	73	1.5%	$0.00	0.000%	0.00%
64	Insurance agents, brokers, and service	$47,083,678	119,907	$392.7	6.83%	$26,800	616	0.5%	$0.00	0.000%	0.00%
65	Real estate	$142,479,284	230,304	$618.7	13.31%	$82,340	1,139	0.5%	$0.00	0.000%	0.00%
67	Holding and other investment offices	$35,174,755	21,022	$1,673.2	24.01%	$401,733	116	0.6%	$0.00	0.000%	0.00%
70	Hotels and other lodging places	$24,876,889	47,698	$521.5	6.96%	$36,302	1,070	2.2%	$0.84	0.000%	0.00%
72	Personal services	$36,957,629	176,477	$209.4	5.86%	$12,262	7,222	4.1%	$0.30	0.000%	0.00%
73	Business services	$188,061,601	337,126	$557.8	4.79%	$26,703	9,637	2.9%	$0.84	0.000%	0.00%
75	Auto repair, services, and parking	$66,003,052	167,057	$395.1	4.39%	$17,356	22,771	13.6%	$0.99	0.000%	0.01%
76	Miscellaneous repair services	$25,861,556	63,328	$408.4	5.44%	$22,198	2,756	4.4%	$6.67	0.002%	0.03%
78	Motion pictures	$13,026,870	29,959	$434.8	5.14%	$22,341	9	0.0%	$0.00	0.000%	0.00%
79	Amusement and recreation services	$47,922,810	90,742	$528.1	4.28%	$22,604	1,231	1.4%	$0.00	0.000%	0.00%
80	Health services	$243,370,668	413,561	$588.5	6.17%	$36,312	11,837	2.9%	$0.18	0.000%	0.00%
81	Legal services	$54,265,197	156,877	$345.9	17.50%	$60,534	47	0.0%	$0.00	0.000%	0.00%
82	Educational services	$25,677,552	40,592	$632.6	8.14%	$51,502	398	1.0%	$0.00	0.000%	0.00%
83	Social services	$50,553,841	117,544	$430.1	4.44%	$19,088	3,960	3.4%	$0.16	0.000%	0.00%
84	Museums, botanical, zoological gardens	$2,928,264	4,912	$596.1	21.45%	$127,873	186	3.8%	$0.00	0.000%	0.00%
86	Membership organizations	$78,452,141	242,081	$324.1	7.21%	$23,371	429	0.2%	$0.00	0.000%	0.00%
87	Engineering and management services	$151,671,072	271,169	$559.3	6.39%	$35,745	8,091	3.0%	$2.93	0.001%	0.01%
89	Services, n.e.c.	$8,169,059	16,395	$498.3	6.80%	$33,882	4	0.0%	$0.00	0.000%	0.00%
	Totals	$5,197,315,827	5,382,627	$965.6	4.67%	$45,139	191,294	3.6%	$6.40	0.001%	0.01%

BILLING CODE 4510–26–C

When costs exceed one percent of revenues or five percent of profits, OSHA considers the impact on small entities significant for the purposes of complying with the RFA. For all classes of affected small entities, the Agency found that the costs were less than one percent of revenues and five percent of profits. Therefore, OSHA certifies that this regulation would not have a significant impact on a substantial number of small entities.

VI. Summary and Explanation of the Final Standard

This section of the preamble provides a summary and explanation of each revision made to OSHA's Respiratory Protection Standard involving APFs.

A. Definition of Assigned Protection Factor

As part of its 1994 proposed rulemaking for the Respiratory Protection Standard, OSHA proposed a definition for APFs that read as follows: ''[T]he number assigned by NIOSH [the National Institute for Occupational Safety and Health] to indicate the capability of a respirator to afford a certain degree of protection in terms of fit and filter/cartridge penetration'' (59 FR 58938). OSHA proposed this definition on the assumption that NIOSH would develop APFs for the various respirator classes, building on the APFs in the 1987 NIOSH RDL (59 FR 58901–58903). However, NIOSH subsequently decided not to publish a list of APFs as part of its 42 CFR 84 Respirator Certification Standards (60 FR 30338), and reserved APFs for a future NIOSH rulemaking.

During his opening statement on June 15, 1995, at an OSHA-sponsored expert-panel discussion on APFs, Adam Finkel, then Director of the Agency's Directorate of Health Standards Programs, noted that OSHA would explore developing its own list of APFs (H–049, Ex. 707–X). The Agency then announced in the preamble to the final Respiratory Protection Standard (63 FR 1182) that it would propose an APF table ''based on a thorough review and analysis of all relevant evidence'' in a subsequent rulemaking. In the final Respiratory Protection Standard, OSHA reserved space for a table for APFs, a paragraph ((d)(3)(i)(A)) for APF requirements, and a definition of APF under paragraph (b).

In its 1987 RDL, NIOSH defined an APF as ''[t]he minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users'' (Ex. 1–54–437Q). ANSI subsequently developed a definition for an APF in its Z88.2–1992 Respiratory Protection Standard that reads, ''The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to properly fitted and trained users'' (Ex. 1–50). The ANSI Z88.2 subcommittee that developed the 1992 standard used the NIOSH definition of an APF as a template for its APF definition. However, the Z88.2 subcommittee revised the phrase ''minimum anticipated protection'' in the NIOSH definition to ''expected workplace level of respiratory protection.'' It also removed the NIOSH phrase ''to a given percentage'' from its definition.

The phrase ''a given percentage'' implies that some respirator users will not achieve the full APF under workplace conditions. The ''given percentage'' usually is about five percent, which is a percentage derived from statistical analyses of results from WPF studies. In this regard, five percent represents the 5th percentile of the geometric distribution of individual protection factors in a WPF study. Therefore, the 5th percentile is the threshold for specifying the APF for the respirator tested under those workplace conditions. Using the 5th percentile means that about five percent of the employees who use the respirator under these workplace conditions may not achieve the level of protection assigned to the respirator (or class of respirators), even after they receive proper fit testing and use the respirator correctly under a comprehensive respiratory protection program. However, ANSI dropped the phrase ''to a given percentage'' to reduce confusion (i.e., the phrase did not specify a percentage), and to emphasize the level of protection needed by the vast majority of employees who use respirators in the workplace. See also subsection E.4 (''Analysis of Updated Database on APRs'') of Section III (''Methodology for Developing APFs for Respirators'') of this preamble.

The Agency's review of the available data on respirator performance, as well as findings from surveys of personal protective equipment (Exs. 6–1 and 6–2), indicate that existing APF definitions are confusing to the respirator-using public. Accordingly, OSHA has developed its own definition in this final rule that will reduce confusion among employers and employees regarding APFs, thereby assisting employers in providing their employees with effective respirator protection, consistent with its Respiratory Protection Standard.

The major revision the Agency made to the ANSI APF definition in developing the proposed APF definition included adding the phrase ''when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134.'' The Agency added this phrase to emphasize the already existing requirement that employers must select a respirator in the context of a comprehensive respiratory protection program. Also, the Agency revised the phrase ''as specified by 29 CFR 1910.134'' at the end of the proposed APF definition to read ''as specified by this section'' to conform to style conventions for referencing an entire standard. Therefore, the Agency is adopting the APF definition that was proposed in the NPRM except for this minor revision. OSHA's final definition for APF reads as follows:

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

B. APF Provisions

1. Paragraph (d)(3)(i)(A)—APF Provisions

Paragraph (d)(3)(i)(A) is the provision in OSHA's Respiratory Protection Standard that requires employers to use the APFs in Table 1 of this final standard to select respirators. The language of the final provision is the same as the language in the proposal. Therefore, paragraph (d)(3)(i)(A) in the final rule reads as follows:

(A) *Assigned Protection Factors (APFs).* Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

The proposed language in paragraph (d)(3)(i)(A) also contained the following note that addressed two issues related to APFs:

Note to paragraph (d)(3)(i)(A): The assigned protection factors listed in Table 1 are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance and use requirements. These assigned protection factors do not apply to respirators used solely for escape.

The first sentence of the note was proposed to remind employers that the APFs in Table 1 are effective only when they have a complete respirator program that meets the requirements of OSHA's Respiratory Protection Standard. Table 1 of the final rule already contains a note (footnote 2) that essentially repeats this language. Therefore, to avoid unnecessary duplication, the Agency decided to remove this language for the final rule. However, the Agency is retaining the last part of the note as a footnote in Table 1 of the final rule (see discussion of footnote 5 in the following subsection).

2. Table 1—APF Table

The NPRM contained Table 1 (''Assigned Protection Factors''), which listed the APFs for the various respirator classes. The final APFs for these respirators are discussed in detail in subsection C (''Assigned Protection Factors for Specific Respirator Types'') of this section.

The proposed APF Table also contained a set of footnotes that informed users regarding the application of APFs in the table. In the final rule, footnote 1 remains essentially unchanged from the proposal. Footnote 2 has been clarified to explain when APFs are effective, rather than when APFs apply. All employers who use respirators need to comply with the Respiratory Protection Standard. The language in footnote 3 of the proposed table was revised from the proposal. Proposed footnote 3 stated ''This APF category includes quarter masks, filtering facepieces, and half-masks.'' The reference to quarter masks has been removed from this footnote since quarter mask respirators have been assigned a separate APF in Table 1. Also, the phrase ''with elastomeric facepieces'' has been added to the description of half masks to clarify that elastomeric facepieces are included in the half mask respirator class. Final footnote 3 reads as follows in the final rule: ''This APF category includes filtering facepieces, and half masks with elastomeric facepieces.''

Footnote 4 relates to the testing of PAPRs with helmets or hoods to demonstrate that these respirators can perform at the required APF of 1,000 or greater for this class. The proposed footnote and the changes made to it in the final standard are discussed in subsection C (''Assigned Protection Factors for Specific Respirator Types'') in item 4 (''APF for Powered Air-Purifying Respirators (PAPRs)'') of this section.

Footnote 5 in the proposal described limitations for the APF of 10,000 (maximum) for pressure-demand SCBAs. The proposed footnote 5 described an SWPF study demonstrating that, when test subjects used pressure-demand SCBAs under high work rates, a few of the study results indicated that the respirators may not achieve an APF of 10,000. Consequently, the proposed footnote cautioned employers not to use these respirators under conditions that would require protection above this level. In discussing this footnote in the proposal, OSHA stated that, ''the employer must restrict [pressure-demand SCBA] use to conditions in which the required level of employee protection is at or below an APF of 10,000'' (68 FR 34105). While the Agency received no comments on the proposed footnote, it believes that, when employers use these respirators, they must assess the exposure conditions prior to such use as required by paragraph (d)(1)(iii) of OSHA's Respiratory Protection Standard. In view of the already existing requirement, the Agency decided that the information in proposed footnote 5 was unnecessary, and, therefore, removed it from the final rule.

As noted previously under subsection B (''Paragraph (d)(3)(i)(A)—APF Provisions'') of this section, OSHA is adding a new footnote 5 to Table 1 in the final rule. The new footnote will remind employers that they cannot apply the APFs specified in Table 1 to emergency-escape conditions. OSHA believes this footnote is important because precise exposures levels, which serve as the basis for determining APFs, cannot be assessed accurately for emergency-escape conditions. Under these conditions, the only appropriate respirators for employee use are respirators designated for escape (i.e., escape respirators), consistent with the requirements specified by OSHA's Respiratory Protection Standard at 29 CFR 1910.134(d)(2)(ii). New footnote 5 is similar to the APF provisions of the Agency's substance-specific standards that designate appropriate respirators for use under emergency-escape conditions. Because both the substance-specific standards and 29 CFR 1910.134(d)(2)(ii) contain requirements for selecting escape respirators, the Agency is revising the note slightly to ensure that employers refer to the appropriate provisions. Therefore, footnote 5 to Table 1 in the final rule will read as follows:

> These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR part 1910 subpart Z, employers must refer to the appropriate substance-specific standard in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134(d)(2)(ii).

C. Assigned Protection Factors for Specific Respirator Types

OSHA received comments on APFs during the public comment period following publication of the NPRM, and at the public hearing. These comments and hearing testimony are addressed in the following sections.

1. APF for Quarter Mask Air-Purifying Respirators

Introduction. OSHA proposed an APF of 10 for quarter mask air-purifying respirators (i.e., quarter masks/quarter mask respirators), including them in the same category as filtering facepieces and half mask air-purifying respirators (68 FR 43115). However, the Agency specifically requested comment on whether this action was appropriate (see 68 FR 34112).

The following recommendations include all of the issues raised by commenters regarding quarter mask respirators: assign them an APF of 10; assign them an APF of 5; prohibit their use altogether; or refrain from assigning an APF to them until more studies become available. In general, those commenters who recommended an APF of 10 for quarter mask respirators based their recommendations on the analogous structural characteristics (i.e., similarities in design) of quarter mask and half mask respirators. Commenters who recommended an APF of 5 pointed out that the only available APF data for quarter mask respirators were in the 1976 study by Edwin C. Hyatt entitled ''Respiratory Protection Factors'' (i.e., the ''Hyatt Study'' (Ex. 2)). Based on this study, Hyatt assigned quarter masks an APF of 5.

Comments regarding quarter mask respirators. The commenters who advised OSHA to give quarter mask respirators an APF of 10 believed that when these respirators are used in a workplace where the employer has implemented a complete respirator program as required by 29 CFR 1910.134, their performance should be the same as that of half mask respirators. For example, Thomas Nelson of Nelson Industrial Hygiene Systems, Inc. testified,

> There is no unique property of a quarter mask respirator that makes it[s] use different from half facepiece respirators provided the person using the respirator is trained, fitted and maintains the respirator. OSHA should include quarter masks in the half facepiece category. (Ex. 10–17.)

Michael Runge of 3M Corporation recommended that both half mask and quarter mask respirators should receive an APF of 10 because of their similarity in performance, which he described as follows:

> [L]eakage into a respirator can occur through three pathways[:] defects, filter penetration or faceseal leakage. Leakage through defects is controlled by the respirator maintenance program. Quarter facepiece respirators are no harder to maintain than half facepiece respirators; they have many of the same parts * * * Filter leakage is controlled by the NIOSH certification process * * * Faceseal leakage is controlled through fit testing. The same fit tests can be used with either type of respirator, hence the same maximum face seal leakage would be expected for the quarter and half facepiece respirator. (See Ex. 9–16.)

Daniel Shipp and Janice Bradley of the International Safety Equipment Association and Kenneth V. Bobetich of MSA made similar statements (Exs. 9–22, 9–37, and 16–14).

Thomas Nelson asserted that the Hyatt Study may have underestimated the APF for quarter mask respirators because the study did not control adequately for respirator leakage. His comment was based on the fact that the authors of the study: (1) Did not administer a proper fit test to the test subjects prior to measuring particle contamination inside the respirator, and (2) used a fine particle (sodium chloride) as a test aerosol, that may have penetrated both the faceseal and filter, thereby artificially increasing concentrations inside the respirator (Tr. at 163 and Ex. 18–9).

The commenters who recommended that OSHA assign quarter mask respirators an APF of 5 stressed that no studies, including WPF and SWPF studies, on quarter mask respirators have been performed since the Hyatt Study. Few quantitative data are thus available on which OSHA can rely to set an APF for quarter mask respirators. These commenters, who include NIOSH, pointed out that NIOSH used the Hyatt Study to set the APF for quarter mask respirators at 5 in its 1987 RDL. NIOSH commented further that, ''quarter mask respirators should be separated from half mask respirators into a class of their own with an APF of 5. The data from Hyatt's study [1976] do not support an APF of 10'' (Ex. 17–7–1). Similarly, James S. Johnson stated, ''We object to the agency's proposed APF of 10 for quarter mask respirators. There is no evidence in the record, from either WPF or simulated workplace protection factor (SWPF) studies that support this conclusion'' (Ex. 16–9–1). Johnson's comments were echoed by the AFL–CIO (Exs. 9–27 and 19–1–1). These comments indicate that the Hyatt Study was not a valid WPF or SWPF study because it was a fit test protocol, not an experimental study.

The International Brotherhood of Teamsters and the AFL–CIO Building and Construction Trades Department supported an APF of 5 for quarter mask respirators because they believed that quarter mask respirators were more likely than half mask respirators to move around on workers' faces when the workers communicate, or because of movement, exertion, or perspiration. These commenters stated:

> Since the lower seal of the facepiece in quarter mask respirators is on the chin, rather than below the chin, the seal is much more likely to be compromised than the seal on a half face respirator. Additionally, in use factors such as movement, exertion, and perspiration add to the likelihood that the seal of these masks will be compromised in the work place. (Exs. 9–12 and 9–29.)

The Nuclear Regulatory Commission commented that its regulations prohibit the use of quarter masks because of ''the potential lack of stability of fit and the availability of acceptable alternatives (half-face respirators)'' (Ex. 10–7). Tracy Fletcher of Parsons-Oderbrecht JV recommended that OSHA prohibit the use of both quarter and half masks, stating, ''Employees are required to wear eye protection with the respirator, and use of the two together is difficult as the wearer will find that the glasses rest on the nose piece of the respirator creating an entry point for an overspray, splash or whatever.'' (Ex. 10–1.)

A small number of commenters expressed the opinion that, because the Hyatt Study provides the only data on the protection afforded by quarter mask respirators, OSHA should reserve its decision on the APF for these respirators until more studies can be completed. ORC Worldwide commented that ''[q]uarter masks should be evaluated as individual respirator models. In the absence of comprehensive testing data over the last 27 years, there is no valid basis for giving them an APF of any kind'' (Ex. 10–27). David Spence, an industrial hygienist, stated:

> We recommend that SWPF studies be performed on quarter masks respirators in a manner analogous to the ORC SWPF studies performed on powered air-purifying respirators and supplied-air respirators. To not delay publishing APFs for the other classes of respirators, the section on APF of quarter masks could be reserved pending completion of SWPF studies. (Ex. 10–6.)

Summary and conclusions. In light of these comments, the Agency has reconsidered the proposed APF of 10 for quarter masks. The comments recommending an APF of 10 for quarter mask respirators are based solely on structural analogies between quarter masks and half masks, and not on the functional characteristics of these respirators. Accordingly, the rulemaking record contains no quantitative or qualitative data or other convincing evidence confirming that quarter mask and half mask respirators function in a similar fashion to provide employees with equal levels of respiratory protection. No WPF or SWPF studies conducted on quarter mask respirators were submitted to the record. The Hyatt Study, which consisted of testing quarter masks using a fit testing protocol, provides the only data available for quarter mask respirators, and it supports an APF of 5. Therefore, OSHA has decided to separate quarter mask respirators into their own category and assign them an APF of 5.

It is possible that the facepieces of quarter masks and half masks are not functionally analogous. Some commenters noted that half masks rest *under* the chin while quarter masks rest *on* the chin. Consequently, quarter masks are more prone than half masks to slip and compromise the face seal when a worker talks or performs heavy work. While the record contains no quantitative evidence supporting such assertions, there is ample qualitative evidence, and OSHA is entitled under these circumstances to take a conservative approach in weighing the available evidence (see, e.g., 29 U.S.C. 655(b)(5) and *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1248 (D.C. Cir. 1980)). Moreover, OSHA believes that these respirators can be used safely at an APF of 5 because properly administered fit testing protocols (including administering the fit test with glasses and other protective equipment worn during respirator use),[9] as well as appropriate respirator training, will inform employees of this problem and the procedures they can use to prevent it.

In further response to those commenters who advised OSHA to prohibit quarter masks, OSHA does not believe that this approach is reasonable. As discussed at the public hearing, quarter mask respirators are not widely used, but they do have some popularity in particular industries (Tr. at 558). All existing quarter mask respirators have received an N95 rating under NIOSH's certification program, indicating that the respirators are designed to prevent at least 95% of the challenge agent from penetrating the filter. Therefore, these certification results, along with the

[9] As required under Appendix A (Part IA, paragraph 13) of 29 CFR 1910.134.

other evidence in the rulemaking record, have convinced OSHA that employees can use these quarter mask respirators safely at an APF of 5 in workplaces that implement a respirator program that complies with 29 CFR 1910.134.

Regarding those commenters who advised OSHA to delay the APF decision for quarter mask respirators until WPF or SWPF studies are available, OSHA notes that in the intervening 29 years following the Hyatt Study, no WPF or SWPF studies have been conducted on quarter mask respirators. If OSHA was to delay setting an APF for quarter mask respirators pending further study, it could in effect be deciding to delay setting an APF for these respirators indefinitely. OSHA has not been persuaded by the record to delay setting an APF for quarter mask respirators. Moreover, as noted in the previous paragraph, OSHA has concluded that the record evidence supports an APF of 5 for quarter mask respirators.

2. APF for Half Mask Air-Purifying Respirators

Introduction. OSHA proposed an APF of 10 for both elastomeric and filtering facepiece half mask respirators. During the public comment period, interested parties expressed two divergent views on this proposed APF. The healthcare industry (Ex. 9–18 to 9–21), NIOSH (Tr. 107 and 112) and other commenters (e.g., Exs. 9–11, 9–22, 9–26, 9–42, and 10–18) agreed to an APF of 10 for both types of respirators, while a number of commenters stated that filtering facepieces should be assigned a protection factor of 5 (e.g., Exs. 9–8, 9–12, 9–29, and 10–6; AFL–CIO Tr. at 122–126). The following sections discuss this issue in detail.

A number of reasons were presented for limiting filtering facepiece half masks to an APF of 5. These reasons can be categorized generally into concerns related to: (1) WPF studies and associated data; (2) design of filtering facepiece respirators; (3) respirator use in the workplace; and (4) ANSI standards. As discussed in Section III above, some commenters believed that the WPF studies evaluated by OSHA suffered from multiple problems (e.g., old data, studies not representative of typical workplaces). While these points are addressed in detail in Section III of this preamble, some of these concerns warrant further discussion here.

Some filtering facepieces do not achieve an APF of 10. Comment was made that the data presented in the studies analyzed by OSHA indicate that not all filtering facepieces achieved an APF of 10. Consequently, these commenters argued that the entire class of respirators should receive an APF of 5 (Exs. 9–29, 9–27, and 10–54). The AFL–CIO stated:

> An examination of the summary table of WPF studies for filtering facepieces and half-mask elastomeric respirators at 68 FR 30495 of OSHA's preamble to this proposed rule justifies our position. Of the seven respirators that had a 5th percentile WPF less than 9, five of [the] respirators that failed consisted of the filtering facepiece style of respirator. Thus [of] the overwhelming majority of the half mask respirators that failed, five of the seven or 71%, were filtering facepieces. At the qualitative level then, this data clearly indicates that most of the problem with failing to provide adequate protection rests with filtering facepieces and not with half-mask elastomerics. (Ex. 9–27.)

The summary table in the proposal at 68 FR 34095 contains several studies that were reviewed by OSHA, but did not meet the selection criteria and were excluded from the quantitative analyses. The two filtering facepiece respirators (one model in each study) evaluated in these excluded studies had WPFs less than 9 (Cohen, Ex. 1–64–11; and Reed, Ex. 1–64–61), while five of the respirators included in OSHA's analyses failed to achieve a WPF of 9. Three of these five respirators were filtering facepiece respirators and the remaining two respirators were elastomeric half masks. As noted at the hearing, OSHA conducted a Chi-square analysis to determine if the proportion of filtering facepieces having a WPF less than 9 differed from the proportion of elastomerics with a WPF less than 9 (Trans. at 135–136). This statistical comparison showed that these proportions did not differ significantly from each other, indicating that similar proportions of filtering facepiece and elastomeric respirators performed at this level—i.e., that the filtering facepiece respirators did not perform more poorly than the elastomeric respirators.

After updating the proposal's half mask WPF database (Ex. 20–2) with new and additional data, Dr. Crump reanalyzed the database (Ex. 20–1). Plotting the observed protection factors for both the elastomeric and the filtering facepiece half masks shows that over 95% of each type of half mask attained an APF of at least 10. Moreover, a review of these updated analyses reveals that more elastomeric than filtering facepiece respirators failed to achieve an APF of 10 (see Table 2 in Ex. 20–1). Even when the data from studies excluded from these analyses were added to the database, over 95% of the WPFs for both types of half mask (separately and combined) are still equal to or greater than 10. (A detailed discussion of Dr. Crump's analyses can be found in section III (Methodology) of this preamble.) Therefore, OSHA does not agree that the evidence in the record supports an APF for filtering facepieces of 5 as suggested by these commenters.

Respirator configuration and certification issues. Commenters also stated that not all configurations (e.g., cups, duckbills, fold flats) of filtering facepiece respirators have been studied (e.g., Exs. 9–17, 9–34, 9–40, 10–33, and 10–34; Tr. at 204–205). In addition, some commenters mentioned that none of the respirators in the studies evaluated by the Agency for the proposal were certified under NIOSH's new 42 CFR 84 requirements (Exs. 9–33, 9–34, 10–22, and 10–38). The focus of these comments was that OSHA should not assume that all filtering facepieces perform the same as those filtering facepieces that were tested. These commenters believed that filtering facepiece half masks should be given an APF of 5 because, in their view, there is a lack of information on 42 CFR 84 filtering facepieces.

OSHA recognizes that its analyses do not encompass all configurations or models of filtering facepiece half masks. However, this is true for all types of respirators, not just filtering facepiece half masks. Since filter efficiency is certified by NIOSH, the filter media of all filtering facepiece (and elastomeric) half mask configurations are equivalent. Therefore, any differences in performance would arise from variations in faceseal leakage among the different configurations. OSHA's Respiratory Protection Standard requires that all respirator users pass a respirator fit test to ensure that a minimum acceptable faceseal performance is achieved. Therefore, because all respirators must be used in accordance with the Respiratory Protection Standard, the Agency sees no reason to conclude that differences in configuration will result in performance variations. In addition, Section III of this preamble discusses two studies that compare the workplace performance of 42 CFR 84 and 30 CFR 11 filtering facepiece half masks. The 42 CFR 84 respirators demonstrated superior performance when compared to the 30 CFR 11 respirators. OSHA concludes that, based on the more stringent filter efficiency certification requirements and these study results, 42 CFR 84 respirators provide performance at least equal to 30 CFR 11 respirators. Therefore, the record evidence does not support lowering the APF for filtering facepieces to 5.

Determining faceseal leakage. Several commenters mentioned that NIOSH had eliminated the fit test portion of its certification procedures. They believed that as a result of this NIOSH action, one could not be sure if a filtering facepiece respirator achieves an adequate faceseal and provides the expected protection (Exs. 9–8, 9–27, 9–29, 9–34, 9–35, 9–40, 9–41, 10–22, 10–33, 10–38, 10–50, and 10–55). During the public hearing, NIOSH indicated that it would establish a new respirator certification testing procedure, stating:

> Such changes would result in additional certification tests to assure or assess the overall performance of every respirator model, and thus assure that every model is capable of providing a level of protection consistent with the class APF. (Tr. at 103.)

Several commenters supported this approach, and indicated that implementing such a procedure would be beneficial. For example, Tim Roberts (Exs. 17–8 and 18–4) stated that the procedure would help to identify respirators that may not have adequate workplace performance. The AFL–CIO (Ex. 19–1) believed that while the procedure would help assure certified filtering facepieces are capable of fitting an employee properly, these respirators should still be given an APF of 5.

Two respirator manufacturers also addressed this issue. The 3M Company commented that no evidence exists showing that employee protection would be enhanced by adding a fit test requirement to NIOSH's certification procedures, and added that proper respirator fit must be determined by fit testing each wearer (Ex. 18–7). When asked by OSHA about the proposed NIOSH testing, Jay Parker of Bullard responded that he believed such testing would be an improvement over the current procedures (Tr. at 497).

OSHA has reviewed this information and supports NIOSH's plans to add performance testing to its respirator certification procedures. The Agency agrees with the 3M Company that proper facepiece fit can only be assured through individual fit testing. However, OSHA also agrees with Tim Roberts that performance testing will assist in identifying respirators with poor fitting characteristics that may not provide protection consistent with the respirator's APF. Thus, OSHA concludes that performance testing will enhance the information needed for selecting appropriate respirators, and encourages NIOSH to expedite its efforts in this area. However, employers and respirator users should note that using a respirator certified by NIOSH through performance tests would not preclude individual fit testing as required by OSHA's Respiratory Protection Standard.

Filtering facepiece design problems. Several commenters urged an APF of 5 for filtering facepiece half masks based on the design characteristics of these respirators. Some commenters expressed concern that, in comparison to elastomeric half masks, filtering facepieces are poorly constructed (e.g., non-adjustable head straps, prone to crushing or denting, facepiece too stiff or too soft) (e.g., Exs. 9–34, 10–37, 10–38, 10–54, and 12–7–1). For example, T.C. Lefford of Fluor Hanford stated:

> Elastomeric half-mask respirators provide a better face seal that filtering facepieces (Disposable respirators or maintenance-free masks). Most elastomeric half-mask respirators are made of more pliable silicone rubber that provides a much better seal on the face. Elastomeric half-mask respirators have three sizes with adjustable head straps and a head cradle to improve stability while the majority of filtering facepieces have one or two sizes and the head straps are non-adjustable. (Ex. 9–32.)

OSHA believes that concerns about loose, dented, or crushed filtering facepieces are addressed adequately by compliance with existing program requirements under 29 CFR 1910.134(d) and (g).

In addition, comment was received alleging that the 42 CFR 84 requirements for increased filter efficiency result in respirators with stiff facepieces, poor face seals, and high breathing resistance, thereby producing filtering facepieces with increased faceseal leakage (e.g., Exs. 9–34, 9–41–1, 10–46, and 10–50). Mark Haskew, Tim Roberts, and Ching-tsen Bien (Exs. 12–7–1, 16–12, 16–20–3, and 17–5) also expressed concern about the increased filter efficiency requirements of the new 42 CFR 84 certification standards and their effect on the performance of filtering facepiece respirators. In their written comments, Mark Haskew and Tim Roberts stated that the 42 CFR 84 filter efficiency requirements "would increase the breathing resistance and in turn cause an increase in faceseal leakage when compared to 30 CFR part 11 filtering facepieces" (Ex. 12–7–1). Haskew, Roberts and Bien also questioned the ability of 42 CFR 84 filtering facepieces to fit the user's face, and the applicability of 30 CFR part 11 study data to 42 CFR 84 respirators. For example, Mark Haskew testified:

> The other problem with the old data is that the 30 CFR 11 respirators are significantly different in performance, or at least we would anticipate that they may be different in the performance that they provide. Based on the newer filter media with the 95, 99 and 100 series, there's an allowance for increased breathing resistance. And because the efficiency has to be greater, the filter media itself tends to be stiffer. And the concern we have, of course, which is untested in the research as far as we know, is that it may not conform as well to a wearer's face. (Tr. at 203.)

Based on their opinion that manufacturers would have to produce thicker, stiffer filter media to meet the new filter efficiency requirements, these commenters concluded that the data for 42 CFR 84 filtering facepieces would show a decrease in performance compared to the older 30 CFR 11 respirators. These commenters, based on this assumption, concluded that it would be inappropriate to set the APF for filtering facepieces based on WPF studies of the older 30 CFR 11 respirators. However, they presented no data to substantiate this claim.

When NIOSH published the 42 CFR 84 respiratory protective devices final rule (60 FR 30336), Section 84.180 of this rule increased the maximum allowable breathing resistance levels during inhalation to 35 mm (of water pressure), and during exhalation, to 25 mm. NIOSH explained this increase as follows:

> [It will] enable manufacturers to produce respirators meeting the new requirements more expeditiously and at lower cost. * * * This small increase in maximum allowable breathing resistance for particulate respirators does not add substantially to physiologic burden for respirator users, and will be compensated for by increased worker protection provided by the new filter efficiency tests and classification system. (60 FR 30346.)

However, when respirator manufacturers developed new particulate filters to meet the 42 CFR 84 performance requirements, they were able to meet them without increasing the breathing resistance levels. For example, the 3M Company submitted the following table of breathing resistance values for several classes of 42 CFR 84 filters made by different manufacturers (Ex. 17–9–1, page 6; derived from a paper submitted by 3M to the OSHA docket (Ex. 9–16–1–3)).

Filter Class	Manufacturer A (ΔP mmH_2O)	Manufacturer B (ΔP mmH_2O)
N95	11.5	9.7
R95	No Product	13.6
P95	14.9	No Product
P100	23.9	17.3

No measurement in this table exceeds the 30 CFR 11 limit of 30 mm of water pressure. As the 3M Company stated, ''Breathing resistance of 42 CFR 84 respirators are contained within the range of breathing resistances allowed for 30 CFR 11 respirators, rather than being significantly higher'' (Ex. 16–25–2, page 17).

OSHA also received comments that higher breathing resistance leads to increased faceseal leakage (Exs. 9–34, 9–35, 9–41, 10–38, and 10–50). During the public hearings, 3M submitted two new studies of filtering facepiece respirators certified under 42 CFR 84 (Ex. 16–25–3). The 42 CFR 84 certified filtering facepieces used in these studies performed better, overall, than comparable filtering facepieces certified under 30 CFR 11 (see discussion above under Section III (''Methodology, etc.'')). These results indicate that faceseal leakage, if it existed, did not impair the performance of these filtering facepieces.

At the 2004 AIHCE in Atlanta, Georgia, Larry Janssen of the 3M Company presented the results of a recently completed study (Ex. 17–9–1) using the OHD FitTester 3000 controlled negative pressure (CNP) fit testing instrument to measure faceseal leak rate (i.e., a drop in pressure inside the mask). Leak-rate measurements first were made using the negative pressure and flow-rate settings listed for the CNP fit test in Appendix A of 29 CFR 1910.134. Without disturbing the fit of the respirator, four additional leak-rate measurements then were made at four different negative pressures and flow rates ranging from 5.6 through 20.1 mm of water pressure, followed by a final measurement at the CNP fit test rates. Janssen found that test subjects with a fit equal to or greater than a fit factor of 100:

> [D]id not show any increase in leak rate as pressure drop increased. Subjects with a fit factor below 100 * * * showed significant variability in leakage as the settings were changed, but the amount of leakage did not correlate with increasing pressure drop, i.e., sometimes the leakage was higher and sometimes lower. (Ex. 18–7, page 49.)

The 3M Company concluded that the study ''demonstrates the value of fit testing: respirators that fit well enough to be assigned to a worker do not exhibit increased leakage as pressure drop increases'' (Ex. 18–7, page 49). Janssen, in a summary of this study that he presented at the May 2004 AIHCE stated, ''Results of this study do not support the concept of increased faceseal leakage with increased pressure drop.''

While concern was expressed by some commenters about increased filter efficiency requirements resulting in increased breathing resistance and faceseal leakage, no data were submitted to support this viewpoint. However, studies were submitted that demonstrated that 42 CFR 84 filtering facepiece respirators perform at least as well as 30 CFR 11 filtering facepieces, and that increased filter efficiency does not result in increased faceseal leakage. After reviewing this information, OSHA is persuaded that 42 CFR 84 half masks are as protective as 30 CFR 11 half masks and that increased face seal leakage in such respirators has not been demonstrated by evidence in the record. Therefore, these arguments do not support an APF for filtering facepieces of 5.

The efficacy of user seal checks provided by respirator manufacturers also was questioned by several commenters. These commenters stated that user seal checks for filtering facepieces either could not be performed or were more difficult than user seal checks with elastomeric facepieces (e.g., Exs. 9–27, 9–31, 9–34, 9–35, 9–40–1, 9–41–1, and 10–54). In general, their opinion was that the inability to perform an adequate user seal check on filtering facepiece respirators would lead to decreased protection, thereby warranting a reduced APF for this type of respirator.

Bill Kojola of the AFL–CIO (Exs. 9–27 and 19–1) stated that ''user seal checks are rarely performed on filtering facepieces in the field and * * * it is extremely difficult, if not impossible, to perform effective user seal checks on filtering facepieces.'' He stated that it was ''easy for wearers to perform effective user seal checks on elastomerics.'' Kojola cited this difficulty in performing user seal checks as a reason for separating filtering facepieces from elastomerics, and giving filtering facepieces an APF of 5. However, he did not provide any data to support his experience that filtering facepieces demonstrate a difference in user seal check performance compared to elastomerics.

Similar concerns were voiced by Mark Haskew (Exs. 17–5 and 18–3), Tim Roberts (Exs. 9–8, 10–55, and 17–8), and Ching-tsen Bien (Exs. 9–43–2 and 18–5). In addition, Mark Haskew stated that filtering facepieces with adjustable nose pieces cannot normally obtain repeatable fit factors. However, these commenters did not submit any supporting data for this contention. In his post-hearing submission, Tim Roberts (Ex. 18–4) stated that data demonstrating this difference in performance are not available.

James Johnson (Exs. 10–33, 16–9–1, and 17–10) also stated that filtering facepieces cannot be fit checked effectively, and presented results from a series of fit tests he performed on himself with filtering facepieces and elastomeric half masks. Three of the four elastomeric half masks that he tested passed a positive or negative user seal check, and consistently achieved a fit factor of 1500 or more using the Portacount fit test instrument. One elastomeric half mask did poorly (fit factor of less than 100), and it was identified clearly as a failure by a user seal check and a subsequent fit test. He found that it was difficult to achieve a minimum fit factor of 100 or greater with filtering facepieces using the Portacount Companion fit test instrument. However, two of the eight filtering facepiece models he tested achieved fit factors of 100 or greater. He stated that he was able to identify obvious leaks with the filtering facepieces he tested by exhaling heavily and sensing the airflow, but that cupping his hands over the facepiece was not an effective user seal check for him. He stated further that these preliminary fit test results demonstrated a significant difference in performance between elastomeric and filtering facepiece half masks, and that OSHA should give filtering facepieces an APF of 5 based on these results.

The numerical differences in fit factors between filtering facepieces and elastomeric half masks reported by Johnson may not be significant. Achieving a fit factor of 170, as Johnson did with the 3M 9211 foldable filtering facepiece using the Portacount Companion, is not necessarily worse than achieving a fit factor of 2200 with a MSA Comfo elastomeric half mask using the Portacount alone. In this regard, the fit test instruments identified the elastomeric half masks and filtering facepieces that provided adequate fits on Johnson (i.e., they met their required fit factor of 100), and he was able to perform user seal checks with both respirators. Therefore, OSHA finds that these fit test measurement differences are not a convincing argument for an APF for filtering facepiece respirators of 5. The Agency believes that Johnson's pilot study proves only that some makes and models of filtering facepieces are not suitable for his face size and shape. When he wore a filtering facepiece or elastomeric respirator that fit him, an APF of at least 10 was achieved.

In response to these concerns, the 3M Company (Ex. 17–9–2) and the Aearo Company (Ex. 17–3–1) submitted to the record instructions for conducting user seal checks on their filtering facepiece respirators. The Aearo Company instructs users to cup their hands over the respirator to test the seal, stating: ''If air flows around your nose, tighten the nosepiece; if air leaks around the edges, reposition the straps to fit better (Ex. 17–3–1).'' User seal check instructions for 3M filtering facepieces read, ''If air leaks between the face and faceseal of the respirator, reposition it and readjust the nose clip for a more secure seal'' (Ex. 17–9–2).

In their post-hearing comments (Exs. 9–16, 17–9–1, 18–7, and 19–3), 3M responded to the comments raised at the public hearing regarding the difficulty or impossibility of performing user seal checks on filtering facepiece respirators. The 3M Company pointed out that no data were offered to support this position, nor was recognition given to the methods contained in both the 1980 and 1992 editions of the ANSI Z88.2 respirator standard for performing user seal checks. The 3M Company also cited a study in the docket by Myers et al. (Ex. 9–16–1–13), which concluded that no difference was found in the effectiveness of performing user seal checks on filtering facepiece respirators or elastomeric respirators. This study also referenced a comment by Daniel K. Shipp of the ISEA (Ex. 9–22) that user seal checks can be performed with filtering facepieces. A second evaluation of user seal checks submitted by 3M (Ex. 17–9–10) involved the use of a 3M flat-fold filtering facepiece by novice respirator users. It showed that novice respirator users can be trained to effectively perform user seal checks, and that the use of seal checks improved the overall quality of respirator fit.

The 3M Company also stated that the ease or difficulty in performing user seal checks is based on many factors. These factors include difficulty in performing a user seal check on some elastomeric respirators when the exhalation valve cover must be removed without disturbing the fit. Also, it can be difficult to perform a user seal check on elastomerics by blocking off the filter when a respirator user has small hands. In addition, 3M cited an analysis from its report at the 2001 AIHCE (Ex. 4–10–7) that showed no significant differences in WPF results for filtering facepieces measured in the morning and afternoon, with repeated redonnings of the respirators performed during each of these periods. These results indicate that the user seal check conducted after each redonning was effective in ensuring proper respirator fit.

During the rulemaking, several commenters referred to the use of fit check cups to perform user seal checks. These devices are designed to assist the respirator user in performing a positive and negative pressure seal check by covering the surface of a filtering facepiece respirator. For example, Tim Roberts stated:

> One of the manufacturers did recognize that there was difficulty in doing these types of fit checks, and they designed, and constructed, and sold a fit-check cup that actually fit over the facepiece of a respirator, a filtering facepiece respirator, so that it would actually check the seal in a more conventional manner. We think that that may be another alternative approach to assuring that these respirators fit properly if there was a requirement to do that. (Tr. at 216.)

Another commenter who discussed the use of fit check cups was Donald Faulkner of the United Steelworkers, who stated during his questioning of Warren Myers:

> [W]e don't see a real good fit with the hands-over filtering facepiece. That's why the cups were developed by many manufacturers, but we don't see them being utilized, bought, or anything else. (Tr. at 95.)

He elaborated in his post-hearing comment: ''Filtering facepieces do not allow seal checks to be performed without the assistance of additional equipment [i.e., fit check cups] that is never provided by the employers, as being cost prohibitive.'' (Ex. 19–2.)

Bill Kojola of the AFL–CIO (Tr. at 132) and George Macaluso of the Building Construction Trades Department of the AFL–CIO (Tr. at 654) made similar statements regarding the infrequent use of fit check cups, i.e., that they are generally not used in the workplaces their unions represent. They asserted that user seal checks that involve cupping the hands over the facepiece were not effective, and that the use of fit check cups should be required by OSHA. They implied that fit check cups are a generic device for doing user seal checks, and that one manufacturer's fit check cup can be used with other types of filtering facepieces. On the other hand, Ken Wilson of the Ohio Board of Water Quality, Division of Safety and Hygiene (Ex. 10–3) stated that he has not seen fit check cups used in the field, and doubted that their use would allow a respirator user to achieve a successful fit check.

OSHA has considered carefully the opinions presented about fit check cups and user seal checks. The Agency recognizes that the use of a fit check cup is one way of performing a user seal check. However, these cups can be inconvenient when used in the workplace on a daily basis. In this regard, each respirator user would need ready access to a fit check cup, not only to perform the required user seal checks when initially donning the respirator, but for any repeated respirator donnings that occur throughout the workday. The fit check cup would be another piece of equipment for respirator users to carry with them, and it can be misplaced. However, most respirator manufacturers have not adopted the use of fit check cups, and these manufacturers recommend cupping the hands over the filtering facepiece to perform a user seal check. As the 3M Company stated in describing the use of fit check cups, ''Based on our experience, user seal checks without cups are effective, more convenient, and easier to perform'' (Ex. 17–9–1, page 4).

Since only a few respirator manufacturers have fit check cups, it is not surprising that they are seldom used in the workplace. The fit check cups that exist are designed by the respirator manufacturer to work with a specific facepiece configuration and respirator model, and the cups do not necessarily work with other models of respirators, even models made by the same manufacturer. OSHA knows of only one series of 42 CFR part 84 filtering facepiece respirators that have fit check cups available.

OSHA does not find merit in the comments that fit check cups are necessary to perform user seal checks with filtering facepieces. While a fit check cup designed to work with a particular model of respirator can be used to perform a user seal check, it is not the only way to perform this function. Accordingly, the Agency believes that respirator users can follow a respirator manufacturer's instructions to perform a user seal check, e.g., whether the seal check involves cupping the hands over the facepiece or the use of a fit check cup.

The OSHA Respiratory Protection Standard requires that an employee perform a user seal check to use a respirator. The WPF database that OSHA developed contains over 1,000 WPF data points for half mask respirators collected from workers using respirators in programs that included user seal checks. Analyses of these data showed that the filtering facepiece respirators achieved an APF of 10. These data are derived from WPF studies in which user seal checks were performed on filtering facepiece respirators by 100s of workers. In addition, 3M's analysis (Ex. 4–10–7) indicates that user seal checks performed on filtering facepieces ensure proper redonning of these respirators. When a respirator user cannot perform a user seal check with a particular respirator model, then that respirator cannot be used by that employee, and the employer must find another respirator model on which a user seal check can be performed. This requirement applies to all tight-fitting facepieces, including filtering facepieces and elastomeric half masks. How easy or difficult it is for an employee to perform a user seal check on a particular type of respirator is not an issue that precludes other employees from using that respirator. Therefore, the comments on user seal checks do not provide convincing evidence that would support decreasing the APF for filtering facepieces to 5.

OSHA argued previously in *National Cottonseed Products Association* v. *Brock*, 825 F.2d 482 (D.C. Cir. 1987) that filtering facepieces used to protect employees against exposure to cotton dust should have an APF of 5 based on the difficulty of fit testing, particularly fit checking on a daily basis. However, the Agency now believes that the record evidence for this rulemaking shows that the industrial-hygiene research community has developed and refined qualitative and quantitative fit tests, as well as developed sophisticated techniques for determining respirator leakage. Several commenters (Exs. 16–25–3 and 17–9–1) provided evidence that filtering facepieces could be fit tested and then used effectively. Seal-check techniques and procedures (e.g., fit-test cups, manual testing) also have been developed to help ensure that filtering facepieces maintain their fit while being worn in the workplace. These new developments allowed the Agency to reassess filtering facepieces and find that these respirators can be reliably fit tested and fit checked.

The WPF studies provide further support for this conclusion. In fact, every WPF study of filtering facepieces in the OSHA APF database involved fit testing the respirator, using the new and refined methods, prior to the worker using the respirator in the study. Researchers used the available fit testing and checking technologies and methodologies in the studies to be assured that employees would be protected during the study by the respirators when exposed to airborne contaminants up to 10 times the PEL, and so that they could determine the results of the study would be accurate.

Non-compliance and economic incentive issues. Several commenters asserted that filtering facepiece half masks should be given an APF less than 10 because employers do not comply with the Respiratory Protection Standard (e.g., by not performing fit testing) (e.g., Exs. 9–40–1, 10–33, and 10–52; Tr. at 663). In this regard, Donald Faulkner of the United Steelworkers of America (USWA) stated:

> We observe in many worksites that the employers are issuing filtering masks as if they were candies. They don't have respiratory protection programs, requirements to be clean shaven, and no medical or no idea of the MUC of the contaminant that the worker needs to be protected from. (Ex. 9–40–1.)

However, the 3M Company commented that non-compliance with the Respiratory Protection Standard should not be a factor in determining APFs, noting:

> OSHA has appropriately made the proposed APFs contingent upon the existence of an effective and well-managed respiratory protection program. This is the only circumstance under which APFs can be used. Setting APFs on assumptions of poor fit and lack of training is impossible because of the countless variables that exist in the workplace and workforce. APFs can only apply under properly managed respiratory protection programs. This is supported by following the American Industrial Hygiene Association Respiratory Protection Committee definition of APFs: An APF is the level of respiratory protection that a properly functioning respirator or class of respirators would be expected to provide to properly fitted and trained users in the workplace. The APF takes into account all expected sources of facepiece penetration (e.g., face seal penetration, filter penetration, valve leakage). It is not intended to take into account factors that degrade performance such as poor maintenance, failure to follow manufacturers' instructions, and failure to wear the respirator during the entire exposure period. (Ex. 9–16.)

Several commenters voiced concern that assigning a protection factor of 10 to both elastomeric and filtering facepiece half masks will result in an economic incentive for employers to provide filtering facepiece respirators to employees rather than elastomeric half masks. These commenters assumed that the less expensive filtering facepiece respirators were less protective than the more expensive elastomerics (e.g., Exs. 9–29, 10–38, and 10–54; Tr. at 212–213 and 659–660). The USWA expressed this concern, stating, ''If OSHA gives the filtering face piece type of respirator an APF of 10, employers would interpret this as 'let's take the cheap way out.' It will be a dis-incentive to issue to workers the proven protection of the elastomeric face piece respirator'' (Ex. 9–40–1). Responding to an OSHA question about this issue, Thomas O'Connor of the National Grain and Feed Association stated:

> Well, clearly, if [you] had two respirators that provided the comfort and fit to the employee that's needed and one was half the cost of the other one, obviously anybody would select the lower cost respirator. But as I noted, that's not the primary motivation, cost. The primary motivation is complying with the standard, making sure that the employee[s] wear it and it fits properly and it's comfortable. * * * If an employee's wearing a respirator that's not comfortable, there's going to be an incentive for them possibly not to wear that respirator * * * when they should be wearing it. So from our perspective, comfort is one of the primary considerations in selecting a respirator for an employee. (Tr. at 684–685.)

OSHA considered these comments and concludes that neither cost nor non-compliance with the Respiratory Protection Standard is an appropriate basis for determining the final APF for half masks. Employers are required to comply with all the provisions of the Respiratory Protection Standard. Non-compliance is not an option for employers. Thus, there is no compliance reason to reduce the APF for half masks.

As to whether assigning a protection factor of 10 to filtering facepiece half masks will provide an economic incentive to use these respirators, OSHA concludes that so long as a respirator achieves an APF of 10, it doesn't matter what respirator an employer uses. Once again, OSHA's data analyses, as well as consensus standards, show that filtering facepieces can attain an APF of 10.

ANSI's updated APF of 5. Several commenters noted that the recent draft of the ANSI Z88.2 respirator standard gave filtering facepieces an APF of 5 (e.g., Exs. 9–8, 10–51, and 10–54; Tr. at 124–125 and 197–201). For example, Bill Kojola of the AFL–CIO testified:

> The AFL–CIO's position that filtering facepieces should be given an APF of 5 is

also provided by other organizations with considerable expertise on respiratory protection. Indeed, the ANSI Z88.2 Committee, charged with the responsibility for the American standard for respiratory protection, has recently proposed an APF of 5 for filtering facepiece respirators. We believe that OSHA should give serious consideration to this ANSI position as well when it issues its final rule. (Tr. at 124–125.)

OSHA considered the draft ANSI standard during this APF rulemaking. However, this draft standard currently is under appeal, and has not been designated by ANSI as a final standard (Ex. 17–9–10–2). Jill Snyder, Standards Coordinator for the AIHA secretariat of the ANSI Z88 committee, addressed the status of the draft ANSI Z88.2 revised respiratory protection standard in an e-mail sent to participants in Roundtable 228 held at the 2004 AIHCE. This e-mail stated:

Until a standard is approved by ANSI, it is not an ANSI standard. Therefore, we should not say things like 'ANSI completed drafting * * *' etc. It is actually the Accredited Standards Committee (ASC) Z88 or Z88.2 that put together what is still the DRAFT standard. We also have to make sure we call it a draft standard, not a standard at this point. (Ex. 17–9–10–2.)

The method used by ANSI to determine the draft APFs also differs from OSHA's approach, which used data analyses and expert opinion to arrive at the final APF for half masks. James Johnson, representing the ANSI Z88.2 subcommittee, stated that the subcommittee did not perform an extensive quantitative analyses similar to OSHA's in determining the draft APFs (Tr. at 357). In response to questions from Thomas Nelson, ANSI subcommittee member George Macaluso confirmed that an overall tabulation and review of available WPF data was not conducted by the ANSI subcommittee in determining APFs (Tr. at 663–666).

With regard to the decision of the ANSI subcommittee, James Johnson agreed that a subcommittee composed of other members may have reached a different conclusion regarding the APF for filtering facepiece half masks (Tr. at 354–355). He also stated:

There's nothing in the consensus process that says every part of the standard has to have an absolute defendable, scientific, technically traceable base. It doesn't exist. It's not there. We have tremendous numbers of standards that are out there that the professionals develop with the best knowledge and experience that they have, and this is the process. (Tr. at 363.)

Summary and conclusions. In this section, OSHA considered the issue of the appropriate APF for filtering facepieces. OSHA's data analyses in the record support an APF of 10 for filtering facepiece respirators. Moreover, a number of commenters supported the APF of 10. Some commenters recommended a lower APF for filtering facepieces than proposed based on the poor structural integrity of the mask, the availability of additional models of respirator protection, poor compliance with the respirator program requirements, difficulty performing user seal checks, increased breathing resistance among filtering facepieces approved under 42 CFR part 84, and the recent ANSI draft APF for filtering facepieces. As discussed in the previous sections, the evidence in the record with regard to these issues justifies retaining in this final rulemaking the proposed APF of 10 for filtering facepieces.

3. APF for Full Facepiece Air-Purifying Respirators

Introduction. In a 1976 report, Ed Hyatt of LANL developed an APF table that included this respirator class (Ex. 2). In this report, Hyatt used the results from quantitative fit testing to assess six models of full facepiece negative pressure air-purifying respirators equipped with HEPA filters. Five of these respirators achieved a protection factor of at least 100 for 95% of the respirator users. The sixth respirator attained this level of protection for 70% of the users. Based on the results for the sixth respirator, Hyatt recommended an APF of 50 for the respirator class as a whole.

The 1980 ANSI respirator standard listed an APF of 100 for full facepiece air-purifying respirators with DFM filters (Ex. 7–3). ANSI increased the APF for this respirator class from 50 to 100 because the poorly performing respirator in Hyatt's study was no longer in production. Using the 1976 LANL quantitative fit testing results, the 1980 ANSI standard increased this APF to a maximum of 1,000 when the respirator used HEPA filters and respirator users received quantitative fit testing (Ex. 7–3).

Based on Hyatt's 1976 data, the 1987 NIOSH RDL recommended that this respirator class receive an APF of 50 when equipped with a HEPA filter. However, the RDL gave these respirators an APF of 10 when using DFM filters. NIOSH gave these respirators an APF of 10 when equipped with DFM filters because testing that it conducted showed that the filters had relatively low efficiency.

The 1992 ANSI respirator standard retained the 1980 ANSI standard's APF of 100 for full facepiece air-purifying respirators, but required that respirator users perform quantitative fit testing and achieve a minimum fit factor of 1,000 prior to using the respirators. QNFTs were necessary because no QLFTs could achieve a fit factor of 1,000. The ANSI standard kept this APF because the ANSI committee found, as it did in 1980, that no WPF or SWPF studies had been performed for this respirator class.

The following table summarizes the previous APFs assigned to full facepiece air-purifying respirators.

Fully facepiece air-purifying respirators	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
All respirators in the class	50 (with HEPA filter)	10 (with QLFT) 100 maximum (with QNFT)	10 (with DFM filter) 50 (with HEPA filter)	100

In the proposal, OSHA also discussed a WPF study that Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) conducted in a lead smelter. The respirator used in this study was a 3M 7800 full facepiece air-purifying respirator equipped with HEPA filters. The authors found a 5th percentile protection factor of 95 for the sample, but concluded that the respirator only provided reliable protection at a protection factor of 50. In addition, a LANL SWPF study by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) measured the protection afforded by the MSA Ultra Twin respirator with HEPA filters. The authors reported fit factors with geometric means ranging from 1,000 to 5,300. However, 23 of the 60 measurements reported were less than 1,000, seven were less than 100, and three were less than 50. Based on a careful review of these studies, OSHA proposed an APF of 50 for full facepiece air-purifying respirators.

OSHA requested comment in question #7 of the proposal on whether it should limit full facepiece negative pressure respirators to an APF of 20 when N95 filters are used. The NIOSH certification tests for 42 CFR part 84 filters are conducted using monodisperse aerosols of the most penetrating particle size (0.3 μm) delivered at a high flow rate of 85 liters per minute. Also, the 42 CFR part 84 certification standards allow up to 5% filter leakage with an N95 filter. If this level of leakage were to occur in the workplace, an APF of 20 would be appropriate for a full facepiece respirator using N95 filters. However, as several commenters noted (Exs. 9–16, 9–22, 9–23, 9–37, 10–6, 10–17, 10–27, 10–59, and 10–60), workplace filter penetration is always much less than filter penetration estimated from certification testing. Kenneth Bobetich of MSA (Ex. 9–37) stated that while 5% leakage is the worst case, such leakage does not occur in the workplace. Compared to the aerosols used in certification testing, workplace aerosols are not monodisperse, are many times larger, and are delivered through the filters at a lower flow rate. In addition, the 3M Company (Ex. 9–16) cited studies performed by Janssen (Exs. 9–16–1–3 and 9–16–1–4) that compared the performance of N95 and P100 filters made by two manufacturers and used during grinding operations in a steel plant. Workplace performance of both filters was equivalent statistically, and the study showed that N95 filter performance was adequate under these conditions. Lisa Brosseau of the University of Minnesota (Ex. 10–59) stated that it was entirely inappropriate for OSHA to consider a 5% leakage effect for N95 filters because such leakage would only occur when the aerosol is monodisperse and of a small size, conditions that she said are unlikely to occur in most workplaces.

Bill Kojola of the AFL–CIO (Ex. 9–27), Pete Stafford of the Building Construction Trades Department of the AFL–CIO (Ex. 9–29), and Michael Watson of the International Brotherhood of Teamsters (Ex. 9–7) supported limiting the APF for full facepieces to 20 when N95 filters are used. Watson stated that if OSHA gave these respirators an APF higher than 20, employees would likely be exposed to hazardous levels of workplace contaminants. Kojola stated further that OSHA should take into account both sources of leakage (filter and faceseal), and lower the APF accordingly. However, neither Watson nor Kojola provided any evidence to support these misgivings about the performance of these respirators.

NIOSH (Ex. 9–13) recommended that OSHA consider the limitations of the filter, but did not have any WPF or SWPF data on the performance of full facepiece respirators certified under 42 CFR part 84 using N, R, or P95 filters. NIOSH stated that because the filters are tested at the most penetrating particle size, filter efficiency in the workplace should exceed certification efficiency. However, NIOSH noted that some workplace tasks, such as welding and grinding, may result in high leakage rates through the N95 filter because the tasks produce fine or ultra fine particles.

Loraine Krupa-Greshman of the American Chemistry Council (Ex. 10–25) stated that OSHA could not justify using a simplistic, generalized treatment of N95 filter efficiency to limit the APF to 20. She noted that using N95 or N100 filters is a matter of professional judgment, based on the type and concentration of the contaminant. Frank White of ORC Worldwide (Ex. 10–27) stated that reducing the APF to 20 was unnecessary because protection factors and filter performance need to be considered separately as part of the respirator selection process. Ted Steichen of the American Petroleum Institute (API) (Ex. 9–23) mentioned that API believes that OSHA should further evaluate the data before assigning, based on worst-case assumptions, an APF of 20 to these respirators. Thomas O'Connor of the National Grain & Feed Association (Ex. 10–13) commented that he was not aware of any scientific information that refuted assigning an APF of 50 to full facepiece respirators or justified lowering the APF for N95 filters to 20. He supported retaining the proposed APF of 50 for this class of respirators. Sheldon Coleman of the Hanford Site Respiratory Protection Committee (Ex. 10–40) stated that, based on fit testing data, an APF of 50 for these respirators already is conservative.

OSHA agrees with these commenters that full facepiece respirators with N95 filters provide sufficient protection to maintain an APF of 50, and Table 1 of the final standard reflects this decision. Any effect of filter penetration on respiratory protection is best addressed during respirator selection, which also is the case for half masks and other respirator classes using particulate filters. In rare cases, when workplace exposures consist of a large percentage of particles of the most penetrating size, this information must be taken into account by the employer when selecting the appropriate class of particulate filter for any respirator, not just for full facepieces.

Summary and conclusions. In the proposal, OSHA asked for any additional studies of full facepiece air-purifying respirators, but none was submitted. After carefully evaluating the original studies reviewed in the proposal, the Agency is setting an APF of 50 for full facepiece air-purifying respirators. The final APF agrees with the conclusion of Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) cited earlier in this discussion that this class of respirators provides reliable protection at an APF of 50. Importantly, an APF of 50 corresponds with the APF previously assigned to full facepiece air-purifying respirators by OSHA in its substance-specific standards, and by NIOSH in its 1987 RDL. Therefore, OSHA is assigning an APF of 50 to full facepiece air-purifying respirators based on: the results of WPF and SWPF studies (which used N95 filters at moderate to high contaminant levels); The APFs given previously to this respirator class by NIOSH and ANSI; comments in the record indicating that N95 filters function effectively under the workplace exposure conditions in which they are used; and years of experience showing that these respirators, when equipped with an N95 filter, are safe when used in the manner prescribed by OSHA's respiratory protection standards. However, as with any respirator, if a full facepiece air-purifying respirator is unsuitable for the exposure conditions, paragraph (d)(1) of OSHA's Respiratory Protection Standard requires that employers select a respirator that will protect employees from the exposure hazards.

4. APF for Powered Air-Purifying Respirators (PAPRs)

Half mask tight-fitting PAPRs. In the proposal, OSHA assigned an APF of 50 to tight-fitting half mask PAPRs (68 FR 34098 and 34115) based on the 1987 NIOSH RDL and the Z88.2–1992 ANSI respirator standard. In arriving at a proposed APF of 50 for these respirators, the Agency relied heavily on the WPF study conducted by Lenhart and Campbell (Ex. 1–64–42), instead of the WPF study performed by Myers and Peach (Ex. 1–64–46) and the SWPF studies of Skaggs et al. (Ex. 1–38–3) and da Roza et al. (Ex. 1–64–94). In explaining its position, OSHA stated:

> [The Lenhart and Campbell] study was well controlled and collected data under actual workplace conditions; these conditions ensure that the results are reliable and represent the protection employees likely would receive under conditions of normal respirator use. The Agency did not consider the Myers and Peach WPF study * * * for this purpose because of problems involving filter assembly leakage and poor facepiece fit reported by the authors; consequently, the abnormally high levels of silica measured inside the mask would most likely underestimate the true protection

afforded by the respirator. The two SWPF studies * * * reported much higher geometric mean protection factors than did the WPF study performed by Lenhart and Campbell. However, OSHA believes that the higher protection factors reported for these SWPF studies are consistent with the proposed APF of 50 based on data obtained for this respirator class in the Lenhart and Campbell WPF study because SWPF studies typically report significantly higher protection factors than WPF studies of the same respirator. (68 FR 34098.)

During this rulemaking, OSHA received no substantive comments or other information regarding the proposed APF of 50 for these respirators. Nevertheless, OSHA believes that the existing WPF and SWPF studies on this class proved adequate support for OSHA's conclusion that an APF of 50 is an appropriate level to predict the protection capabilities of this class of respirators.

Full facepiece PAPRs and PAPRs with hoods or helmets. In the proposal, OSHA assigned an APF of 1,000 to tight-fitting full facepiece PAPRs (68 FR 34099). In support of the proposed APF, OSHA cited a WPF study by Colton and Mullins that found a corrected 5th percentile protection factor of 1,335 for these respirators. OSHA received no substantive comments or other information regarding the proposed APF of 1,000 for these respirators. However, the ANSI Z88.2–1992 respirator standard and the 2004 draft revision to the ANSI standard both assign an APF of 1,000 to this respirator class. Based on its review of these consensus standards and the existing WPF research literature (see Exs. 1–64–12 and 1–64–40), and SWPF research studies (Ex. 3–4), OSHA concludes that this respirator class warrants an APF of 1,000.

In proposing an APF of 1,000 for PAPRs with helmets or hoods, the Agency stated in footnote 4 of proposed Table 1 that ''only helmet/hood respirators that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with performance at a level of protection of 1,000 or greater, receive an APF of 1,000'' and that ''[a]ll other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.'' (See 68 FR 34115.) OSHA proposed this condition because available WPF and SWPF studies found that some of these hood/helmet respirators achieved protection factors well below 1,000 (Exs. 3–4 and 3–5). Under the proposed condition, the burden of conducting any testing likely would fall on respirator manufacturers, but the employer would be responsible for selecting a properly tested respirator.

According to James Johnson of LLNL, simple and effective equipment and procedures are available for detecting leaks in these respirators. In this regard, Johnson noted that LLNL developed equipment that monitors and records positive pressure in these respirators using a commercially available device. As he stated at the hearing:

[T]his is the one we chose, a data logging micro manometer, the TSI–DP Calc, with a range of –5 to +15 inches of water gauge, and data recording intervals of one second and longer were chosen. * * * We plan on using this technique periodically to monitor actual high-contamination work activities to assure this PAPR maintains a positive pressure. (Ex. 16–9–1.)

A number of commenters provided additional support for using positive pressure inside the facepiece as the criterion for protection. For example, Rick Givens of the Atlanta, GA Utilities Department stated that ''the maintenance of positive pressure is an appropriate method for distinguishing high-performing hood/helmet respirators from others'' (Ex. 10–2), while Sheldon Coleman of the Hanford, Washington DOE site asserted:

In the last three years, our program has used approximately 10,000 PAPR hoods. We have conducted some limited fit testing using particulate fit testers (although the hood manufacturer does not recommend using a particulate tester due to the extensive dead space in the hood). All of our information suggests that an APF of 1,000 is appropriate for a PAPR hood that maintains positive pressure inside of the hood. (Ex. 10–40.)

Several commenters took exception to the positive pressure criterion. Craig Colton of 3M stated that ''3M disagrees with OSHA's proposed requirement that hoods and helmets demonstrate that they maintain positive pressure at all times of use to receive an APF of 1,000'' (Tr. at 390). In this regard, Colton argued that the recent study conducted on PAPRs with hoods/helmets by ORC and LLNL showed that every respirator tested in the study ''had two or more brief negative pressure spikes within the respiratory inlet covering. Under the current proposal, all of these respirators, except the poorest performing supplied-air respirator would have received an APF of 25, even though the 5th percentile SWPFs found in the study ranged from 86,000 to 250,000'' (Tr. at 391). Colton then added, ''This study indicates that pressure within the respiratory inlet covering is only one of a complex set of factors that determine the protection provided by PAPRs and supplied-air respirators, and should not be considered by itself'' (Tr. at 391). John P. Farris of Safe Bridge Consultants echoed this concern (Exs. 9–11 and 10–32).

Other comments focused either on the need for a protocol to determine if the respirators could perform at an APF level of 1,000, or on design characteristics that would permit respirator users to select appropriate respirators. In advocating the testing approach, Stephan Graham of the U.S. Army Center for Health Promotion and Preventative Medicine noted that respirators that have high APFs should receive credit for their design and performance. Graham recommended that manufacturers test their hooded and helmeted respirators, and set the maximum APF (to a maximum of 1,000) based on the results (Ex. 9–42–1). The 3M Company stated that if OSHA retains a testing requirement in the final rule, it must specify the testing conditions. The 3M Company recommended testing at a work rate of 40 liters per minute, ensuring that pressure inside the hood or helmet is maintained at a minimum level of one atmosphere at this work rate, measuring this pressure at the flow rate recommended by the manufacturer, and maintaining the maximum static pressure inside the hood or helmet at 38 mm of water pressure (Ex. 18–7). Similarly, Jay Parker of the Bullard Co. stated that ''without oversight and guidance, testing performed may not achieve such goals. This may lead to the use of respirators and an APF of 1,000 that actually should not be used at that level because the testing performed was not really capable of ensuring that level of performance'' (Tr. at 492).

ORC Worldwide stated that ''the approach proposed by OSHA would hold hood/helmet or loose-fitting facepiece PAPRs and SARs to a higher standard than that required of other respirator classes, based simply on the results of one model'' (Ex. 10–27), a point made as well by Alice E. Till of the Pharmaceutical Research and Manufacturers Association (PhRMA) (Ex. 9–24). Nevertheless, ORC concluded that, ''[s]hould OSHA retain this requirement, the final rule should clearly specify acceptable testing criteria to which respirator manufacturers must conform'' (Ex. 10–27). PhRMA believed that OSHA should consider the proposed APF table to be an interim step in a transition toward the development of a certification protocol by NIOSH that provides APFs for each respirator model (Ex. 9–24). Thomas Nelson of NIHS, Inc. agreed, stating, ''Specific test conditions and performance criteria must be identified'' (Ex. 10–17).

NIOSH provided the following information that addressed the concerns of these commenters:

> Respirator models should not be assigned to the higher APF level following promulgation of the proposed APF rule unless the respirator manufacturer provides evidence that testing of that model demonstrates performance at the higher APF level. A standard test protocol is needed to assure reliable and reproducible results when determining if a hood/helmet PAPR * * * can consistently achieve a protection factor of 1000. NIOSH will assist in developing this protocol. With implementation of new NIOSH certification criteria, every respirator model could be evaluated using this protocol as a condition of certification to assure overall performance consistent with the established APF. Thus, NIOSH will assure that approved respirators are capable of providing this assigned level of protection so that employers have appropriate guidance and APF values when selecting respirators for their workers. (Ex. 16–4.)

Proponents of using design criteria, instead of testing, to assess the protection afforded by these respirators recommended that poorer performing respirators should be identifiable by either their appearance or technical specifications. For example, John Ferris of Safe Bridge Consultants, stated:

> In my experience, the most important factor in achieving workplace protection factors of 1,000 or greater with these devices is the ability to tuck the inner bib (or shroud) into the outer work garment with the outer shroud placed over the shoulders on the outside of the garment. I support the use of a 1000-fold APF for helmet hood PAPRs without the footnote. (Ex. 9–11.)

Robert Barr of Alcoa noted that design flaws need to be identified, stating, ''For example, flip-front types could be designated 25; and helmets with shrouds at 1000'' (Exs. 9–26 and 10–31). PhRMA, ORC, and the American Chemistry Council argued that OSHA should base the APFs for these respirators on design and construction characteristics that would ''enable a more exacting selection process, and * * * would be conducive to eventually assigning protection factors based on individual model performance'' (Exs. 9–24 and 10–27). However, Jay Parker of the Bullard Co. noted that the latest ANSI Z88.2 subcommittee ''was unable to agree on the design characteristics of a hood or helmet that would lead to a performance level equivalent to an APF of 25'' (Tr. at 480). Continuing, Jay Parker stated:

> I don't see that we will ever be able to define the performance of a respirator by its design. We don't want to stifle innovation. We want to be able to allow respirator manufacturers to develop new hoods and helmets. If OSHA comes up with a definition that limits a hood or helmet to a certain design, then that would limit the manufacturer's ability to innovate with new designs. (Tr. at 480.)

After reviewing the comments on proposed footnote 4, OSHA concludes that: no single parameter (e.g., positive pressure inside the facepiece) will identify respirators that consistently perform at a high APF level; no agreement exists on how to determine APFs for these respirators based on design characteristics alone; no uniform testing criteria are available to use in determining APFs for these respirators; and ample evidence demonstrates that WPF or SWPF studies conducted under a variety of conditions reliably determine reliable and safe protection factors for these respirators. Therefore, OSHA is revising footnote 4 to Table 1 in the final standard to read as follows:

> The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

The Agency is setting an APF of 1,000 for tight-fitting facepiece PAPRs with hoods and helmets when the manufacturers of these respirators conduct testing that demonstrates that the respirators provide a level of protection of at least 1,000(*e.g.*, demonstrating WPFs of at least 10,000 or greater divided by a safety factor of 10, or lower fifth percentile SWPFs of at least 25,000 divided by a safety factor of 25). Based on its review of the record regarding these respirators, the Agency believes that tight-fitting facepiece PAPRs with hoods and helmets tested in a manner that is consistent with the SWPF testing performed previously under the ORC–LLNL study of respirators in this class (Ex. 3–4–1) will provide the required level of protection for employees who use these respirators.

While proposed footnote 4 emphasized that respirator manufacturers have responsibility for testing these respirators, it did not address who is responsible for selecting properly tested respirators. Consistent with Section 5 of the OSH Act (29 U.S.C. 654), which places the responsibility for employee protection on employers, footnote 4 in the final rule now clearly places the responsibility for proper respirator selection on employers. Accordingly, employers may use a respirator at an APF of 1,000 only when they have appropriate test results provided by the respirator manufacturer demonstrating that the respirator performs at a protection level of 1,000 or greater.

Evidence in the rulemaking record indicates that the technology exists to measure any leakage into the facepiece from the ambient atmosphere that could lessen the protection afforded by a PAPR or SAR with a helmet or hood (Ex. 16–9–1). This evidence also shows that small amounts of leakage measured by this technology during testing did not reduce the performance of the respirator below a level that was consistent with an APF of at least 1,000 (Exs. 3–4–1, 1–38–3, 1–64–12, and 1–64–40) Based on this evidence, OSHA believes that it is important for respirator manufacturers to determine, using available technology, that leakage into a respirator does not compromise the respirator's capability to maintain a level of performance throughout testing that is consistent with an APF of at least 1,000. Therefore, the Agency removed from footnote 4 in the final rule the language in proposed footnote 4 stating that ''only helmet/hood respirators that ensure the maintenance of positive pressure inside the respirator during use * * * receive an APF of 1000.''

Loose-fitting facepiece PAPRs with hoods or helmets. OSHA proposed an APF of 25 for loose-fitting PAPRs with hoods or helmets based on WPF studies described in the proposal (68 FR 34100), the NIOSH RDL, and the Z88.2–1992 ANSI respirator standard. In supporting the proposed APF, ISEA commented that ''as the reports of many WPF studies have shown, the performance of loose-fitting PAPRs with loose-fitting facepieces warrants a lower APF than for loose-fitting hoods and helmets'' (Ex. 9–24). Additional support came from Warren Myers, OSHA's expert witness at the rulemaking hearing, who stated:

> Our summary conclusion was that PAPRs were incorrectly considered as positive pressure devices by the respirator community and that a minimum certification air flow of 170 liters a minute, at least for the loose-fitting class of devices, does not necessarily provide a positive pressure operational characteristic with the respirator. And then finally, that the assigned protection factor for these devices with those types of air flows would be 25. (Tr. at 69.)

The WPF studies previously cited (68 FR 34100) demonstrate that OSHA based the proposed APF on valid data that were substantiated by the Myers study. OSHA concludes that an APF of 25 is appropriate for loose-fitting facepiece PAPRs with hoods or helmets, and therefore is retaining this APF for this respirator class in the final rule. No adverse comments regarding the proposed APF were submitted.

5. APFs for Supplied-Air Respirators (SARs)

Half mask SARs. The Agency based its proposed APF of 10 for this respirator class on the analogous performance between these respirators and negative pressure half mask air-purifying respirators tested in WPF and SWPF studies (68 FR 34100). Furthermore, the Agency proposed to give half mask SARs that function in continuous flow or pressure-demand modes an APF of 50, consistent with the analogous performance between these respirators and half mask PAPRs operated in a continuous flow mode during WPF and SWPF studies. Additional support for the proposed APFs came from the Z88.2–1992 ANSI respirator standard that assigned an APF of 10 to half mask airline SARs operated in the demand mode, and an APF of 50 to these respirators when operated in the continuous flow or pressure-demand modes. The 1987 NIOSH RDL also gave half mask demand SARs an APF of 10, but recommended an APF of 1,000 for these respirators when functioning in the pressure-demand or other positive-pressure modes.

OSHA received no comments or other information during this rulemaking regarding these proposed APFs. However, the Agency is confident that the available WPF and SWPF studies for half mask air-purifying respirators cited in the proposal provide sufficient data to retain an APF of 10 for half mask SARs when operated in the demand mode, and an APF of 50 for these respirators when operated in the continuous flow or pressure-demand modes. Therefore, OSHA is retaining these APFs in Table 1 of the final rule.

Full facepiece SARs. OSHA stated in the proposal that ''[n]o WPF or SWPF studies were available involving tight-fitting full facepiece SARs operated in the demand mode. Therefore, in the absence of any such quantitative data, the Agency assigned this respirator class an APF of 50'' (68 FR 34102). OSHA based the proposed APF on the analogous operational characteristics of these respirators and negative pressure full facepiece air-purifying respirators tested under WPF conditions in the demand mode. Also, the proposed APF is the same as the APF recommended for this respirator class by the 1987 NIOSH RDL.

The Agency proposed an APF of 1,000 for full facepiece SARs operated in continuous flow, pressure-demand, or other positive-pressure mode (68 FR 34102). It based the proposed APF on a SWPF study (Ex. 1–38–3) in which the results for these respirators showed geometric mean protection factors ranging from 8,500 to 20,000. Further justification for the proposed APF came from the similarity in operational characteristics between these respirators and tight-fitting full facepiece continuous flow PAPRs, which had a proposed APF of 1,000. The proposed APF for these respirators also was consistent with the APFs of 1,000 assigned to them under the Z.88.2–1992 ANSI respirator standard, and was substantially lower than the APF of 2,000 recommended for these respirators by the 1987 NIOSH RDL.

OSHA received no comments on full facepiece SARs operated in a demand, pressure-demand, or other positive-pressure mode. The Agency believes that the evidence in the proposal is sufficient to support an APF of 50 for these respirators when operated in the demand mode, and an APF of 1,000 when the respirators function in a pressure-demand or other positive-pressure mode, and has included these APFs in the final standard.

SARs with hoods or helmets. Based on a number of WPF studies, OSHA proposed an APF of 1,000 for continuous flow SARs with hoods or helmets, contingent on the manufacturers' demonstration that the respirators meet the criteria specified in Table 1 of the proposed standard (68 FR 34103). In responding to the proposed APF, Paul Schulte of NIOSH noted that an APF of 1,000 is appropriate for these respirators only when the manufacturer demonstrates that the models performed at this level (Ex. 9–13). ORC Worldwide stated that only SWPF data would give employers the assurance that the SAR offers the necessary protection for their workers (Ex. 10–27). ISEA recommended that further testing be performed before assigning an APF of 1,000 for continuous flow SARs with hoods and helmets (Ex. 9–22). MSA concluded that an APF of 1,000 is appropriate (Ex. 16–10) because, it asserted, every credible WPF study demonstrates that continuous flow SARs with hoods and helmets perform at an APF of 1,000.

These commenters generally agree that continuous flow SARs with hoods or helmets should be assigned an APF of 1,000 only after manufacturers demonstrate through appropriate WPF or SWPF studies that the respirators are capable of performing at an APF of 1000. Therefore, based on the evidence cited in the proposal, the comments from ORC Worldwide, NIOSH, and ISEA, and the absence of any new studies or evidence submitted in response to the proposal, OSHA is assigning these respirators an APF of 1,000 in the final rule only when the employer can provide evidence from the respirator manufacturers that demonstrates the respirators perform at that level; absent such testing, these respirators must receive an APF of 25.

Loose-fitting facepiece SARs. OSHA proposed an APF of 25 for this class of respirators based on analogous performance between these respirators and loose-fitting facepiece PAPRs (68 FR 34104). Additional support cited in the proposal included data from NIOSH showing that the two types of respirators (i.e., loose-fitting facepiece SARs and PAPRs) have the same minimum airflow rates when evaluated under 42 CFR part 84. The proposed APF also is consistent with the APF specified for respirators in the 1987 NIOSH RDL and the Z88.2–1992 ANSI respirator standard.

Commenters agreed with OSHA's proposed APF of 25 (Exs. 9–22 and 10–39; Tr. at 75 and 546). For example, Warren Myers stated, ''I believe it is reasonable for OSHA to use analogous operational characteristics between PAPRs and SARs equipped with loose-fitting hoods or helmets to set the APF for the SARs devices at 25'' (Tr. at 75). ISEA noted that WPF studies conducted on loose-fitting facepieces justify an APF of 25 for these respirators (Ex. 9–22). Based on these comments, the analogous performance with loose-fitting PAPRS, NIOSH certification testing at the same minimum flow rates, and the APFs given these respirators in the 1987 NIOSH RDL and the ANSI Z88.2–1992 respirator standard, OSHA has concluded that an APF of 25 is appropriate for this respirator class. Therefore, the final rule will list an APF of 25 for SARs with loose-fitting facepieces.

6. APF for Self-Contained Breathing Apparatuses (SCBAs)

Ed Hyatt, in 1976, assigned a protection factor of 50 to a full facepiece SCBA operated in the demand mode, the same protection factor he assigned to full facepiece SARs used in this mode. Based on results from a panel of 31 respirator users tested at LANL, he gave full facepiece SCBAs used in the pressure demand mode an APF of 10,000+ (Ex. 2). The 1980 ANSI respirator standard listed half mask and full facepiece SCBAs operated in the demand mode with APFs of 10 and 100, respectively, when qualitatively fit tested. The APFs for half mask or full facepiece SCBAs functioning in the demand mode were the protection factors obtained during quantitative fit testing, with this APF limited to the sub-IDLH value. Full facepiece SCBAs used in the pressure-demand mode received an APF of 10,000+. The 1987 NIOSH RDL recommended that half mask and full facepiece SCBAs operated in the demand mode receive APFs of 10 and 50, respectively, and that the APF for full facepiece SCBAs operated in the pressure-demand or other positive pressure mode be 10,000.

The Z88.2 subcommittee responsible for the 1992 ANSI respirator standard could not reach a consensus on an APF for full facepiece pressure-demand SCBAs. Available WPF and SWPF studies reported that, in some cases, the respirators did not achieve an APF of 10,000 (Ex. 1–50). Nevertheless, the subcommittee found that a maximum APF of 10,000 was appropriate when employers use the respirators for emergency-planning purposes and could estimate levels of hazardous substances in the workplace.

Two respirators equipped with hoods, Draeger's Air Boss Guardian and Survivair's Puma, have operational characteristics similar to SCBAs. The facepiece of the Draeger respirator consists of a hood with an inner nose cup and a tight-fitting seal at the neck, and an air cylinder that supplies breathing air to the facepiece. NIOSH reviewed this respirator in accordance with its 42 CFR part 84 certification requirements, and in January 2001 certified the respirator as a tight-fitting full facepiece demand SCBA when equipped with a cylinder having a 30-minute service life. NIOSH also approved the respirator for use in entering and escaping from hazardous atmospheres. In a May 16, 2001 letter to OSHA's Directorate of Enforcement Programs (Ex. 7–1), Richard Metzler of NIOSH justified the classification of the Draeger respirator as an SCBA on the basis that the neck seal, which is integral to the facepiece, forms a gas-tight or dust-tight fit with the face consistent with the definition of a tight-fitting facepiece specified by 42 CFR 84.2(k). This letter also noted that the fit testing procedures used for full facepiece demand SCBAs apply to the Draeger SCBA, and that, as a full facepiece demand SCBA, NIOSH recommended that the respirator receive an APF of 50 in accordance with its 1987 RDL.

NIOSH subsequently certified the Survivair Puma respirator, which has a tight-fitting hood supplied by an air cylinder, as a pressure-demand SCBA with a tight-fitting facepiece. As part of the 42 CFR part 84 certification process, NIOSH specified that the fit testing requirement for tight-fitting SCBAs would apply to this respirator. However, Steve Weinstein of Survivair (Ex. 7–2) stated that the hood totally encapsulates the respirator user's hair, making quantitative fit testing (e.g., with a Portacount) impossible. In such cases, the fit testing instrument treats dander and other material shed by the hair as particulates originating from outside the respirator, causing the fit factor to be artificially low. Nevertheless, qualitative fit testing with the hood is possible because Survivair provides an adapter and P100 filters for this purpose. Such fit testing meets the fit-testing requirements for tight-fitting SCBAs specified in paragraph (f)(8) of OSHA's Respiratory Protection Standard.

The table below provides a summary of APFs given to the half mask and full facepiece SCBAs by different groups.

SCBAs	APFs			1992 ANSI standard
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	
Tight-fitting half mask	10 (demand)	10 (demand; with QLFT) Same as QNFT factor (demand; sub-IDLH value max.).	10 (demand).	
Tight-fitting Full facepiece.	50 (demand)	100 (demand; with QLFT) Same as QNFT factor (demand; sub-IDLH value max.).	50 (demand).	
Tight-fitting Full facepiece.	10,000 (pressure demand).	10,000+ (pressure demand)	10,000 (pressure demand).	10,000 maximum (emergency planning purposes only).

OSHA received no new WPF or SWPF studies for tight-fitting half mask SCBAs and tight-fitting full facepiece SCBAs operated in the demand mode in response to the proposal. In the only WPF study conducted on full facepiece positive-pressure SCBAs, Campbell, Noonan, Merinar, and Stobbe of NIOSH assessed the performance of two different models of full facepiece pressure-demand SCBAs that met the NFPA 1981 air-flow requirements for respirators used by firefighters (Ex. 1–64–7). While the authors could not determine protection factors for these respirators because contaminant levels measured inside the facepiece were too low, pressure measurements taken inside the facepiece proved more useful. These measurements showed that four of the 57 test subjects (i.e., firefighters) experienced one or more negative pressure incursions inside the facepiece while performing firefighting tasks. After analyzing the data for these firefighters using two different methods, the authors estimated that the overall protection factor exceeded 10,000.

In the first of two SWPF studies performed on full facepiece SCBAs used in the pressure-demand mode, McGee and Oestenstad determined the protection afforded to members of a respirator test panel who used the Biopack 60 closed-circuit SCBA (Ex. 1–64–86). Three members of the panel had protection factors of 4,889, 7,038, and 18,900, with the remaining members having protection factors over 20,000. In the second study, Johnson, da Roza, and McCormack of LLNL (Ex. 1–64–98) tested the Survivair Mark 2 SCBA that met NFPA 1981 air-flow requirements. During testing, a panel of 27 test subjects exercised on a treadmill at 80% of their cardiac reserve capacity. Although the authors found negative pressure incursions inside the facepiece at high work rates, they concluded that the respirator ''provided [a minimum] average fit factor of 10,000 [for any single subject], with no single subject having a fit factor less than 5,000 at a high work rate.'' The tables below summarize the results of the WPF and SWPF studies performed on full facepiece pressure-demand SCBAs.

WPF studies for tight-fitting full facepiece pressure demand SCBAs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Campbell et al. (Ex. 1–64–7) Unspecified model (with NFPA-compliant airflow).	57	....	....	>10,000 (estimated).

SWPF studies for ight-fitting full facepiece pressure demand SCBAs (by name of authors & mode of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
McGee and Oestenstad (Ex. 1–64–86) Biopack 60 (closed circuit)	23	>20,000	....	....
Johnson et al. (Ex. 1–64–98) Survivair mark 2 with NFPA-compliant airflow)	27	29,000	1.63	....

Janice Bradley (Ex. 9–22) of the International Safety Equipment Association and Kenneth Bobetich of the MSA Company (Ex. 9–37) both stated that footnote 5 in the proposed OSHA APF Table 1 was not necessary because most SCBA models now meet the increased air-flow requirements in the NFPA 1981 standard. They further noted that the study that served as the basis of the footnote was more than 15 years old, and that OSHA should remove the footnote. They recommended that the APF should be 10,000 for pressure-demand SCBAs that meet the air-flow requirements of NFPA 1981. Janice Bradley (Tr. at 531) cited the WPF study NIOSH performed with firefighters (Ex. 1–64–7) as supporting the conclusion that SCBAs meeting the NFPR 1981 requirements would provide APFs of 10,000.

Summary and conclusions. OSHA is setting APFs of 10 and 50, respectively, for tight-fitting half mask SCBAs and tight-fitting full facepiece SCBAs operated in the demand mode. In the absence of any new WPF and SWPF studies on these respirators, the Agency is basing the final APFs on analogous operational characteristics between these respirators and half mask facepiece and full facepiece air-purifying respirators, that have APF values of 10 and 50, respectively. In addition, the final APFs are consistent with the APFs recommended by the 1987 NIOSH RDL for these respirators. (Note that the 1992 ANSI standard did not assign APFs for these respirator classes.)

For tight-fitting full facepiece SCBAs used in the pressure-demand or other positive pressure modes, OSHA is setting an APF of 10,000 in the final standard, which is consistent with the 1987 NIOSH RDL and the 1992 ANSI respirator standard. Empirical support for the final APF comes from the WPF study conducted by Campbell, Noonan, Merinar, and Stobbe (Ex. 1–64–7). This study showed that protection factors for these respirators, when operating at NFPA-compliant air flows, far exceed 10,000. While four respirator wearers experienced momentary negative-pressure spikes inside their facepieces, which indicates possible leakage into the facepiece under some workplace conditions, these spikes did not impair overall respirator performance. The Agency concludes that these study results justify an unrestricted APF of 10,000 for tight-fitting full facepiece SCBAs.

For the class of respirators designated as pressure-demand SCBAs with tight-fitting hoods or helmets, including the Survivair Puma, OSHA is setting an APF of 10,000. The basis for this final APF is the analogous operational characteristics between these respirators and tight-fitting full facepiece pressure-demand SCBAs.

D. Definition of Maximum Use Concentration

Employers use MUCs to select appropriate respirators, especially for use against organic vapors and gases. MUCs specify the maximum atmospheric concentration that an employee can experience while wearing a specific respirator or class of respirators. MUCs are a function of the APF determined for a respirator (or class of respirators), and the exposure limit of the hazardous substance in the workplace.

1. Introduction

Ed Hyatt, in the 1976 LASL report on respiratory protection factors (Ex. 2, Docket H049), recounted the early history of MUCs, starting with the MUC recommendations of the joint AIHA–ACGIH committee in 1961. This committee recommended that, for highly toxic compounds, full facepiece respirators with HEPA filters use a maximum limit of 100 times the TLV. Hyatt noted that Dr. Letts in 1961 in the United Kingdom, recommended that half mask dust respirators provided effective protection against airborne contaminant levels no greater than 10 times the TLV.

In 1974, NIOSH and OSHA started the Standards Completion Program to develop standards for substances with existing PELs. As part of this process, the initial respirator decision logic was developed and the concept of MUCs began to be used. NIOSH Criteria Documents also recommended MUCs for different types of respirators. The information for these MUCs were obtained from various sources, including NIOSH Current Intelligence Bulletins and recognized industrial hygiene references. NIOSH later published this information in its Pocket Guide to Chemical Hazards. Other source documents for MUC definitions and regulations include the 1987 NIOSH RDL, and the ANSI Z88.2–1980 and ANSI Z88.2–1992 respiratory protection standards.

OSHA's 1994 proposed Respiratory Protection Standard contained the following definition of MUC:

> *Maximum use concentration (MUC)* means the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor. The MUC cannot exceed the use limitations specified on the NIOSH approval label for the cartridge, canister, or filter. The MUC can be determined by multiplying the assigned protection factor for the respirator by the permissible exposure limit for the air contaminant for which the respirator will be used. (59 FR 58884.)

Several commenters to this 1994 proposal recommended alternatives to this definition. Reynolds Metal Company recommended defining MUC as "the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor" (Ex. 1–54–222). The American Petroleum Institute (API) noted NIOSH developed the term "MUC," and that, to avoid confusion, OSHA should not use the term (Ex. 1–54–330). API proposed using the term "assigned use concentration" to replace MUC. API defined "assigned use concentration" as "the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor'' (Ex. 1–54–330). However, when the Agency published the final Respiratory Protection Standard in 1998, it reserved the definition of MUC in paragraph (b), and the MUC requirements in paragraph (d)(3)(i)(B), for future rulemaking because it reserved the APF provisions of the respirator selection section of the standard (i.e., MUCs could not be determined without knowing the APF values).

In the June 6, 2003 proposal, OSHA defined MUC as follows:

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC usually can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the permissible exposure limit, short-term exposure limit, ceiling limit, peak limit, or any other exposure limit used for the hazardous substance. (68 FR 34036.)

Under this definition, MUC represents the maximum atmospheric concentration of a hazardous substance against which a specific respirator or class of respirators with a known APF can protect employees who use these respirators. Accordingly, MUCs are a function of the APF determined for a respirator (or class of respirators) and the exposure limit of the hazardous substance in the workplace.

The last sentence in the definition describes the MUC in terms of a mathematical calculation, i.e., that employers can ''usually'' determine the MUC by multiplying the APF for the respirator by the exposure limit used for the hazardous substance.[10] The last sentence of the proposed definition also specifies the exposure limits as ''permissible exposure limit (PEL), short-term exposure limit (STEL), ceiling limit (CL), peak limit, or any other exposure limit used for the hazardous substance.'' Although OSHA received no comments on the proposed definition, it nevertheless is making several minor revisions to the definition in the final rule. First, the Agency is removing the term ''usually'' from the definition because multiplying the assigned protection factor by the exposure limit for a hazardous substance is the currently accepted method used by safety and health professionals for calculating MUCs. Absent any other accepted method, the term ''usually'' is confusing and unnecessary.

The second revision to the proposed MUC definition involves the last part of the second sentence, which required employers to consider an ''exposure limit'' when determining an MUC. OSHA is making two changes to this proposed language to make clear its intent regarding the information employers need to consider when making this calculation. First, OSHA is clarifying the language to require employers to calculate an MUC using an OSHA exposure limit in those instances where one exists. OSHA was concerned that employers could have misinterpreted the language in the proposed MUC definition as meaning that they could use any available exposure limit for calculating an MUC (and, by implication, for protecting employees from hazardous airborne contaminants). This revision emphasizes the priority that OSHA exposure limits have in regulating hazardous airborne contaminants.

Second, OSHA is changing the language to make clear the information employers need to consider to determine an MUC in the absence of an OSHA exposure limit. The Agency revised the language to require employers to use relevant available information and informed professional judgment when determining an MUC when no OSHA exposure limit exists. This language more clearly states OSHA's intent that employers can utilize a wide range of available information in calculating an MUC when OSHA has not yet promulgated an exposure limit for a hazardous airborne contaminant. While not required, some employers may choose to conduct individualized risk assessments of hazards. Others may consult information from manufacturers or other published exposure limits (e.g., the NIOSH RELs or the AIHA WEELs) for making MUC determinations. However, whatever approach employers choose to take, the MUC must provide adequate protection for their employees. OSHA believes this approach provides employers with greater flexibility than the proposed MUC definition while still maintaining employee protection.

The Agency also broadened the language in this second sentence by requiring employers to ''take the best available information into account'' when determining an MUC in the absence of an OSHA exposure limit. This language is consistent with the guidance that the Agency provided to employers in the preamble to the Respiratory Protection Standard for determining APFs in the absence of a final APF standard (see, e.g., 63 FR 1203). OSHA believes this language gives employers maximum flexibility to develop MUCs that protect their employees from hazardous airborne contaminants, including the use of other exposure limits when appropriate.

In the proposal to this final rule, OSHA requested comments on the development of the MUC for substances with no OSHA PEL, limiting factors such as eye irritation, LELs and IDLHs, and mixtures of substances (68 FR 34112). OSHA received numerous comments on these issues, as well as on hazard ratios, an issue raised by several commenters. These issues are discussed in the following sections.

2. MUCs for Substances With No OSHA PEL or Other Limiting Factors

OSHA received many comments on this issue. Some commenters believed that in the absence of a PEL it is appropriate for the Agency to require calculation of MUCs based on other information (Exs. 10–54, 9–27, and 10–3). Other commenters supported using any occupational exposure limit for this purpose, but some of these commenters specified that no other limiting factors should be used (Exs. 9–26, 9–42, 10–27). Others specified that additional limiting factors were needed (Exs. 9–13, 9–15, 9–29, 10–6, and 10–60). Several commenters recommended using only the OSHA PELs with limiting factors (Ex. 10–17, 10–25, and 9–16) or without limiting factors (Exs. 9–22 and 9–23). A few commenters addressed limiting factors only, either supporting specific factors (Exs. 9–12 and 10–1) or stating that no limiting factors were needed when determining MUCs (Ex. 9–37). These comments are discussed in the following paragraphs.

W.M. Parris of Alabama Power (Ex. 9–15) proposed the following generic definition of MUC that would include all possible MUCs:

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator. The MUC will be the lowest of the following: (1) IDLH value for the substance, (2) the LEL value, (3) limitations set by manufacturer, or (4) mathematically determined by multiplying the assigned protection factor specified for the respirator by the permissible exposure limit, short term exposure limit, ceiling limit, peak, or another occupational exposure limit used for the hazardous substance.

Paul Schulte of NIOSH (Exs. 9–13, 13–11–1, and 16–4) recommended that

[10] For example, when the hazardous substance is lead (with a PEL of 50 $\mu g/m^3$), and the respirator used by employees has an APF of 10, then the calculated MUC is 500 $\mu g/m^3$ or 0.5 mg/m^3 (i.e., 50 $\mu g/m^3 \times 10$).

employers use the RELs, or in the absence of a REL, another appropriate exposure limit. Schulte also stated that, for both regulated and non-regulated substances, the MUC for any respirator other than a pressure-demand SCBA should never exceed the IDLH value. Schulte noted further that NIOSH did not agree with the use of the LEL as an appropriate respirator-selection factor for MUCs unless the respirator is the source of an ignition hazard (e.g., respirators with communication systems). Accordingly, Schulte (Ex. 9–13) proposed revising the MUC definition to read as follows:

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the lesser of

- APF times (x) exposure limit
- The respirator manufacturer's maximum use concentration for a hazardous substance (if any)
- The IDLH, unless the respirator is a positive-pressure, full facepiece SCBA

Daniel K. Shipp of the International Safety Equipment Association (ISEA) (Ex. 9–22) commented that ISEA believed that OSHA should not expand the MUC definition to include MUCs for hazardous substances not regulated by OSHA, and that the definition should not involve limiting factors. He indicated that employers should have the flexibility to determine what to do in these situations. Shipp also stated that the NIOSH approval labels on chemical cartridges already read ''Do not exceed maximum use concentrations established by regulatory standards.'' In this regard, he suggested that OSHA rewrite the MUC definition to require that MUCs used to select respirators shall not be exceeded.

Michael Sprinker of the International Chemical Workers Union Council of the United Food and Commercial Workers Union (Ex. 10–54) believed that OSHA's definition of MUC should be revised because it is unclear whether the MUC is a concentration never to be exceeded or a time weighted average. He also stated that OSHA should require employers to determine MUCs for substances for which no OSHA PEL is available, and that these MUCs can be derived from occupational exposure limits issued by NIOSH, ACGIH, EPA, or the manufacturer.

Robert W. Barr and Linda M. Maillet of Alcoa, Inc. (Exs. 9–26 and 10–31) said that OSHA should not expand the definition and application of MUCs to hazardous substances it does not regulate because that would constitute adoption of these exposure limits as OSHA rules. The Alcoa representatives said that employers should be free to select the criteria for calculating MUCs based on their own risk assessments. Also, they did not want the lower NIOSH RELs to replace OSHA PELs in calculating MUCs. They did not believe that OSHA should specify the LEL or 10% of the LEL as a limiting factor because LEL is an independent indicator of a physical hazard. They asserted that respirator users who could be exposed to an explosive level of a substance must not enter such an area because of the physical hazard—the characteristics of their respirators are irrelevant in such situations. Similarly, Daniel P. Adley and William L. Shoup of the Society for Protective Coatings (Ex. 9–10) did not agree with the ''or any other exposure limit'' in the definition of MUC, which would give regulatory authority to TLVs, RELs, and other industry—established exposure limits.

Bill Kojola of the AFL–CIO (Exs. 9–27 and 16–5) believed that OSHA should expand the definition and application of MUC to include substances it does not regulate, and that the exposure limits issued by NIOSH, ACGIH, EPA, or the manufacturer should be used when available. Pete Stafford of the Building and Construction Trades Department, AFL–CIO (Ex. 9–29) recommended that OSHA expand the definition of MUC to include appropriate exposure values because thousands of harmful and potentially harmful chemicals used in the workplace are not regulated by OSHA. He indicated that alternative MUCs calculated for chemicals using a non-OSHA exposure limit should be used when these MUCs are lower than the MUCs determined from using PELs. He also recommended that OSHA specify 10% of the LEL as a limiting factor for MUCs.

Stephan C. Graham of the United States Army Center for Health Promotion and Preventive Medicine (Exs. 9–42, 9–42–1, and 9–42–2) indicated that OSHA should expand the MUC definition to include hazardous substances it does not regulate. However, he did not believe that NIOSH MUCs should be used when they are lower than the MUCs calculated using OSHA PELs. Rick N. Givens of Augusta Utilities Department (Ex. 10–2) also agreed that OSHA should require employers to calculate MUCs for substances that do not have OSHA PELs. Ken M. Wilson of the Division of Safety & Hygiene, Ohio Board of Water Control (Ex. 10–3) stated that OSHA should require employers to determine MUCs for substances that have no OSHA PEL because many of these substances can harm employees.

David L. Spelce (Ex. 10–6) stated that the PELs in 29 CFR 1910.1000 were adopted by OSHA in 1971 and came mostly from the 1968 ACGIH TLVs. He recommended that OSHA require employers to use the ACGIH TLVs and AIHA Workplace Environmental Exposure Levels when no OSHA PEL exists. He indicated that these alternative values also should be used when they are more stringent than the OSHA PELs. He agreed with OSHA that when the IDLH level is lower than the calculated MUC, the IDLH concentration must take precedence. In such circumstances, only the most protective atmosphere-supplying respirators should be used. He also stated that IDLH limits should be established based on toxicological data, but, in the absence of toxicological data, 10% of the LEL should be used as the limiting factor (i.e., having the same weight as the IDLH for flammable substances).

Thomas C. O'Connor of the National Grain and Feed Association (NGFA) (Exs.10–13 and 16–19) recommended a revised MUC definition that would read as follows:

Maximum use concentration (MUC) * * * usually can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the permissible exposure limit or ceiling value as appropriate. In a situation when such regulatory limits have not been set by OSHA, the employer may rely on limits established by non-regulatory organizations based on professional judgment and the working environment.

However, he (Ex. 10–13) said that NGFA strongly opposes requiring employers to determine MUCs for substances for which no OSHA PELs are available. The NGFA also opposed any requirement that employers rely on MUCs developed by NIOSH, but supported the use of non-OSHA exposure limits as aids employers can use in establishing MUCs.

Thomas Nelson of NIHS, Inc. (Ex. 10–17) indicated that OSHA should not require employers to determine MUCs for substances that have no OSHA PELs. Nelson said that OSHA first must determine when a need for such exposure limits exists, and then issue new PELs. Furthermore, Nelson stated that OSHA cannot rely on other groups to establish limits for OSHA's use. He also said that the only limiting factors that should be used in calculating MUCs are APFs and IDLHs, and that the Agency should specify the LEL, or a value close to the LEL (e.g., 90% of the

LEL), when no IDLH exists for a substance.

Lorraine Krupa-Greshman of the American Chemistry Council (ACC) (Ex. 10–25) indicated that NIOSH MUCs should not be adopted as a specific requirement, but should remain available for guidance. The ACC also does not support requiring compliance with NIOSH MUCs when they are lower than OSHA's MUCs. The ACC recommends a requirement for employers to determine the appropriate MUCs for substances that do not have an OSHA PEL. However, employers should be allowed to designate and document the basis for these MUCs using either the OSHA formula or other criteria. She stated that the IDLH is a reasonable limit on the MUC for some types of respirators, and that an IDLH should be based on health effects. She noted that using the LEL or a percentage of the LEL to limit MUCs is confusing and inappropriate because an LEL is used to determine whether an employee can safely enter an area with a fire hazard, not for selecting respirators.

Frank A. White of ORC Worldwide (Ex. 10–27) stated that OSHA should not require employers to calculate MUCs for substances that have no OSHA PEL, but that employers should have the freedom to select the occupational exposure limits used for calculating MUCs based on their own risk assessments. He emphasized that it is important that employers be able to show the documented evidence used to support their MUC decisions. ORC Worldwide also indicated that OSHA should not expand the application of MUCs to hazardous substances it does not regulate because these exposure limits (e.g., developed by chemical manufacturers, ACGIH, NIOSH, EPA) would become OSHA regulations. He also stated that OSHA should not enforce the 1994 NIOSH IDLHs, but instead should continue to rely on those IDLHs that NIOSH developed in 1990. OSHA should not use either the LEL or 10% of the LEL as a limiting factor because these factors are not health-based, and are used as indicators of a physical hazard.

Ted Steichen of the American Petroleum Institute (Ex. 9–23) believed that the determination of MUCs for substances with no OSHA PELs should be left to the good practices of the employer. He stated that OSHA would be exceeding its authority if it expanded the definition and application of MUC to hazardous substances that it does not regulate. Steichen said that the use of the LEL to limit the MUC is confusing and inappropriate. He stated that the LEL has no relationship to the protection provided by a respirator, but is an essential factor to consider when working with flammable or combustible materials.

Paul Hewett of Exposure Assessment Solutions, Inc. (Ex. 10–60) believed that OSHA should require employers to determine MUCs for those substances that have no OSHA PEL. He pointed out that employers already are required to consider all hazardous substances, including those substances without an OSHA PEL, under the ''recognized hazards'' provision of the general-duty clause of the OSH Act. He recommended that OSHA indicate, either by regulation or by repeated emphasis in the preamble of this final standard and in all respirator guidelines, that these requirements also apply to overexposures involving unregulated substances. Hewett also stated that OSHA should not require employers to comply with MUCs calculated using NIOSH RELs when these MUCs are lower than the MUCs calculated using OSHA PELs. He recommended as well that OSHA should specify an upper bound on MUCs that is a percentage of the IDLH for a substance, e.g., the MUC is no more than 25% of the IDLH.

Michael Watson of the International Brotherhood of Teamsters, AFL–CIO (Ex. 9–12), Pete Stafford of the Building and Construction Trades Department, AFL–CIO (Ex. 9–29), and Rick N. Givens of the Augusta Utilities Department (Ex. 10–2) agreed with using the IDLH as a limiting factor for MUCs. Givens also recommended that OSHA specify 10% of the LEL as an additional limiting factor for MUCs.

Michael Runge of the 3M Company (Exs. 9–16, 16–25, and 16–25–2) said that only APFs and IDLHs should be used to calculate MUCs. The LEL and eye irritation, as well as all other limitations, already are considered in the respirator selection process, and do not necessarily need to be considered when establishing specific MUCs. He did not support use of 10% of the LEL as a limiting factor, but stated that OSHA should specify the LEL when no IDLH is available for a chemical. He also stated that when employers use the REL for an unregulated contaminant to select a respirator, the APF and MUC principles specified in the proposal should apply.

Kenneth Bobetich of Mine Safety Appliances (Ex. 9–37) believed that OSHA's definition of MUC is sufficient to cover the limitations, and that MUCs should not be based on eye irritation. Tracy C. Fletcher of Parsons-Odebrecht JV (Ex. 10–1) recommended that OSHA use 10% of the LEL as an MUC-limiting factor. Accordingly, when the atmosphere reaches 10% of the LEL, the employee should be removed and steps taken to make the work area safe (e.g., ventilate the area). When the area cannot be made safe, the employer should provide the employee with a fire-retardant suit and supplied air.

3. Summary and Conclusions

As noted above in the discussion of the MUC definition, the final standard will require employers to use an OSHA exposure limit when available. However, absent an OSHA exposure limit, employers must use relevant available information combined with informed professional judgment to determine MUCs. The purpose of this approach is to permit employers to rely on existing data sources and professional judgment when determining an MUC that will provide adequate protection for their employees from hazardous airborne contaminants that have no OSHA exposure limit.

E. MUCs for Mixtures and Hazard Ratios

1. MUCs for Mixtures

Paragraph (d)(3)(i)(B)(1) requires employers to select respirators for employee use that maintains the employees exposure to the hazardous substance at or below the MUC. However, a question arises regarding how to make these calculations for mixtures. Question 12 in Section VIII. (''Issues'') of the proposal addressed this issue by requesting comments on the proposed MUC for mixtures., About half of the commenters supported the MUC provisions as proposed, but believed that insufficient data were available to perform the calculations for mixtures (Exs. 9–23, 9–37, 10–17, 10–25, and 10–59). Another group of commenters supported performing the calculations based on information that each component of a mixture has a non-additive effect on independent organ systems. In this case, the commenters suggested either a separate MUC for each component, or lowering the MUC according to the proportion of each component in the mixture (Exs. 9–12, 9–13, 9–22, 9–29, and 9–37). Still others recommended lowering the MUC by an unspecified proportion when individual components of the mixture have synergistic effects on organ systems (Ex. 9–42), or simply requiring employers to use supplied-air respirators when employees are exposed to mixtures (Ex. 10–1).

Daniel K. Shipp of the International Safety Equipment Association (Ex. 9–22) pointed out that the effect of the mixture on canister/cartridge service life must be evaluated, and an appropriate change schedule established for a mixture of gases or vapors. Shipp indicated that no MUC equation is available for mixtures. He suggested that when the health effects of a mixture's components are not additive, then each component should be evaluated separately, and the respirator must be appropriate for the sum of the individual chemical concentrations.

Kenneth Bobetich of Mine Safety Appliances (Ex. 9–37) noted that no evidence exists to indicate that respirator performance is different when the exposure is to a mixture of particulates versus a single particulate. However, the effect of a mixture of gases or vapors on canister/cartridge service life must be evaluated, and an appropriate change schedule established. He further mentioned that Dr. Gerry Wood of LANL is conducting a study to evaluate the effect of mixtures on service life, and is developing a model to predict cartridge service life. Bobetich indicated that when the health effects of the mixture components are on the same organ system and these effects are additive, an additive formula can be used to establish the PEL for the mixture. However, when the health effects are not additive, then each component should be evaluated individually and the respirator must be appropriate for the sum of the individual chemical concentrations.

Thomas Nelson of NIHS, Inc. (Ex. 10–17) said that, because exposures to multiple organic vapors will affect the service life of a cartridge, the employer already is required to consider multiple contaminants in setting a cartridge change schedule. He recommended that, to determine the MUC for a mixture that affects the same organ system, employers should assume that the health effects of each component are additive.

Frank A. White of ORC Worldwide (Ex. 10–27) indicated that exposure to multiple gas or vapor contaminants may affect the service life of respirator filters and cartridges differently than exposure to a single contaminant. He, too, mentioned that Dr. Gerry Wood is working on this issue with NIOSH, and that a service life calculation model for multiple contaminants will soon be available. He emphasized that the more important consideration in determining MUCs for mixtures is the health effects of multiple contaminants. He stated that the employers are in the best position to apply recommendations from chemical manufacturers and information on health effects to their specific workplaces. He noted that industrial hygienists should determine if the contaminants have additive health effects, and they should use the additive mixture formula set by ACGIH and OSHA to calculate the MUC.

Michael Watson of International Brotherhood of Teamsters, AFL-CIO (Ex. 9–12) and Pete Stafford of the Building and Construction Trades Department, A FL-CIO (Ex. 9–29) stated:

> The presence of multiple contaminants in the workplace should be taken into consideration when the employer determines the MUC and respirator change schedules for gases and vapors. Mixtures may have similar effects on chemical cartridge loading, so the MUC of each component of a mixture should be lowered in proportion to its percentage of the total concentration of contaminants in air.

Paul Schulte of NIOSH (Exs. 9–13, 13–11–1, and 16–4) recommended that the equation $C_1/MUC_1 + C_2/MUC_2 + * * * + C_n/MUC_n = 1$ should be used to determine MUCs for mixtures. He asserted that the MUC would be safe only when the result is ≥1. Schulte also stated that the rated service life of the cartridge may be shortened during exposure to a mixture (i.e., one or more of the mixture's components may break through before the rated end-of-service-life).

Ted Steichen of American Petroleum Institute (Ex. 9–23) indicated that no data are available comparing respirator performance during exposure to multiple contaminants and exposure to single contaminants, and that it is impractical to discuss establishing different MUCs for mixtures. Stephan C. Graham of the United States Army Center for Health Promotion and Preventive Medicine (Exs. 9–42, 9–42–1, and 9–42–2) stated that MUCs for mixtures should differ from MUCs for single compounds depending on whether the health effects are additive or synergistic.

Tracy C. Fletcher of Parsons-Odebrecht JV (Ex. 10–1) believed that supplied-air respirators should be used to eliminate the risk of filter failure caused by chemical reactions that may occur among the components of a mixture. Lorraine Krupa-Greshman of the American Chemistry Council (ACC) (Ex. 10–25) indicated that by addressing contaminants with additive effects, 29 CFR 1910.1000(d)(2)(i) and the proposal provide adequate means of achieving suitable protection. Also, she said that MUCs can be developed for multiple contaminants that have independent health effects by using the change schedule provisions of 1910.134(d)(3)(iii)(B)(2). The ACC does not believe that adequate information and data are available to develop MUCs for mixtures with synergistic effects.

Lisa M. Brosseau of the University of Minnesota (Ex. 10–59) believed that the issue of mixtures, as addressed in the proposal, is confusing and incorrect. She stated that the only requirements needed are to assure that respirators have the required filters and that gases and vapors have appropriate cartridges.

2. Use of Hazard Ratios

Michael Runge of the 3M Company (Ex. 9–16), Daniel K. Shipp of the International Safety Equipment Association (Ex. 9–22), and Lisa M. Brosseau of the University of Minnesota (Ex. 10'59) supported another method for selecting respirators, the hazard ratio (HR). The HR is defined as the ratio of the workplace concentration of an airborne contaminant divided by the occupational exposure limit (e.g., PEL). Any respirator that has an APF equal to or greater than the HR may be selected. They stated that the HR is more useful to employers than MUCs because employers likely will have information on airborne concentrations and occupational exposure limits when selecting respirators. Both Runge and Shipp said that the HR is similar to the MUC. Brosseau noted that it makes more sense to use the HR rather than the MUC to select respirators, and she recommended that OSHA require the HR method, and use the MUC as guidance.

OSHA is not adopting hazard ratios under this final rulemaking because it was not addressed in the notice of proposed rulemaking. Accordingly, OSHA would have to provide the public with notice and an opportunity for comment on this issue before taking such action.

3. Summary and Conclusions

OSHA agrees with the commenters who stated that the data on mixtures are limited, and that no revision is needed for OSHA's proposed single-contaminant MUC definition (Exs. 9–23, 9–37, 10–17, 10–25, and 10–59). The existing requirement for setting change schedules for respirator cartridges and canisters specified in 29 CFR 1910.134 (d)(3)(iii)(B)(2) already requires that employers consider the effects of each component in organic vapor mixtures when they develop change schedules. The Agency recognizes that reliable methods are not available to develop MUCs for mixtures based on whether the components of the mixture act additively or synergistically, and whether they affect the same organ or different organs. Therefore, OSHA will rely on the provisions at 29 CFR 1910.1000(d)(2)(i) to assist employers in calculating MUCs.

While the determination of MUCs and service life are both necessary for respirator selection, they should not be confused. MUCs can be used to decide if a certain type of respirator even qualifies for consideration for use in defined workplace concentrations. Service life estimation identifies how long a properly selected respirator can be expected to provide worker protection and, therefore, is useful for setting change schedules.

OSHA has established at 29 CFR 1910.1000(d)(2)(i) an equivalent exposure requirement for mixtures of air contaminants. Accordingly, MUCs for respirators used in a mixture of contaminants must satisfy the following equation:

$$E_m = (C_1 \div L_1 + C_2 \div L_2) + * \ * \ * + (C_n \div L_n)$$

Where:

E_m is the equivalent exposure for the mixture

C is the concentration of a particular contaminant

L is the exposure limit for that substance

The value of E_m shall not exceed unity (1).

OSHA is maintaining the MUC as a requirement in the final standard for determining the maximum concentration of an airborne contaminant from which a respirator will protect an employee. In addition, the Agency cannot revise the final rule to mandate the use of hazard ratios because the regulated community must have adequate notice of, and an opportunity to comment on, any such revision to the standard.

F. MUC Provisions

1. Paragraph (d)(3)(i)(B)—MUC Provisions

These final requirements consist of three separate paragraphs ((d)(3)(i)(B)(*1*) through (d)(3)(i)(B)(3)). Paragraph (d)(3)(i)(B)(*1*), which sets the requirements for the use and application of MUCs, reads, ''The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.'' This paragraph, which has the same designation in the proposal, requires employers to select respirators for employee protection that are appropriate to the ambient levels of the hazardous substance found in the workplace, i.e., that the ambient level of the hazardous substance must never exceed the MUC, which is the exposure limit specified for the hazardous substance multiplied by the respirator's APF. Accordingly, this provision ensures that employers maintain employees' direct exposure to hazardous substances (i.e., inside the respirator) below levels specified by OSHA's Z tables and substance-specific standards, and, when OSHA has no standards, below exposure levels determined by the employer. Therefore, this provision provides employee protection consistent with existing regulatory requirements and prevailing industrial-hygiene practice.

In the MUC provision following paragraph (d)(3)(i)(B)(*1*) in the proposal, OSHA had incorporated a note that stated: ''MUCs are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance and use requirements.'' The Agency is removing this note because the program already is required under its Respiratory Protection Standard for all employers using respirators, and OSHA believes that duplicating this information in a note is unnecessary.

The second MUC provision in the proposal, paragraph (d)(3)(i)(B)(*2*), required employers to use MUCs determined by respirator manufacturers when those MUCs were lower than the MUCs determined using the general calculation (i.e., MUC = APF × PEL). Several commenters objected to the proposed provision, stating that it gave regulatory status to manufacturer's MUCs (e.g., Exs. 9–10, 9–22, 9–23, 9–24, 9–26, and 10–13). However, the Agency often defers in its rules to instructions and other documents published by manufacturers (e.g., no fewer than seven provisions of OSHA's Respiratory Protection Standard refer to manufacturers' instructions or recommendations). Nevertheless, the Agency believes that the proposed provision is unnecessary because using the general calculation specified in the MUC definition is an accepted safe practice in the industrial-hygiene community.

Paragraph (d)(3)(i)(B)(2) of the final MUC provisions (which was designated as paragraph (d)(3)(i)(B)(*3*) in the proposal) specifies that employers must not use MUCs to select respirators for employees who are entering an IDLH atmosphere. OSHA previously specified the requirements for selecting respirators for use in IDLH atmospheres in paragraph (d)(2) of its Respiratory Protection Standard. Paragraph (d)(2) requires employers to select for this purpose a full facepiece pressure-demand SCBA certified by NIOSH to have a service life of at least 30 minutes, or a combination full facepiece pressure-demand supplied-air respirator with an auxiliary self-contained air supply. In the preamble to the final Respiratory Protection Standard, the Agency justified selecting these respirators as follows: ''In [IDLH] atmospheres there is no tolerance for respirator failure. This record supported OSHA's preamble statement that IDLH atmospheres 'require the most protective types of respirators for workers' '' (59 FR 58896). Commenters to the APF proposal, including NIOSH, ANSI, and representatives of both labor and management, agreed that employees should use these respirators, which are the most protective respirators available, when exposed to IDLH atmospheres. (See 63 FR 1201 for a more complete discussion of these comments.)

Ted Steichen of the American Petroleum Institute (Ex. 9–23) requested that OSHA clarify that a pressure-demand full facepiece SAR with auxiliary SCBA can be used at an APF higher than 1,000. He said that positive-pressure SARs with auxiliary SCBAs often are used by the petroleum industry for non-emergency work in high-hazard operations (e.g., cleaning refinery flare systems) that may involve potential exposures greater than 1,000 times the PEL. Under proposed Table 1, he questioned whether OSHA would consider this use of SARs with auxiliary SCBAs to be acceptable. The Agency notes that paragraph (d)(2)(i)(B) of its Respiratory Protection Standard already permits employers to use a combination full facepiece pressure-demand supplied-air respirator (SAR) with auxiliary self-contained air supply in IDLH atmospheres. Also, paragraph (d)(3)(i)(A) of this final standard states, ''When using a combination respirator * * * employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.'' In this case, the combination pressure-demand full facepiece SAR with auxiliary SCBA respirator is equivalent to an SCBA, and, therefore, the APF for an SCBA applies.

The last MUC provision, proposed paragraph (d)(3)(i)(B)(*4*), would have required that ''[w]hen the calculated MUC exceeds another limiting factor such as the IDLH level for a hazardous substance, the lower explosive limit (LEL), or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.'' Accordingly, the IDLH limits for hazardous substances would take precedence over the calculated MUC when the IDLH limits result in lower employee exposures to the hazardous substances. Consequently, this provision increases employee protection against these hazardous substances. OSHA is retaining a revised version of this proposed provision in the final rule (redesignated as paragraph (d)(3)(i)(B)(*3*)). The remaining paragraphs of this subsection discuss the revisions.

The previous discussion of MUCs for substances with no OSHA PEL or other limiting factors (see subsection 2 (''MUCs for Substances with No OSHA PEL or Other Limiting Factor'') of this section) addressed the use of the LEL as a limiting factor to be considered when calculating the MUC. NIOSH did not agree with the use of the LEL as a limiting factor for MUCs in respirator selection unless the respirator is the source of an ignition hazard (Ex. 9–13). Alcoa, Inc. did not believe OSHA should use the LEL as a limiting factor for MUCs since the LEL ''is not health-based, rather it is an independent indicator of a physical hazard'' (Ex. 10–31). The American Chemical Council commented using the LEL to set MUCs was confusing and inappropriate, because the LEL is used to determine whether an employee can safely enter an area with a fire hazard, not for selecting respirators (Ex. 10–25). The American Petroleum Institute also questioned the use of the LEL to limit the MUC because the LEL has no relationship to the protection provided by a respirator, but is a factor to consider when working with flammable or combustible substances (Ex. 9–23). The 3M Company stated that the LEL already is required under the Respiratory Protection Standard when selecting respirators, and does not need to be taken into account when establishing specific MUCs (Ex. 9–16).

The Agency agrees with these commenters that the LEL is not appropriate as a limiting factor in setting MUCs. Therefore, OSHA removed from paragraph (d)(3)(i)(B)(*3*) in the final rule the language that identified the LEL as a limiting factor in setting MUCs. The Agency made this revision to the proposal because the LEL is not related to the performance of the respirator, but is an independent indicator of a physical hazard (i.e., the flammability or combustibility of a substance) that already must be considered when determining whether an employee can safely enter a hazardous area.

The revised and redesignated final paragraph (d)(3)(i)(B)(*3*) now reads as follows:

(*3*) When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

G. Superseding the Respirator Selection Provisions of Substance-Specific Standards in Parts 1910, 1915, and 1926

1. Introduction

OSHA proposed to revise the provisions in its substance-specific standards under 29 CFR parts 1910, 1915, and 1926 that regulate APFs (except the APF requirements for the 1,3-Butadiene Standard at 29 CFR 1910.1051). These substance-specific standards specify numerous requirements for regulating employee exposure to toxic substances. The proposed revisions would have removed the APF tables from these standards, as well as any references to these tables, and would have replaced them with a reference to the APF and MUC provisions specified by proposed paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of the Respiratory Protection Standard at 29 CFR 1910.134. In justifying these proposed revisions, the Agency stated that the proposed revisions would simplify compliance for employers by removing many APF requirements across its substance-specific standards. The proposed revisions would enhance consolidation and uniformity of these requirements, and conform them to each other and to the general APF and MUC requirements specified by 29 CFR 1910.134 (68 FR 34107).

As noted elsewhere in this preamble to the final APF rule, OSHA developed the final APFs using the best available evidence. The development of these final APFs included a careful review of the comments, testimony, data, and other evidence submitted to the rulemaking record, a quantitative (i.e., statistical) analysis of the results from WPF studies performed among workers wearing air-purifying half mask respirators (both filtering facepieces and elastomerics) discussed above in this preamble, and a thorough quantitative and qualitative review of existing WPF and SWPF studies performed with other types of respirators. Using the best data and analytic techniques available, as well as the extensive comments and testimony provided to the rulemaking record, lends a high degree of reliability and validity to the final APF determinations.

The Agency believes that the final APFs developed under this rulemaking will improve the substance-specific standards. The final APFs will provide employers with confidence that their employees will receive the level of protection from airborne contaminants signified by these APFs when they implement a respiratory protection program that complies with the requirements of 29 CFR 1910.134. In addition, applying the final APFs to the substance-specific standards is consistent with OSHA's goal of bringing uniformity to its respiratory protection requirements. Moreover, protection for workers likely will be increased because the final APFs result in regulatory consistency, enhanced employer compliance, and reduced the compliance burden on the regulated community, and, consequently, further increases the protection afforded to employees who use respirators.

In its Respiratory Protection Standard, OSHA noted that the revised standard was to ''serve as a ''building block'' standard with respect to future standards that may contain respiratory protection requirements.'' (See 63 FR 1265, 1998.) However, in the proposed APF rulemaking that would provide generic APFs and MUCs as part of the Respiratory Protection Standard, the Agency decided to retain former respirator selection provisions in the existing substance-specific standards that it found supplemented or supplanted the proposed APFs and MUCs (e.g., organic vapor cartridge and canister procedures, prohibiting use of filtering facepieces or half mask respirators). OSHA did so because these provisions enhance the respirator protection afforded to employees.

2. Comments Regarding the Respirator Selection Provisions of the 1,3-Butadiene Standard

The former respirator selection provisions being retained in this final rule include those provisions in the 1,3-Butadiene (BD) Standard. In issue 13 of the proposed APF rule (68 FR 34112), OSHA asked if exclusion of this standard was warranted. The responses to this question addressed only the service life requirement for cartridges used to absorb atmospheric BD. Typical of these responses is the following comment from the 3M Company:

> A short service life does not affect the ability of a specific respirator to reduce a concentration of a contaminant below the PEL. * * * [W]ith the cartridge change requirements in 1910.134 there is no need to limit the use of organic vapor cartridges or canisters to specific levels of BD. The employer is required to determine a useful service life. If that service life is very short, the employer will need to determine if the replacement schedule is realistic. (Ex. 18–7.)

However, two other commenters made important observations. First, the American Chemistry Council representative noted that ''[E]xclusion of [the BD] standard is reasonable since this standard has a more comprehensive respirator section that includes end of service life specifications' (Ex. 10–25). Second, ORC Worldwide stated, ''Excluding [BD] is warranted. Additional verbiage relative to service lives developed under a negotiated rulemaking process should not be changed'' (Ex. 10–27).

Commenters who recommended adopting the change-out schedule provisions of 29 CFR 1910.134 provided no compelling rationale for disturbing the extensive change-out schedules developed for the BD Standard on the recommendation of industry and labor representatives . Substituting the performance-based provisions that regulate change schedules under 29 CFR 1910.134 for the existing BD Standard's change schedule provisions for the sake of convenience is insufficient justification for revisiting these relatively recently promulgated provisions. In this regard, the latter two commenters clearly recognized the importance of the process that resulted in the existing change schedule requirements.

In the preamble to the final BD Standard, the Agency reviewed test data that demonstrated short breakthrough times for BD concentrations above 50 ppm. Accordingly, these short breakthrough times justified setting at 50 ppm the upper limit at which employees can use air-purifying respirators for protection against BD exposures. The Agency used these data to develop change schedules for cartridges and canisters that are unique for BD exposures (see Table 1 of the BD Standard). OSHA reviewed the test data when it published the final standard in 1996 and found that these conclusions remain valid. The Agency believes that it would impose an unnecessary burden on employers who are subject to the BD Standard to require them to repeat the review already conducted by OSHA on BD breakthrough times, and then develop their own change-out schedules under 29 CFR 1910.134. Moreover, employee protection from exposure to BD is unlikely to be increased.

The Agency acknowledged in the preamble to the final BD Standard that it took a conservative approach to employee protection. In this regard, OSHA noted that its ''decision to rely on the more protective NIOSH APFs is based on evidence showing that organic vapor cartridges and canisters have limited capacity for adsorbing BD and may have too short a service life when used in environments containing greater than 50 ppm BD.'' (See 61 FR 56816.) With regard to the change-out schedules, the Agency concluded:

> Allowing for a reasonable margin of protection, and given that test data were available only for a few makes of cartridges and canisters, OSHA believes that air-purifying devices should not be used for protection against BD present in concentrations greater than 50 ppm, or 50 times the 1 ppm PEL. Thus, OSHA finds that the ANSI APFs of 100 for full facepiece, air-purifying respirators and 1,000 for PAPRs equipped with tight-fitting facepieces are inappropriate for selecting respirators for BD.

Accordingly, OSHA is retaining the respirator selection provisions of the BD Standard to avoid imposing on employers the new burden of developing their own change-out schedules, and to ensure maximum protection for employees exposed to BD.

3. Comments Regarding the Respirator Selection Provisions of Other Substance-Specific Standards

The Agency proposed to retain a number of special respirator selection provisions in the existing substance-specific standards. In this regard, OSHA noted that the respirator selection requirements proposed for retention were developed in rulemakings to provide protection against a hazardous characteristic or condition that is unique to the regulated substance. Additionally, the Agency stated that retaining these requirements would not increase the existing employer burden because they already must comply with these requirements. Consequently, retaining these provisions would maintain the level of respiratory protection currently afforded to employees. These provisions were in the substance-specific standards regulating employee exposure to vinyl chloride, inorganic arsenic, asbestos, benzene, coke oven emissions, cotton dust, ethylene oxide, and formaldehyde.

Under issue 13 in the proposal, OSHA requested comments on the need to standardize the respirator selection provisions being proposed for retention. The Agency received numerous comments and hearing testimony on this issue. Most of these comments and testimony encouraged OSHA not to retain these provisions in their existing form, but instead to subsume these provisions under the Respiratory Protection Standard at 29 CFR 1910.134. An example of such a recommendation was provided by the 3M Company (3M) when it stated, in its hearing testimony, ''It is neither necessary nor justified to retain any of the specific requirements in the substance-specific standards. * * * They do not reflect the changes in science and technology, respirator design, respirator certification, or respirator regulation under 29 CFR 1910.134'' (Tr. at 393). In subsequent testimony, a representative from 3M stated, ''We contend that requiring separate respirator APFs and selection requirements in the substance-specific standards as proposed would only add confusion to the respirator selection process, and is not justified by any scientific or practical evidence'' (Tr. at 394). Thomas Nelson of NIHS, Inc., provided similar rationale in support of standardizing these provisions, stating:

> The proposal would retain information [on] cartridge change schedules, filter selection and some specific respirator selection requirements in the substance specific standards. None of these requirements are necessary in the substance specific standard[s]. The current 1910.134 with the addition of an assigned protection factor table contains requirements that are protective. (Ex. 18–9.)

Many of these comments addressed issues involving single substance-specific standards, including their cartridge, canister, and filter requirements. The following paragraphs provide a summary of the comments that pertain to individual substance-specific standards, as well as OSHA's response to these comments.

• *Inorganic Arsenic (29 CFR 1910.1018).* A commenter wanted OSHA to ''[c]larify if filtering facepieces will be acceptable [under this standard],'' and asserted that requiring ''gas masks or SARs for exposures above the PEL is unnecessary (Ex. 9–5). Two commenters, the Mine Safety Appliances Co., and the 3M Company, questioned the need to require a HEPA filter when using a cartridge or canister for exposures above a specified limit (Exs. 9–37, 18–7), while one of these commenters claimed that any filter approved by NIOSH under 42 CFR part 84 would provide the required level of filter efficiency (Ex. 18–7).

The Agency did not address, as part of this rulemaking, the use of filtering facepieces during inorganic arsenic exposures. This question deals with compliance. The other two commenters provided no basis for questioning the requirement for HEPA filters, while the issue of filters approved under 42 CFR part 84 is addressed below (see section entitled ''Substituting N95 Filters for HEPA Filters'').

• *Asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101).* The 3M Company (3M) objected to the provision in this standard that prohibits the use of disposable half masks, but permits the use of elastomeric respirators, at asbestos concentrations that are 10 times the PEL (Ex. 18–7). In these comments 3M stated that this disparity ''is counter to OSHA's analysis of WPF data that does not show a difference between filtering facepieces and elastomeric facepieces.'' The 3M Company continued by noting that NIOSH stated that the aerosol size used in its respirator certification test ensures that filter performance will be at least as efficient ''for essentially all other aerosol sizes'' (see 60 FR 30344). While this comment implies that NIOSH would accept filtering facepieces for protection against asbestos, another commenter observed that the 1997 *NIOSH Pocket Guide to Chemical Hazards* expressly prohibits such use (Ex. 18–5).

The rebuttal made by the last commenter indicates that 3M's concerns regarding the use of disposable respirators are controversial. Consequently, revision would require a new rulemaking.

• *Coke Oven Emissions (29 CFR 1910.1029).* A 3M representative asserted that OSHA made an error when it proposed to revise the term ''single-use respirator'' to ''filtering facepiece respirators'' in item (b)(1) of Table 1 in paragraph (g)(3) of this standard (Ex. 18–7). This commenter supported this assertion by noting that ''[t]he 'single use type' respirator was a term that NIOSH started after promulgation of the coke oven emission standard,'' and that ''[d]isposable dust/mist respirators are not prohibited from use under the * * * standard.'' In conclusion, this commenter remarked that, by revising the term ''single-use respirator'' to ''filtering facepiece respirators,'' the Agency is ''prohibiting disposable particulate respirators from being used, which was not the intent of the original standard.'' However, another commenter took exception to removing the proposed prohibition against all filtering facepiece respirators (Ex. 18–5), claiming that the particle size of coke oven emissions is unknown, and that coke oven fumes may degrade the electrostatic filters used in filtering facepieces. This commenter asserted that employers should use only HEPA filter cartridges, or P100 filtering facepieces that respirator manufacturers demonstrate will not degrade when exposed to coke oven fumes.

The Agency agrees with the first commenter that the term ''single-use respirator'' is outdated. It believes that the regulated community now designates these respirators as filtering facepiece respirators. Accordingly, the definition of filtering facepiece respirators in paragraph (b) of 29 CFR 1910.134 consists of three key characteristics—they function under negative pressure, are used against particulates and vapors, and consist of a filtering medium that is an integral part of the facepiece or that constitutes the entire facepiece. These characteristics also describe single-use respirators. This definition does not specify the functional characteristics of filtering facepieces, only their structural features. In this regard, both filtering facepiece and single-use respirators generally are considered disposable, with the period of effectiveness determined by the functional characteristics of either respirator. Therefore, because single-use and filtering facepiece respirators are identical with regard to their structural characteristics, OSHA is retaining the proposed terminology in the final APF standard. However, while paragraph (b)(1) of the Table I in the Coke Oven Emissions Standard prohibits using a single-use, filtering facepiece respirator, paragraph (b)(2) of this table permits its use when it functions as a ''particulate filter respirator.'' Accordingly, employers may select filtering facepiece respirators when employees are exposed to coke oven emissions and those emissions (1) consist solely of particulates, and (2) the exposure conditions are no more than 10 times the PEL for coke oven emissions. Finally, OSHA simply cannot adopt the recommendation of the second commenter to use only P100 filtering facepieces under these conditions as this issue was not part of this rulemaking.

• *Cotton Dust (29 CFR 1910.1043).* The comments concerning this standard addressed whether filtering facepieces used to protect employees against cotton dust exposure should retain the current APF of 5 or be upgraded to an APF of 10. In this regard, one commenter believed that revising this standard to upgrade the APF of filtering facepieces to 10 would be consistent with the results of OSHA's statistical analysis of WPF studies for filtering facepiece respirators (Ex. 18–7). This commenter stated, ''[F]iltering facepieces should have the same APF of 10 for cotton dust as they would for all other dusts. Filtering facepieces do not show selective performance to cotton dust versus other aerosols.'' Three additional commenters echoed a similar concern with regard to filtering facepieces used against cotton dust. Two of these commenters noted that no technical reason exists ''to reduce the APF to 5 for filtering facepieces'' (Exs. 9–22 and 9–37), while the third commenter stated that ''[n]ot allowing filtering facepieces for greater than 5 times the PEL is inconsistent with an APF of 10 indicated in [proposed] Table 1'' (Ex. 9–42).

Several commenters responded negatively to the recommendations to raise the APF from 5 to 10 for filtering facepieces used for protection against cotton dust (Exs. 12–7–1 and 18–5; Tr. at 41–43). However, these commenters provided no technical or safety-and-health rationale for their position. Typical of these comments was the following statement made at the rulemaking hearing by one of the participants: ''If OSHA goes ahead and assigns a 10 * * * for [filtering facepieces] for the cotton dust standard * * *, you're going against what was established way back when and settled by the court [at] an APF of 5.'' (Tr. at 43.)

The first set of commenters recommended revising this standard to raise the APF for filtering facepieces from 5 to 10, consistent with the APF for filtering facepieces proposed for 29 CFR 1910.134. However, the Agency did not propose to raise the APF for filtering facepieces used against cotton dust, and the record is inadequate to make that decision at this time. The second set of comments noted that revising the APF from 5 to 10 for filtering facepieces used during exposures to cotton dust would be foreclosed by the court's decision in *Minnesota Mining and Manufacturing Co.* v. *OSHA,* 825 F.2d 482 (D.C. Cir. 1987); this decision upheld the Cotton Dust Standard's assignment of an APF of 5 for disposable respirators. While OSHA is not revising the APF for filtering facepieces used against cotton dust at this time, the Agency notes that the court's decision in this case does not preclude it from revising the Cotton Dust Standard in the future based on an appropriate rulemaking record.

4. Change-Out Schedules for Vinyl Chloride (29 CFR 1910.1017), Benzene (29 CFR 1910.1028), Formaldehyde (29 CFR 1910.1048), and Ethylene Oxide (29 CFR 1910.1047)

The International Safety Equipment Association (ISEA), the Mine Safety Appliances Co., and the 3M Company (3M) requested OSHA to remove the existing cartridge change-out schedules under the Vinyl Chloride Standard and replace them with the change-out schedule provisions of 29 CFR 1910.134 (Exs. 9–22, 9–37, and 18–7). In its comments on this issue, 3M stated that ''the nature of toxicity of any analyte does not affect the service life of a chemical cartridge'' (Ex. 18–7). ISEA and 3M submitted similar comments regarding the existing cartridge change-out schedules in the Benzene Standard (Exs. 9–22 and 18–7). Accordingly, 3M noted that the Agency should not limit cartridge selection to only organic vapor cartridges specified for benzene absorption, but should expand the permitted cartridges to organic vapor cartridges for acid gas or formaldehyde absorption, as well as multi-gas cartridges (Ex. 18–7). The three commenters also recommended that OSHA remove the requirements for cartridges, filters, and the cartridge change-out schedules in the Ethylene Oxide Standard, as well as the specifications for cartridges/canisters and change-out schedules in the Formaldehyde Standard, asserting that employers could refer to 29 CFR 1910.134 to obtain the necessary information (Exs. 9–22, 9–37, and 18–7).

In response to these commenters, the Agency notes that it believes that the minimum change-out schedules specified by these standards ensure that employers use the designated respirators at appropriate concentration levels of the regulated substance. OSHA also recognizes that retaining these specifications may limit employers' flexibility in adopting change-out schedules. However, it considers this limitation justified because the specified change-out schedules provide a high level of protection for employees against the dangerous properties of these substances. In addition, adopting the change-out schedule provisions of 29 CFR 1910.134 for current OSHA health standards is beyond the scope of this APF rulemaking. The Agency cannot make revisions to this final rule based on these comments because the regulated community must have adequate notice of, and an opportunity to comment on, any proposed revisions.

5. Miscellaneous Comments Regarding Superseding Other Substance-Specific Standards

A number of comments were general, and did not address a single substance-specific standard. These comments centered on respirator selection issues that involved two or more of the substance-specific standards, such as HEPA filters and training. The following paragraphs identify the issues addressed in these comments, and provide a summary of the comments that address these general issues, including OSHA s response to them.

• *Skin absorption and eye irritation.* Three commenters argued that it was unnecessary to preclude the use of half masks against eye irritants in the Ethylene Oxide, Methylene Chloride, and Formaldehyde standards when employees wear appropriate eye protection with half masks (Exs. 9–22, 9–37, and 9–42). A fourth commenter made a similar statement regarding protection against eye irritants, but did not identify any specific substances (Ex. 9–59). One of these commenters asked, ''Why make it a requirement to wear eye protection unless the concentrations are at irritant levels?'' (See Ex. 9–42.) This commenter also noted that OSHA does not permit the use of half mask respirators during exposure to arsenic trichloride, but did not apply this prohibition to other chemicals that employees may absorb rapidly through the skin. This commenter recommended that the Agency ''[p]rovide consistent recommendations that involve chemicals that can be absorbed through the skin in significant amounts (e.g., chemicals with PEL or TLV with 'skin' notations).'' Another commenter took a different approach to this issue, proposing that OSHA should ''[r]emove all references to [the] use of respirators for protection from substances that can be absorbed through the skin or irritate the skin or eyes. There are other ways that the skin can be protected'' (Ex. 10–59).

The purpose of this rulemaking was to provide the regulated community with notice of, and an opportunity to comment on, specific respirator selection provisions that the Agency proposed for revision. In this regard, OSHA proposed no revisions to any requirements in the substance-specific standards that addressed protection against eye or skin irritants. Accordingly, these provisions will remain intact. The Agency believes that the requirements of existing substance-specific standards that specify the use of protective clothing and the other personal protective equipment requirements of 29 CFR 1910 subpart D will prevent serious skin absorption of toxic substances. Moreover, provisions in the substance-specific standards that require the use of full facepiece respirators and other high-end respirators for eye protection will provide employees with an integrated protection system that assures maximum respiratory and eye protection.

• *HEPA Filters.* Several commenters took exception to requirements in many substance-specific standards that some respirators use HEPA filters. For example, one commenter stated that NIOSH's updated respirator testing protocol in 42 CFR 84 eliminated the need for HEPA filters (Ex. 9–22). Similarly, a second commenter noted that HEPA filters were no longer listed in the NIOSH certification categories, and that OSHA should update the language in the Respiratory Protection Standard to be consistent with these categories (Ex. 10–59). A third commenter recommended that the Agency remove references to HEPA filters from a number of its substance-specific standards because ''[p]article properties such as size and form are no longer needed in filter selection'' (Ex. 9–37). Another commenter stated that P100 filters were equivalent to HEPA filters, and that OSHA should ''[p]rovide clear generic guidance on when HEPA or P100 filters should be used, as opposed to another less efficient filter''(Ex. 9–42).

In addressing other issues, one commenter stated that OSHA would be breaching an earlier decision if it superseded dust-mist-fume respirators with respirators using HEPA filters at lead levels that are equal to or below 0.5 mg/m^3 (Ex. 10–4).[11] Another commenter recommended limiting the use of all electrostatic (fiber) filters (Ex. 18–5). This commenter based this recommendation on evidence presented at the 1994 NIOSH hearing on the proposed filter certification requirements of 42 CFR 84. This commenter stated that the evidence showed, when tested with a heated DEHP aerosol challenge agent, the average filter efficiency for electrostatic P100 filters was less than the average filter efficiency for respirators that used a mechanical filter media. In one of these tests, the average filter efficiency for a P100 electrostatic filter was as low as 84.5%.

While it is beyond the scope of this rulemaking to make the revisions recommended by these commenters, the Agency notes that the definition of HEPA filters in paragraph (b) of 29 CFR 1910.134 equates these filters with high-end filters tested under the NIOSH certification scheme specified by 42 CFR 84. In this regard, the definition notes that, under 42 CFR 84, HEPA filters are equivalent to the N100, R100, and P100 particulate filters certified by NIOSH. Therefore, the Respiratory Protection Standard already describes HEPA filters in language that equates them to N100, R100, and P100 filters certified by NIOSH (i.e., the terms are interchangeable). OSHA Directive No. CPL 2–0.120 of September 25, 1998 (''Inspection Procedures for the Respiratory Protection Standard'') also states, ''When HEPA filters are required by an OSHA standard, N100, R100, and P100 filters can be used to replace them.'' In addition, an Agency letter of interpretation to Neoterik Health Technologies, Inc. dated March 18, 1996 concludes that, ''when any OSHA standard requires the use of HEPA filters[,] then the employer may satisfy

[11] OSHA published this decision at 44 FR 5446 (January 26, 1979).

the requirement by choosing to use a P100, N100, or R100 filter certified under 42 CFR 84, since such filters would exhibit minimum leakage.'' Therefore, for over eight years, OSHA has consistently equated HEPA filters to the high-end filters certified by NIOSH under 42 CFR 84.

OSHA believes that this definition is sufficient to meet the recommendations of these commenters regarding the need to update the description of HEPA filters consistent with the NIOSH certification program, including the need to provide the ''clear generic guidance'' requested by one of the commenters (Ex. 9–42). As noted by another commenter (Ex. 9–37), the definition of HEPA filters contained in the Respiratory Protection Standard also specifies the filtering criterion that these filters must meet in terms of particulate size. The definition recognizes that the N100, R100, and P100 filters meet this criterion, thereby updating the HEPA definition as recommended by this commenter.

Contrary to the assertions made by one of the commenters (Ex. 10–4), the Agency is not breaching its earlier decision to permit the use of dust-mist-fume respirators (instead of respirators configured with HEPA filters) when employees are exposed to lead levels that are equal to or below 0.5 mg/m^3. Although this commenter mentioned that the decision covered N95 respirators as well, N95 respirators were not even available in 1979 when the Agency published the decision and, therefore, were never part of the decision. The remarks of the last commenter (Ex. 18–5) described special testing conditions (using a heated DEHP aerosol challenge agent) that appeared to degrade specific types of filters. While this information may be of interest to NIOSH in determining the efficacy of its filter certification program, it is unclear how useful this information would be in selecting respirators for use in workplaces that vary substantially from these specialized testing conditions.

• *Substituting N95 Filters for HEPA Filters.* A representative for the 3M Company (3M) argued strongly that OSHA should require only N95 particulate filters for respirators, noting that OSHA based the existing requirement to use HEPA filters under some exposure conditions on NIOSH's outdated filter certification process specified in 30 CFR 11 (Tr. at 396). The 3M Company then described a WPF study conducted by Jensen et al. in a steel foundry on employees who performed a grinding operation involving a heavy work load (i.e., as shown by high airflow rates through the filters) and exposure to an iron aerosol. The 3M Company claimed that under these conditions, no significant difference existed between P95 and P100 particulate filters used by these employees with regard to the percentage of workplace iron penetration inside the filter. In addition, they asserted that neither type of filter permitted any detectable oil mist penetration (Ex. 18–7; Tr. at 397).

Later in the hearing, when asked about the test conditions under which NIOSH certifies filter efficiency, the 3M representative stated:

> NIOSH's testimony yesterday, which I agree with, is that they've got a worst case, or close to worst case, testing, and, as they've stated, * * * they expect performance in the workplace to be better than that rating. * * * So I believe that in the N95 filter[s], while you see a difference in their performance in the laboratory, when they're used against workplace aerosols, there is no difference. (Tr. at 429.)

In his testimony the previous day, the NIOSH representative made the following statement:

> Well, NIOSH does not accept the premise that efficiency levels for filters that we test should be considered at higher efficiency levels. The approval program designates an efficiency level for the filters, which is well known to be tested with a near-worst case aerosol. However, this is done so that every workplace does not have to conduct sizing tests before they selected proper filters in the workplace. We think that this is a proper way to go, and we also do not think that assuming particle sizes and greater efficiencies on the filters is a very wise approach for protecting workers. (Tr. at 121.)

The 3M Company also mentioned that another justification for substituting N95 filters for N100 filters is that ''increased breathing resistance caused by use of a 100 filter may decrease overall respirator effectiveness by reducing user comfort and thereby reducing the time the respirator is worn'' (Ex. 18–7).

In its post-hearing comments, NIOSH acknowledged, ''It is possible that a specific NIOSH certified 95-level filter may have filter penetration less than 5% in a specific workplace. However, this type of workplace-specific result may not be generalized to all 95-level filters in all workplace settings''' (Ex. 17–7–1). Later in these comments it stated, ''NIOSH has included rigorous certification tests to help assure that filter performance in the workplace will be maintained at least at the certification level even under severe conditions,'' and ''the NIOSH certification criteria are designed to assure that filters meet minimum performance requirements. NIOSH does not certify that they will perform any better than these criteria.''

Revising the existing respirator selection requirements for HEPA filters, or for filters certified by NIOSH as N100, R100, and P100 under 42 CFR part 84, is beyond the scope of the present rulemaking. Additionally, the commenters did not provide any evidence demonstrating that 95-level filters would protect employees when used under the worst-case conditions simulated during the NIOSH certification tests. However, from the evidence presented here, OSHA believes that NIOSH's filter certification program provides a substantial margin of protection to employees who use respirators. In addition, it is unclear from the study discussed by these commenters whether the results are applicable to the extreme range of exposure conditions used by NIOSH in its filter certification testing. Consequently, the Agency believes that adopting the recommendations made by these commenters may enable employers to purchase respirators that do not perform at the designated level of efficiency under extreme workplace exposure conditions, thereby jeopardizing seriously the health of their employees. Absent data demonstrating that 95-level filters perform effectively under near worst-case experienced conditions, OSHA is retaining its existing HEPA filter requirements.

• *Mixed-Versus Single-Substance Contaminants.* Several commenters recommended superseding the individualized canister/cartridge change-out schedules in the substance-specific standards with the performance-based provisions for developing change-out schedules described in OSHA's Respiratory Protection Standard. Their rationale for this recommendation is that schedules developed using the Respiratory Protection Standard provisions are capable of accommodating employee exposure to multiple contaminants, while the schedules provided in the substance-specific standards are limited to a single atmospheric contaminant. For example, 3M noted that:

> [T]he benzene standard requires the cartridges be changed before the beginning of the next shift. In a refinery, workers may be exposed to benzene along with [toluene] and [x]ylene. The change schedule should be based on the exposure to the mixture as required by 29 CFR 1910.134, not just the benzene, because the mixture may result in requiring the cartridge to be changed sooner than eight hours. By following the requirements of 134, a change schedule would be established resulting in changing

the cartridge before loss of service life, thereby, increasing worker protection. (Tr. at 396.)

The International Safety Equipment Association and Thomas Nelson of NIHS, Inc., made similar statements (Tr. at 518 and Ex. 18–9). In further justification, 3M remarked that ''[r]espirator program administrators may not be aware that the cartridge change schedules contained in the substance specific [standards] may not be protective if multiple contaminants are present'' (Ex. 18–7).

These comments are a variation of the comments cited earlier in this section that recommended removing the change-out schedules specified for substance-specific standards and replacing them with the provisions of 29 CFR 1910.134 governing change-out schedules. This recommendation involves a major revision to these standards, and, therefore, is beyond the scope of this rulemaking. However, such a revision likely is unnecessary because change-out schedules involving multiple-contaminant exposures would not be covered under the substance-specific standards. Instead, employers must develop these change-out schedules for air-purifying respirators not equipped with an end-of-service-life indicator according to the requirements of the Respiratory Protection Standard, notably paragraph (d)(3)(iii)(B)(2).

• *Retaining APF Tables for Lead and Asbestos.* Several unions requested that OSHA retain the revised APF tables in the construction standards for lead and asbestos. During the hearing, a representative from the Building Construction Trades Department of the AFL–CIO (BCTD) stated that union-management training centers ''conduct a great deal of worker training on lead and asbestos,'' and that ''these tables * * * greatly facilitate the understanding of appropriate respirator selection'' (Tr. at 615). This representative stated further:

It is much more usable for these parties to go directly to the substance-specific standard with the air-monitoring results and choose the appropriate type of respirator. If employers had to do calculations to determine the appropriate type of respirator to select, that is simply an added barrier to compliance. Additionally, the tables are of great help when communicating the need for respirators to employers who may not normally be engaged in lead and asbestos work. (Tr. at 615.)

The BCTD representative later noted that ''[i]t's the idea of jumping from [the respiratory protection] standard to [the lead/asbestos construction] standard, that's why we don't want the table [removed]'' (Tr. at 647). The BCTD post-hearing comments expanded on this testimony, stating, ''Calculations to determine appropriate respirator add [a] barrier to compliance * * *'' (Ex. 9–29).

A representative of the Insulators and Asbestos Workers International (''IAWI'') found the tables to be invaluable as a teaching aid, and added that:

I am asked by all types of people, regulators, legislators, facility engineers, owners of companies, [and] consultants where to find the information [about APFs]. I just tell them [to] look in the tables. * * * The common worker knows where to find this. It is where it should be. There are no OSHA libraries on the job sites. * * * I am asked by a lot of people in charge of sites where these [APFs] are in writing. If it is taken out of the rules, if it is not written, it will not be adhered to. (Tr. at 623.)

However, this representative later admitted that ''[e]very one of our supervisors gets a copy of an updated [construction] standard,'' and ''[h]e gets the 1910.134 [i.e., the Respiratory Protection Standard]'' (Tr. at 645.) Similarly, another commenter remarked that ''[e]mployers covered by [substance-]specific standards are already required to refer to 29 CFR 1910.134 for most respirator program elements including fit testing, inspection and cleaning, and program evaluation,'' and that ''[i]f some employers would not bother to consult 29 CFR 1910.134 for APFs, these same employers are most likely not complying with other necessary program elements''(Ex. 18–7).

The Agency believes that employers know they are required to use the Respiratory Protection Standard. Retaining the APF tables in the construction standards for lead and asbestos is unlikely to result in any savings or convenience to employers or other parties because these tables cannot be used safely and effectively without consulting the requirements of 29 CFR 1910.134. Even one of the union representatives recognized this necessity when stating that supervisors must have access to both the construction standards and the Respiratory Protection Standard at the job site (Tr. at 646). In addition, OSHA believes that any respirator selection requirements that are unique to a substance-specific standard (i.e., not subsumed by this rulemaking under the Respirator Protection Standard) will remain available for easy access under the particular standard. In this regard, the Agency concludes that it is unnecessary to retain the APF tables for the lead and asbestos standards in the construction standards because the required APF tables can be assembled readily for training purposes from the available information in the revised substance-specific standards and the Respiratory Protection Standard.

• *Upgrading Respirator Type at Employee Request.* At the hearing, the BCTD representative mentioned that several of the substance-specific standards required employers to upgrade respirators when requested to do so by employees. The representative encouraged the Agency to include such a requirement in current and future substance-specific standards (Tr. at 616). The IAWI representative commented:

[S]ome of our members, for a variety of reasons, like working in PAPRs. * * * Some people work in them, feel comfortable in them. They want them. And it makes them more at ease at doing their work. * * * It makes the person more productive, cools them down; there's a variety of reasons. (Tr. at 648.)

When asked how often employers upgrade respirators when doing so is discretionary, this representative replied, ''I wouldn't say it's 100 percent. I'd say a portion of them would allow somebody that activity'' (Tr. at 649).

Placing a burden on employers to upgrade respirators at an employee's request is beyond the scope of this rulemaking. However, the Agency recognizes the advantages, as well as disadvantages, to upgrading a respirator at an employee's request. As it stated in the preamble to the Respiratory Protection Standard with regard to PAPRs:

OSHA continues to believe that under some circumstances PAPRs provide superior acceptability. These include situations where employees wear respirators for full shifts, where employees frequently readjust their negative pressure respirators to achieve what they consider a more comfortable or tighter fit, and where the air flow provided by a PAPR reduces the employee's psychological and physiological discomfort. However, where ambient temperatures are extremely high or low, PAPRs are often unacceptable because of the temperature of the airstream in the facepiece. * * * (63 FR 1201.)

OSHA noted further, ''The Agency continues to believe that it is good industrial hygiene practice to provide a respirator that the employee considers acceptable'' (63 FR 1201). Therefore, employers are free to upgrade respirators voluntarily at an employee's request when the employee meets the medical qualifications for using the respirator and receives the necessary training.

5. Summary of Superseding Actions

The following table summarizes final revisions to the existing respirator selection provisions of OSHA's substance-specific standards. Section VIII (''Amendments to Standards'') of this rulemaking notice provides the full, plain-language regulatory text of these final revisions.

SUMMARY OF SUPERSEDING ACTIONS FOR SUBSTANCE-SPECIFIC STANDARDS

Existing provisions	Final action
29 CFR 1910.1001(g)(2)(ii)	Revise.
.1001(g)(3)	Remove Table 1 and revise.
.1001(l)(3)(ii)	Redesignate Table 2 as Table 1.
.1017(g)(3)(i)	Remove table and revise.
.1017(g)(3)(iii)	Remove.
.1018 (Tables I and II)	Remove.
.1018(h)(3)(i)	Revise.
.1018(h)(3)(ii)	Remove.
.1018(h)(3)(iii)	Redesignate as .1018 (h)(3)(ii).
.1025(f)(2)(ii)	Remove Table II.
.1025(f)(3)(i)	Revise.
.1027(g)(3)(i)	Remove Table 2 and revise.
.1028(g)(3)(ii)	Remove Table 1.
.1028(g)(2)(i)	Revise.
.1028(g)(3)(i)	Revise.
.1029(g)(3)	Remove Table I and revise.
.1043(f)(3)(i)	Remove Table I and revise.
.1043(f)(3)(ii)	Revise.
.1044(h)(3)	Remove Table 1 and revise.
.1045(h)(2)(i)	Revise.
.1045(h)(3)	Remove Table I and revise.
.1047(g)(3)	Remove Table 1 and revise.
.1048(g)(2)	Revise.
.1048(g)(3)	Remove Table 1 and revise.
.1050(h)(3)(i)	Remove Table 1 and revise.
.1052(g)(3)	Remove Table 2 and revise.
29 CFR 1915.1001(h)(2)(i) through (h)(2)(v)	Remove Table 1 and revise.
29 CFR 1926.60(i)(3)(i)	Remove Table 1 and revise.
.62 (f)(3)(i)	Remove Table 1 and revise.
.1101(h)(3)(i) through (h)(3)(iv)	Remove Table 1 and revise.
.1127(g)(3)(i)	Remove Table 1 and revise.

6. Use of Plain Language

In the proposal, OSHA rewrote into plain language the respirator-selection provisions of the substance-specific standards retained in this final rule. The Agency received no comments on these proposed revisions. OSHA believes that using plain language will improve the uniformity and comprehensibility of these provisions. These improvements will, in turn, enhance employer compliance with the provisions and, concomitantly, increase the protection afforded to employees. The Agency also found that rewriting the respirator-selection provisions of the existing substance-specific standards into plain-language provisions did not alter the substantive requirements of the existing provisions. (The following table lists the plain-language provisions in the final rule and the corresponding provisions in the existing standards.) Therefore, OSHA is retaining these plain-language revisions in the final rule.

PLAIN-LANGUAGE PROVISIONS IN THE FINAL RULE AND CORRESPONDING PROVISIONS IN THE EXISTING STANDARDS

Plain-language provisions	Existing provisions
§ 1910.1001(g)(2)(ii)	§ 1910.1001(g)(2)(ii).
§ 1910.1001(g)(3)(i)	§ 1910.1001(g)(3); Table 1.
§ 1910.1001(g)(3)(ii)	§ 1910.1001(g)(3); Table 1.
§ 1910.1017(g)(3)(i)(B)	§ 1910.1017(g)(3)(i); undesignated table.
§ 1910.1017(g)(3)(i)(C)	§ 1910.1017(g)(3)(i); undesignated table.
§ 1910.1018(h)(3)(i)(B)	§ 1910.1018(h)(3)(i); Table II (footnote 2).
§ 1910.1018(h)(3)(i)(C)	§ 1910.1018(h)(3)(i); Table I and Table II.
§ 1910.1018(h)(3)(i)(D)(*1*)	§ 1910.1018(h)(3)(ii).
§ 1910.1018(h)(3)(i)(D)(*2*)	§ 1910.1018(h)(3)(i); Table II.
§ 1910.1025(f)(3)(i)(B)	§ 1910.1025(f)(3)(i); Table II (footnote 2).
§ 1910.1025(f)(3)(i)(C)	§ 1910.1025(f)(3)(i); Table II.
§ 1910.1025(f)(3)(ii)	§ 1910.1025(f)(3)(ii).
§ 1910.1027(g)(3)(i)(B)	§ 1910.1027(g)(3)(i)(B); Table 2 (footnote b).
§ 1910.1027(g)(3)(i)(C)	§ 1910.1027(g)(3)(i)(B); Table 2.
§ 1910.1028(g)(3)(i)(B)	§ 1910.1028(g)(3)(i); Table 1.
§ 1910.1028(g)(3)(i)(C)	§ 1910.1028(g)(3)(i); Table 1.
§ 1910.1028(g)(3)(i)(D)	§ 1910.1028(g)(3)(i); Table 1 (footnote 1).
§ 1910.1029(g)(3)	§ 1910.1029(g)(3); Table I.
§ 1910.1043(f)(3)(i)(A)	§ 1910.1043(f)(3)(i); Table I.

PLAIN-LANGUAGE PROVISIONS IN THE FINAL RULE AND CORRESPONDING PROVISIONS IN THE EXISTING STANDARDS—Continued

Plain-language provisions	Existing provisions
§ 1910.1043(f)(3)(i)(B)	§ 1910.1043(f)(3)(i); Table I.
§ 1910.1043(f)(3)(ii)	§ 1910.1043(f)(3)(ii).
§ 1910.1044(h)(3)(ii)	§ 1910.1044(h)(3); Table 1.
§ 1910.1045(h)(3)(ii)	§ 1910.1045(h)(3); Table I.
§ 1910.1047(g)(3)(i)	No provision of the original ethylene oxide standard contains this text. However, the only respirators designated for selection are either full facepiece respirators or respirators with hoods and helmets. Also, § 1910.1047(g)(4) (''Protective clothing and equipment'') states, ''When employees could have eye or skin contact with EtO or EtO solutions, the employer must select and provide * * * appropriate protective clothing or other equipment * * * to protect any area of the employee's body that may come in contact with the EtO or EtO solution * * *.''
§ 1910.1047(g)(3)(ii)	§ 1910.1047(g)(3); Table 1.
§ 1910.1047(g)(3)(iii)	§ 1910.1047(g)(3); Table 1.
§ 1910.1048(g)(2)(ii)	§ 1910.1048(g)(2)(ii).
§ 1910.1048(g)(3)(i)(B)	§ 1910.1048(g)(3)(i); Table 1.
§ 1910.1048(g)(3)(i)(C)	§ 1910.1048(g)(3)(i); Table 1.
§ 1910.1048(g)(3)(ii)	§ 1910.1048(g)(3)(i); Table 1 (footnote 2).
§ 1910.1048(g)(3)(iii)	§ 1910.1048(g)(3)(ii).
§ 1910.1050(h)(3)(i)(B)	§ 1910.1050(h)(3)(i); Table 1.
§ 1910.1050(h)(3)(i)(C)	§ 1910.1050(h)(3)(i); Table 1.
§ 1910.1050(h)(3)(i)(D)	§ 1910.1050(h)(3)(i); Table 1 (footnote 2).
§ 1910.1052(g)(3)(i)	No provision of the original methylene chloride standard contains this text. However, the only respirators designated for selection are either full facepiece respirators or respirators with hoods and helmets. Also, § 1910.1052(h)(1) (''Protective work clothing and equipment'') states, ''Where needed to prevent MC-induced skin and eye irritation, the employer shall provide clean protective clothing and equipment which is resistant to MC * * *.''
§ 1910.1052(g)(3)(ii)	§ 1910.1052(g)(3); Table 2.
§ 1915.1001(h)(2)(i)	§ 1915.1001(h)(2)(i); Table 1.
§ 1915.1001(h)(2)(ii)	§ 1915.1001(h)(2)(i); Table 1.
§ 1915.1001(h)(2)(iii)	§ 1915.1001(h)(2)(iii)(A).
§ 1915.1001(h)(2)(iv)	§ 1915.1001(h)(2)(iv).
§ 1915.1001(h)(2)(v)	§ 1915.1001(h)(2)(v).
§ 1926.60(i)(3)(i)(B)	§ 1926.60(i)(3)(i); Table 1.
§ 1926.60(i)(3)(i)(C)	§ 1926.60(i)(3)(i); Table 1.
§ 1926.60(i)(3)(i)(D)	§ 1926.60(i)(3)(i); Table 1 (footnote 2).
§ 1926.62(f)(3)(i)(B)	§ 1926.62(f)(3)(i); Table 1 (footnote 2).
§ 1926.62(f)(3)(i)(C)	§ 1926.62(f)(3)(i); Table 1.
§ 1926.1101(h)(3)(i)(A)	§ 1926.1101(h)(3)(i); Table 1.
§ 1926.1101(h)(3)(i)(B)	§ 1926.1101(h)(3)(i); Table 1.
§ 1926.1101(h)(3)(ii)	§ 1926.1101(h)(3)(ii).
§ 1926.1101(h)(3)(iii)	§ 1926.1101(h)(3)(iii).
§ 1926.1101(h)(3)(iv)	§ 1926.1101(h)(3)(iv).
§ 1926.1127(g)(3)(i)(B)	§ 1926.1127(g)(3)(i); Table 1 (footnote b).
§ 1926.1127(g)(3)(i)(C)	§ 1926.1127(g)(3)(i); Table 1.

VII. Procedural Determinations

A. Legal Considerations

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 et seq. (''the Act'') is to ''assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards (see 29 U.S.C. 654(b) (requiring employers to comply with OSHA standards) and 29 U.S.C. 655(b) (authorizing promulgation of standards pursuant to notice and comment)).

A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' (29 U.S.C. 652(8)). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) of the Act when it substantially reduces or eliminates significant risk, and is technologically and economically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency action, and supported by substantial evidence; it also must effectuate the Act's purposes better than any national consensus standard it supersedes (see *International Union, UAW* v. *OSHA* (*LOTO II*), 37 F.3d 665 (DC Cir. 1994; and 58 FR 16612–16616 (March 30, 1993)).

The APFs specified by this final rule are an integral part of OSHA's Respiratory Protection Standard. This standard ensures that respirators reduce or eliminate the significant risk to employee health resulting from exposure to hazardous airborne substances. Accordingly, employers need the APFs provided in this final rule to select appropriate respirators for employees use when the employers must rely on respirators to maintain hazardous substances at safe levels in the workplace. The APFs in this final rule will help ensure that the Respiratory Protection Standard achieves the annual health benefits estimated for that standard (i.e., 932 averted work-related deaths (best estimate) and 4,046 work-related illnesses (best estimate)) (see 63 FR 1173).

In this rulemaking, OSHA also is superseding the existing APF requirements in its substance-specific standards. As noted in section V of this preamble (''Summary of the Final Economic Analysis and Regulatory Flexibility Analysis''), the Agency estimates that the final APFs will reduce significantly employee exposures to the hazardous airborne substances regulated by these substance-specific standards, especially asbestos, lead, cotton dust, and arsenic. Consequently, employees will receive additional protection against the chronic illnesses resulting from exposure to these hazardous substances, notably a variety of cancers and cardiovascular diseases.

The Agency believes that a standard is technologically feasible when the protective measures it requires already exist, can be brought into existence with available technology, or can be developed using technology that can reasonably be expected to be available (see *American Textile Mfrs. Institute* v. *OSHA* (*Cotton Dust*), 452 U.S. 490, 513 (1981); *American Iron and Steel Institute* v. *OSHA* (*Lead II*), 939 F.2d 975, 980 (DC Cir. 1991)). A standard is economically feasible when industry can absorb or pass on the costs of compliance without threatening the industry's long-term profitability or competitive structure (see *Cotton Dust,* 452 U.S. at 530 n. 55; *Lead II,* 939 F.2d at 980), and a standard is cost effective when the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection (see *Cotton Dust,* 452 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA* (*LOTO III*), 37 F.3d 665, 668 (DC Cir. 1994)).

All standards must be highly protective (see 58 FR 16612, 16614–15 (March 30, 1993); *LOTO III,* 37 F.3d at 669). Accordingly, section 8(g)(2) of the Act authorizes OSHA ''to prescribe such rules and regulations as [it] may deem necessary to carry out its responsibilities under the Act'' (see 29 U.S.C. 657(g)(2)). However, health standards also must meet the ''feasibility mandate'' of section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5). Section 6(b)(5) of the Act requires OSHA to select ''the most protective standard consistent with feasibility'' needed to reduce significant risk when regulating health hazards (see *Cotton Dust,* 452 U.S. at 509). Section 6(b)(5) also directs OSHA to base health standards on ''the best available evidence,'' including research, demonstrations, and experiments (see 29 U.S.C. 655(b)(5)). In this regard, OSHA must consider ''in addition to the attainment of the highest degree of health and safety protection * * * the latest scientific data * * * feasibility and experience gained under this and other health and safety laws'' (Id.). Furthermore, section 6(b)(5) of the Act specifies that standards must ''be expressed in terms of objective criteria and of the performance desired'' (see 29 U.S.C. 655(b)(7)).

The APF and MUC provisions in this final rule are integral components of an effective respiratory protection program. Respiratory protection is a supplemental method used by employers to protect employees against airborne contaminants in workplaces when feasible engineering controls and work practices are not available, have not yet been implemented, or are not in themselves sufficient to protect employee health. Employers also use respiratory protection under emergency conditions involving, for example, the accidental release of airborne contaminants. The amendments to OSHA's Respiratory Protection Standard, and the Agency's substance-specific standards, specified in this final rule will provide employers with critical information to use when selecting respirators for employees exposed to airborne contaminants found in general industry, construction, shipyard, longshoring, and marine terminal workplaces. Since it is generally recognized that different types of respiratory protective equipment provide different degrees of protection against hazardous exposures, proper respirator selection is of critical importance. Failure to select the proper respirator for use against exposure to hazardous substances may result in employees being overexposed to these substances, thereby resulting in an increased incidence of cancer, cardiovascular disease, and other illnesses. The APF and MUC provisions in this final rule will greatly enhance an employer's ability to select a respirator that will adequately protect employees.

The Agency also developed the provisions of this final rule to be feasible and cost effective, and is specifying them in terms of objective criteria and the level of performance desired. In this regard, section V of this preamble (''Summary of the Final Economic Analysis and Regulatory Flexibility Screening Analysis'') provides the benefits and costs of the final rule, and describes several other alternatives as required by section 205 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1535). Based on this information, OSHA concludes that the APF and MUC provisions of the final rule constitute the most cost-effective alternative for meeting its statutory objective of reducing risk of adverse health effects to the extent feasible.

Several benefits will accrue to respirator users and their employers from this rulemaking. First, the standard benefits workers by reducing their exposures to respiratory hazards. Improved respirator selection augments previous improvements to the Respiratory Protection Standard, such as better fit-test procedures and improved training, contributing substantially to greater worker protection. At the time of the 1998 revisions to the Respiratory Protection Standard, the Agency estimated that the standard would avert between 843 and 9,282 work-related injuries and illnesses annually, with a best estimate (expected value) of 4,046 averted illnesses and injuries annually (63 FR 1173). In addition, OSHA estimated that the standard would prevent between 351 and 1,626 deaths annually from cancer and many other chronic diseases, including cardiovascular disease, with a best estimate (expected value) of 932 averted deaths from these causes. The APFs in this rulemaking will help ensure that these benefits are achieved, as well as provide an additional degree of protection. These APFs also will reduce employee exposures to several § 6(b)(5) chemicals covered by standards with outdated APF criteria, thereby reducing exposures to chemicals such as asbestos, lead, cotton dust, and arsenic. While the Agency did not quantify these benefits, it estimates that 29,655 employees would have a higher degree of respiratory protection under this APF standard. Of these employees, an estimated 8,384 have exposure to lead, 7,287 to asbestos, and 3,747 to cotton dust, all substances with substantial health risks.

In addition to health benefits, OSHA believes other benefits result from the harmonization of APF specifications, thereby making compliance with the respirator rule easier for employers. Employers also benefit from greater administrative ease in proper respirator selection. Employers no longer have to consult several sources and several OSHA standards to determine the best choice of respirator, but can make their choices based on a single, easily found standard. Some employers who now hire consultants to aid in choosing the proper respirator should be able to make this choice on their own with the aid of this rule. In addition to having only one set of numbers (i.e., APFs) to assist them with respirator selection for nearly all substances, some employers may be able to streamline their respirator stock by using one respirator type to meet their respirator needs instead of several respirator types. The increased ease of compliance also yields additional health benefits to employees using respirators.

B. Paperwork Reduction Act

After a thorough analysis of the final provisions, OSHA believes that these provisions do not add to the existing collection-of-information (i.e., paperwork) requirements regarding respirator selection. OSHA determined that its existing Respiratory Protection Standard at 29 CFR 1910.134 has two provisions that involve APFs and also impose paperwork requirements on employers. These provisions require employers to: Include respirator selection in their written respiratory protection program (29 CFR 1910.134(c)(1)(i)); and inform employees regarding proper respirator selection (29 CFR 1910.(k)(ii)). The information on respirator selection addressed by these two provisions must include a brief discussion of the purpose of APFs, and how to use them in selecting a respirator that affords an employee protection from airborne contaminants. The burden imposed by this requirement remains the same whether employers currently use the APFs published in the 1987 NIOSH RDL or the ANSI Z88.2–1992 Respiratory Protection Standard, or implement the final APFs in this rulemaking. Therefore, the use of APFs in the context of these two existing respirator selection provisions does not require an additional paperwork-burden determination because OSHA already accounted for this burden under its existing Respiratory Protection Standard (see 63 FR 1152–1154; OMB Control Number 1218–0099).

Both OSHA's existing Respiratory Protection Standard and the final APF provisions require employers to use APFs as part of the respirator selection process. This process includes obtaining information about workplace exposure to an airborne contaminant, identifying the exposure limit (e.g., permissible exposure limit) for the contaminant, using this information to calculate the required level of protection (i.e., the APF), and referring to an APF table to determine which respirator to select. Admittedly, this process involves the collection and use of information, but it does not require employers to inform others, either orally or in writing, about the process they use to select respirators for individual employees, or the outcomes of this process. By not requiring employers to communicate this information to others, OSHA removed this process from the ambit of the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). In the alternative, even if PRA–95 applies, the final provisions involve the same information collection and use requirements with regard to APFs as the existing standard (see paragraphs (d)(1) and (d)(3)(i) of 29 CFR 1910.134, and the rationale for the existing APF requirements in the preamble to the final Respiratory Protection Standard, 63 FR 1163 and 1203–1204). Accordingly, the paperwork burden imposed by the final standard would be equivalent to the burden already imposed under the existing standard.

C. Federalism

The Agency reviewed the final APF provisions according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order allows federal agencies to preempt state law only with the expressed consent of Congress. In such cases, federal agencies must limit preemption of state law to the extent possible.

Under section 18 of the Occupational Safety and Health Act (''the Act''), Congress expressly provides OSHA with authority to preempt state occupational safety and health standards to the extent that the Agency promulgates a federal standard under section 6 of the Act. Accordingly, section 18 of the Act authorizes the Agency to preempt state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA-approved occupational safety and health plan (i.e., is a state-plan state) (see *Gade* v. *National Solid Wastes Management Association,* 112 S. Ct. 2374 (1992)). Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this final rule conforms to the preemption provisions of the Act. Additionally, section 18 of the Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that this final rulemaking does not expand this limitation.

OSHA asserts that it has authority under Executive Order 13132 to issue final APF requirements because the problems addressed by these requirements are national in scope. As noted in section V (''Summary of the Final Economic Analysis and Regulatory Flexibility Screening Analysis'') of this preamble, hundreds of thousands of employers must select appropriate respirators for millions of employees. These employees are exposed to many different types and levels of airborne contaminants found in general industry (including healthcare), construction, shipyard, longshoring, and marine terminal workplaces. Accordingly, OSHA concludes that the requirements in this final rule will provide all covered employers in every state with critical information to use when selecting respirators to protect their employees from the risks of exposure to airborne contaminants. However, while OSHA drafted the final APF and MUC requirements to protect employees in every state, section 18(c)(2) of the Act permits state-plan states to develop their own requirements to deal with any special workplace problems or conditions, provided these requirements are at least as effective as the requirements specified by this final rule.

D. State Plans

The 26 states and territories with their own OSHA-approved occupational safety and health plans must adopt provisions comparable to the provisions in this final rule within six months after the Agency publishes the rule. These State-Plan states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to state and local government employees only. Until a state-plan state promulgates its own comparable provisions, federal OSHA will provide the state with interim enforcement assistance, as appropriate.

E. Unfunded Mandates

The Agency reviewed the final APF and MUC provisions according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed in section V (''Summary of the Final Economic Analysis and Regulatory Flexibility Screening Analysis'') of this preamble, OSHA estimates that compliance with this final rule will require private-sector employers to expend about $4.6 million each year. However, while this final rule establishes a federal mandate in the private sector, it is not a significant regulatory action within the meaning of section 202 of the UMRA (2 U.S.C. 1532).

OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt an OSHA-approved state occupational safety and health plan. Consequently, the provisions of this final rule do not meet the definition of a ''Federal intergovernmental mandate''(see section 421(5) of the UMRA (2 U.S.C. 658(5)). Therefore, based on a review of the rulemaking record, the Agency believes that few, if any, of the affected employers are state, local, and tribal governments. Therefore, the requirements of this final rule do not impose unfunded mandates on state, local, and tribal governments.

F. Applicability of Existing Consensus Standards

Section 6(b)(8) of the Occupational Safety and Health Act (29 U.S.C. 655(b)(8)) requires OSHA to explain ''why a rule promulgated by the Secretary differs substantially from an existing national consensus standard,'' by publishing ''a statement of the reasons why the rule as adopted will better effectuate the purposes of the Act than the national consensus standard.'' Regarding APFs, the American National Standard Institute (ANSI) issued in 1992 is the only publicly available consensus standard (i.e., ANSI Z88.2–1992, ''Respiratory Protection'') that provided APFs for the various respirators covered by this final rule (i.e., ''the 1992 ANSI APFs'') (Ex. 1–50). However, ANSI withdrew this consensus standard in 2003, and it has yet to officially adopt a replacement standard.

The Agency relied heavily on the 1992 ANSI APFs in developing this final standard. Nevertheless, the APFs specified in this final rule differ in important ways from the 1992 ANSI APFs. For example, the APFs for full facepiece air-purifying respirators differ substantially between the two standards. Additionally, the APF of 1,000 for powered air-purifying respirators with helmets or hoods listed in Table 1 of this final rule is based on achieving specific test results, while the 1992 ANSI APF for this respirator class is not contingent on any test results. As noted above in section VI of the preamble to this final rule (''Summary and Explanation of the Final Standard''), OSHA has determined that the differences between the APFs specified in this final rule and the 1992 ANSI APFs will afford employees increased protection when they are exposed to hazardous airborne contaminants. Therefore, the Agency did not adopt outright the 1992 ANSI APFs under this final rule.

In addition to the differences between the APF standards described in the previous paragraph, use of the 1992 ANSI APFs depends on meeting six other respirator-selection provisions, several of which differ substantially from the respirator-selection provisions specified in OSHA's Respiratory Protection Standard. In this regard, use of the 1992 ANSI APFs is contingent on ''the nature of the hazardous operation or process,'' ''the location of the hazardous area in relation to the nearest area having respirable air,'' ''the activities of workers in hazardous areas,'' and ''the physical characteristics and functional capabilities and limitations of the various types of respirators''; none of these conditions is specified in this manner in the Agency's Respiratory Protection Standard. Revising OSHA's Respiratory Protection Standard to accommodate the six respirator-selection provisions that are an integral part of the 1992 ANSI APFs is beyond the scope of this rulemaking, which provides additional justification for the Agency not adopting directly the 1992 ANSI APFs.

Finally, the APFs adopted here represent a clear enforceable requirement, not merely a recommendation. When employers and employees can easily determine what respirator is appropriately protective, compliance is simplified and enhanced.

List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Assigned protection factors, Airborne contaminants, Health, Occupational safety and health, Respirators, Respirator selection.

Authority and Signature

Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210, directed the preparation of this notice. The Agency issues these final sections under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Section 3704 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 3701 *et seq.*); Section 41, the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2002 (67 FR 65008); and 29 CFR part 1911.

Signed at Washington, DC on August 9, 2006.

Edwin G. Foulke, Jr.,

Assistant Secretary of Labor.

VIII. Amendments to Standards

■ For the reasons stated in the preamble of this final rule, the Agency is amending 29 CFR parts 1910, 1915, and 1926 to read as follows:

PART 1910—[AMENDED]

Subpart I—[Amended]

■ 1. Revise the authority citation for subpart I of part 1910 to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (62 FR 50017), or 5–2002 (67 FR 65008), as applicable.

Sections 1910.132, 1910.134, and 1910.138 of 29 CFR also issued under 29 CFR part 1911.

Sections 1910.133, 1910.135, and 1910.136 of 29 CFR also issued under 29 CFR part 1911 and 5 U.S.C. 553.

■ 2. Amend § 1910.134 as follows:

■ a. Add the text of the definitions for ''Assigned protection factor (APF)'' and ''Maximum use concentration (MUC)'' to paragraph (b);

■ b. Add the text of paragraphs (d)(3)(i)(A), including Table 1, and (d)(3)(i)(B); and

■ c. Revise paragraph (n).

The added and revised text reads as follows:

§ 1910.134 Respiratory protection.

* * * * *

(b) * * *

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

* * * * *

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) *Assigned Protection Factors (APFs).* Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

TABLE 1.—ASSIGNED PROTECTION FACTORS [5]

Type of respirator [1,2]	Quarter mask	Half mask	Full facepiece	Helmet/hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	[3] 10	50		
2. Powered Air-Purifying Respirator (PAPR)		50	1,000	[4] 25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode		10	50		
• Continuous flow mode		50	1,000	[4] 25/1,000	25
• Pressure-demand or other positive-pressure mode		50	1,000		
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode		10	50	50	
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)			10,000	10,000	

Notes:

[1] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

[2] The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[3] This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

[4] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

[5] These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

(B) *Maximum Use Concentration (MUC).* (*1*) The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

(*2*) Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

(*3*) When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

* * * * *

(n) *Effective date.* Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective November 22, 2006.

* * * * *

Subpart Z—[Amended]

■ 3. Revise the authority citation for subpart Z of part 1910 to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017); and 29 CFR part 1911.

* * * * *

■ 4. Amend § 1910.1001 by:

■ a. Removing Table 1 in paragraph (g)(3);

■ b. Redesignating Table 2 in paragraph (l)(3)(ii) as Table 1;

■ c. Removing the reference to ''Table 2'' in paragraph (l)(3)(ii) and adding ''Table 1'' in its place; and

■ d. Revising paragraphs (g)(2)(ii) and (g)(3).

The revisions read as follows:

§ 1910.1001 Asbestos.

* * * * *

(g) * * *

(2) * * *

(ii) Employers must provide an employee with a tight-fitting, powered air-purifying respirator (PAPR) instead of a negative pressure respirator selected according to paragraph (g)(3) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee.

* * * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepiece respirators for protection against asbestos fibers.

(ii) Provide HEPA filters for powered and non-powered air-purifying respirators.

* * * * *

■ 5. In § 1910.1017, remove the table in paragraph (g)(3)(i), remove paragraph (g)(3)(iii), and revise paragraph (g)(3)(i) to read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(g) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide an organic vapor cartridge that has a service life of at least one hour when using a chemical cartridge respirator at vinyl chloride concentrations up to 10 ppm.

(C) Select a canister that has a service life of at least four hours when using a powered air-purifying respirator having a hood, helmet, or full or half facepiece, or a gas mask with a front-or back-mounted canister, at vinyl chloride concentrations up to 25 ppm.

* * * * *

■ 6. In § 1910.1018, remove Tables I and II and paragraph (h)(3)(ii), redesignate paragraph (h) (3)(iii) as paragraph (h)(3)(ii), and revise paragraph (h)(3)(i) to read as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(h) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Ensure that employees do not use half mask respirators for protection against arsenic trichloride because it is absorbed rapidly through the skin.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

(D) Select for employee use:

(*1*) Air-purifying respirators that have a combination HEPA filter with an appropriate gas-sorbent cartridge or canister when the employee's exposure exceeds the permissible exposure level for inorganic arsenic and the relevant limit for other gases.

(*2*) Front-or back-mounted gas masks equipped with HEPA filters and acid gas canisters or any full facepiece supplied-air respirators when the inorganic arsenic concentration is at or below 500 mg/m^3; and half mask air-purifying respirators equipped with HEPA filters and acid gas cartridges when the inorganic arsenic concentration is at or below 100 $\mu g/m^3$.

* * * * *

■ 7. In § 1910.1025, remove Table II in paragraph (f)(2)(ii) and revise paragraphs (f)(3)(i) and (f)(3)(ii) to read as follows:

§ 1910.1025 Lead.

* * * * *

(f) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full facepiece respirators instead of half mask respirators for protection against lead aerosols that cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

(ii) Employers must provide employees with a powered air-purifying respirator (PAPR) instead of a negative pressure respirator selected according to paragraph (f)(3)(i) of this standard when an employee chooses to use a PAPR and it provides adequate protection to the employee as specified by paragraph (f)(3)(i) of this standard.

* * * * *

■ 8. In § 1910.1027, remove Table 2 in paragraph (g)(3)(i) and revise paragraph (g)(3)(i) to read as follows:

§ 1910.1027 Cadmium.

* * * * *

(g) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full facepiece respirators when they experience eye irritation.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

* * * * *

■ 9. In § 1910.1028, remove Table 1 in paragraph (g)(3)(ii) and revise paragraphs (g)(2)(i) and (g)(3)(i) to read as follows:

§ 1910.1028 Benzene.

* * * * *

(g) * * *

(2) * * *

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

* * * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with any organic vapor gas mask or any self-contained breathing apparatus with a full facepiece to use for escape.

(C) Use an organic vapor cartridge or canister with powered and non-powered air-purifying respirators, and a chin-style canister with full facepiece gas masks.

(D) Ensure that canisters used with non-powered air-purifying respirators have a minimum service life of four hours when tested at 150 ppm benzene at a flow rate of 64 liters per minute (LPM), a temperature of 25 °C, and a relative humidity of 85%; for canisters used with tight-fitting or loose-fitting powered air-purifying respirators, the flow rates for testing must be 115 LPM and 170 LPM, respectively.

* * * * *

■ 10. In § 1910.1029, remove Table I in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers may use a filtering facepiece respirator only when it functions as a filter respirator for coke oven emissions particulates.

* * * * *

■ 11. In § 1910.1043, remove Table I in paragraph (f)(3)(i) and revise paragraphs (f)(3)(i) and (f)(3)(ii) to read as follows:

§ 1910.1043 Cotton dust.

* * * * *

(f) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepieces for protection against cotton dust concentrations greater than five times (5 ×) the PEL.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators used at cotton dust concentrations greater than ten times (10 ×) the PEL.

(ii) Employers must provide an employee with a powered air-purifying respirator (PAPR) instead of a non-powered air-purifying respirator selected according to paragraph (f)(3)(i) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee as specified by paragraph (f)(3)(i) of this standard.

* * * * *

■ 12. In § 1910.1044, remove Table 1 in paragraph (h)(3) and revise paragraph (h)(3) to read as follows: § 1910.1044 1,2-Dibromo-3-chloropropane.

* * * * *

(h) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) Provide employees with one of the following respirator options to use for entry into, or escape from, unknown DBCP concentrations:

(A) A combination respirator that includes a supplied-air respirator with a full facepiece operated in a pressure-demand or other positive-pressure or continuous-flow mode, as well as an auxiliary self-contained breathing apparatus (SCBA) operated in a pressure-demand or positive-pressure mode.

(B) An SCBA with a full facepiece operated in a pressure-demand or other positive-pressure mode.

* * * * *

■ 13. In § 1910.1045, remove Table I in paragraph (h)(3) and revise paragraphs (h)(2)(i) and (h)(3) to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(h) * * *

(2) * * *

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

* * * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) For escape, provide employees with any organic vapor respirator or any self-contained breathing apparatus permitted for use under paragraph (h)(3)(i) of this standard.

* * * * *

■ 14. In § 1910.1047, remove Table 1 in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1047 Ethylene oxide.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because EtO may cause eye irritation or injury.

(ii) Equip each air-purifying, full facepiece respirator with a front-or back-mounted canister approved for protection against ethylene oxide.

(iii) For escape, provide employees with any respirator permitted for use under paragraphs (g)(3)(i) and (ii) of this standard.

* * * * *

■ 15. In § 1910.1048, remove Table 1 in paragraph (g)(3)(i) and revise paragraphs (g)(2) and (g)(3) to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(g) * * *

(2) *Respirator program.* (i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

(ii) When employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by paragraphs (d)(3)(iii)(B)(1) and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever condition occurs first.

(3) *Respirator selection.* (i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.

(C) For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front-or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.

(ii) Employers may substitute an air-purifying, half mask respirator for an air-purifying, full facepiece respirator when they equip the half mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

(iii) Employers must provide employees who have difficulty using negative pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this standard and that affords adequate protection against formaldehyde exposures.

* * * * *

■ 16. In § 1910.1050, remove Table 1 in paragraph (h)(3)(i) and revise paragraph (h)(3)(i) to read as follows:

§ 1910.1050 Methylenedianiline.

* * * * *

(h) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full facepiece air-purifying respirator.

(D) Provide a combination HEPA filter and organic vapor canister or cartridge with powered or non-powered air-purifying respirators when MDA is in liquid form or used as part of a process requiring heat.

* * * * *

■ 17. In § 1910.1052, remove Table 2 in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1052 Methylene chloride.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because MC may cause eye irritation or damage.

(ii) For emergency escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the continuous-flow or pressure-demand mode; or a gas mask with an organic vapor canister.

* * * * *

PART 1915—[AMENDED]

■ 18. Revise the authority citation for part 1915 to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (20 U.S.C. 653, 655, and 687); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (62 FR 50017), or 5–2002 (67 FR 65008) as applicable.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

Subpart Z—[Amended]

■ 19. In § 1915.1001, remove Table 1 in paragraph (h)(2)(iii) and revise paragraph (h)(2) to read as follows:

§ 1915.1001 Asbestos.

* * * * *

(h) * * *

(2) *Respirator selection.* (i) Employers must select, and provide to employees at no cost, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepiece respirators for use against asbestos fibers.

(ii) Employers are to provide HEPA filters for powered and non-powered air-purifying respirators.

(iii) Employers must:

(A) Inform employees that they may require the employer to provide a tight-fitting, powered air-purifying respirator (PAPR) permitted for use under paragraph (h)(2)(i) of this standard instead of a negative pressure respirator.

(B) Provide employees with a tight-fitting PAPR instead of a negative pressure respirator when the employees choose to use a tight-fitting PAPR and it provides them with the required protection against asbestos.

(iv) Employers must provide employees with an air-purifying, half mask respirator, other than a filtering facepiece respirator, whenever the employees perform:

(A) Class II or Class III asbestos work for which no negative exposure assessment is available.

(B) Class III asbestos work involving disturbance of TSI or surfacing ACM or PACM.

(v) Employers must provide employees with:

(A) A tight-fitting, powered air-purifying respirator or a full facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with either HEPA egress cartridges or an auxiliary positive-pressure, self-contained breathing apparatus (SCBA) whenever the employees are in a regulated area performing Class I asbestos work for which a negative exposure assessment is not available and the exposure assessment indicates that the exposure level will be at or below 1 f/cc as an 8-hour time-weighted average (TWA).

(B) A full facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with an auxiliary positive-pressure SCBA whenever the employees are in a regulated area performing Class I asbestos work for which a negative exposure assessment is not available and the exposure assessment indicates that the exposure level will be above 1 f/cc as an 8-hour TWA.

* * * * *

PART 1926—[AMENDED]

Subpart D—[Amended]

■ 20. Revise the authority citation for subpart D of part 1926 to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (62 FR 50017), or 5.2002 (67 FR 650008); as applicable; and 29 CFR part 11.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.62 of 29 CFR also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 of 29 CFR also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (29 U.S.C. 655 note), and 5 U.S.C. 553.

■ 21. In § 1926.60, remove Table 1 and revise paragraph (i)(3)(i) to read as follows:

§ 1926.60 Methylenedianiline.

* * * * *

(i) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full facepiece air-purifying respirator.

(D) Provide a combination HEPA filter and organic vapor canister or cartridge with air-purifying respirators when MDA is in liquid form or used as part of a process requiring heat.

* * * * *

■ 22. In § 1926.62, remove Table 1 in paragraph (f)(3)(ii) and revise paragraph (f)(3)(i) to read as follows:

§ 1926.62 Lead.

* * * * *

(f) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with a full facepiece respirator instead of a half mask respirator for protection against lead aerosols that may cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

* * * * *

Subpart Z—[Amended]

■ 23. Revise the authority citation for subpart Z of part 1926 to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (62 FR 50017), or 5–2002 (67 FR 65008) as applicable; and 29 CFR part 11.

Section 1926.1102 of 29 CFR not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

■ 24. In § 1926.1101, remove Table 1 in paragraph (h)(3)(i) and revise paragraph (h)(3) to read as follows:

§ 1926.1101 Asbestos.

* * * * *

(h) * * *

(3) *Respirator selection.* (i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepiece respirators for use against asbestos fibers.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators.

(ii) Employers must provide an employee with tight-fitting, powered air-purifying respirator (PAPR) instead of a negative pressure respirator selected according to paragraph (h)(3)(i)(A) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee.

(iii) Employers must provide employees with an air-purifying half mask respirator, other than a filtering facepiece respirator, whenever the employees perform:

(A) Class II or Class III asbestos work for which no negative exposure assessment is available.

(B) Class III asbestos work involving disturbance of TSI or surfacing ACM or PACM.

(iv) Employers must provide employees with:

(A) A tight-fitting powered air-purifying respirator or a full facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with either HEPA egress cartridges or an auxiliary positive-pressure, self-contained breathing apparatus (SCBA) whenever the employees are in a regulated area performing Class I asbestos work for which a negative exposure assessment is not available and the exposure assessment indicates that the exposure level will be at or below 1 f/cc as an 8-hour time-weighted average (TWA).

(B) A full facepiece supplied-air respirator operated in the pressure-demand mode and equipped with an auxiliary positive-pressure SCBA whenever the employees are in a regulated area performing Class I asbestos work for which a negative exposure assessment is not available and the exposure assessment indicates that the exposure level will be above 1 f/cc as an 8-hour TWA.

* * * * *

■ 25. In § 1926.1127, remove Table 1 in paragraph (g)(3)(i) and revise paragraph (g)(3)(i) to read as follows:

§ 1926.1127 Cadmium.

* * * * *

(g) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full facepiece respirators when they experience eye irritation.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

* * * * *

[FR Doc. 06–6942 Filed 8–23–06; 8:45 am]

BILLING CODE 4510–26–P