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: Proposed rule; request for comments and scheduling of informal public hearings.

SUMMARY: OSHA is proposing to revise its existing Respiratory Protection Standard to add definitions and specific requirements for assigned protection factors (APFs) and maximum use concentrations (MUCs). The proposed revisions also would supersede the respirator selection provisions of existing substance-specific standards with these new APFs (except the APFs for the 1,3-Butadiene Standard).

The Agency developed the proposed APFs after thoroughly reviewing the available literature, including chamber simulation studies and workplace protection factor studies. The proposed APFs would provide employers with critical information to use when selecting respirators for employees exposed to atmospheric contaminants found in general industry, construction, shipyard, longshoring, and marine terminal workplaces. Proper respirator selection using APFs is an important component of an effective respirator protection program. Accordingly, OSHA has made a preliminary conclusion that the proposed APFs are necessary to protect employees who use respirators against atmospheric contaminants.

DATES: *Written comments.* The Agency invites interested parties to submit written comments regarding the proposed rule, including comments to the information-collection determination under the Supplementary Information section of this **Federal Register** notice, by mail, facsimile, or electronically. You must send all comments, whether submitted by mail, facsimile, or electronically through OSHA's Web site, by September 4, 2003.

Informal public hearings. The Agency plans to hold an informal public hearing in Washington, DC in late summer or early fall of 2003. OSHA expects the DC hearing to last from 9:30 a.m. to 5:30 p.m. on the first day, and from 8:30 a.m. to 5:30 p.m. on subsequent days; however, the exact daily schedule is at the discretion of the presiding administrative law judge. If an additional hearing is held, the Agency will announce the date, time, and location of this hearing later in the subsequent **Federal Register** notice.

Notice of intention to appear to provide testimony at the informal public hearing. Interested parties who intend to present testimony at the informal public hearing in Washington, DC, must notify OSHA of their intention to do so no later than September 4, 2003.

Hearing testimony and documentary evidence. Interested parties who will be requesting more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the hearing, must provide the Agency with copies of their full testimony and all documentary evidence they plan to present by September 4, 2003.

ADDRESSES: *Written comments.* You may submit three copies of written comments to the Docket Office, Docket No. H049C, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693–2350. If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office, telephone number (202) 693–1648. You do not have to send OSHA a hard copy of your faxed comments. You may submit comments electronically through OSHA's Home page at *http://ecomments.osha.gov/.* If you would like to submit additional studies or journal articles, you must submit three copies of them to the OSHA Docket Office at the address above. These materials must clearly identify your electronic comments by name, date, subject, and docket number so we can attach them to your comments.

Informal public hearings. The informal public hearing to be held in Washington, DC will be located in the Auditorium on the plaza level of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC.

Notice of intention to appear to provide testimony at the informal public hearing. Notices of intention to appear at the informal public hearing should be submitted in triplicate to the Docket Office, Docket No. H049C, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Notices may also be faxed to the Docket Office at (202) 693–1648 or submitted electronically at *http://ecomments.osha.gov.* OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

Hearing testimony and documentary evidence. Interested parties who will be requesting more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the informal public hearing must mail three copies of the testimony and the documentary evidence to the Docket Office, Docket No. H049C, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington DC 20210. Additional information for submitting testimony and evidence is found under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: For technical inquiries, 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 hearing information contact Ms. Veneta Chatmon, OSHA Office of Information, Docket No. H–49C, Room N–3649, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1999). For additional copies of this **Federal Register** notice, contact the Office of Publications, Room N–3103, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1888). Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's Home page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

OMB Review Under the Paperwork Reduction Act

After a thorough analysis of the proposed provisions, OSHA believes that these provisions would 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 APFs proposed in this rulemaking. Therefore, the proposed 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 proposed APF provisions require employers to use APFs as part of the respirator-selection process. This process includes obtaining information about the workplace exposure level 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 proposal involves 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 proposal would be equivalent to the burden already imposed under the existing standard.

Interested parties who want to comment on OSHA's determination that the proposed provisions contain no additional paperwork burden compared to the existing paperwork requirements must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. The Agency also encourages commenters to submit their comments on this paperwork determination to OSHA along with their other comments.

Federalism

The Agency reviewed the proposed 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'' or ''OSH 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 proposal 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 the proposed rulemaking does not expand this limitation.

OSHA asserts that it has authority under Executive Order 13132 to propose APF requirements because the problems addressed by these requirements are national in scope. As noted in section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility 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, construction, shipyard, longshoring, and marine terminal workplaces. Accordingly, the proposed requirements would provide 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 proposed 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 final requirements that result from this proposal.

State Plans

The 26 states and territories with their own OSHA-approved occupational safety and health plans must adopt comparable provisions within six months after the Agency publishes the final APF and MUC requirements. These 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, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey and New York 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.

Unfunded Mandates

The Agency reviewed the proposed 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 VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble, OSHA estimates that compliance with this proposal would require private-sector employers to expend about $4.5 million each year. However, while this proposal 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 proposed provisions 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 to date, the Agency believes that few, if any, of the affected employers are state, local, and tribal governments. Therefore, the proposed APF requirements do not impose unfunded mandates on state, local, and tribal governments.

Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (*i.e.*, a rulemaking that has an annual affect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.*, through air, food, water, soil, product use).

The proposed provisions are not economically significant under Executive Order 12866 (*see* section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble). In addition, after reviewing the proposed APF provisions, OSHA has determined that these provisions do not impose environmental health or safety risks to children as set forth in Executive Order 13045. The proposed provisions would require employers to use APFs in selecting proper respirators for employee use, with the objective of limiting employee exposures to airborne contaminants. To the best of OSHA's knowledge, no employees under 18 years of age work under conditions that require respirator use. However, if such conditions exist, children who use respirators selected according to these proposed provisions would receive adequate protection from the airborne contaminants. In this regard, the Agency is requesting public comment on whether employees under the age of 18 years use respirators, and, if they do, the extent to which the respirators provide them with adequate protection. Based on this discussion, OSHA believes that the APF and MUC requirements proposed in this rulemaking do not constitute a covered regulatory action as defined by Executive Order 13045.

Applicability of Existing Consensus Standards

Section 6(b)(8) of the OSH Act 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.'' [*see* 29 U.S.C. 655(b)(8)]. Accordingly, the Agency compared the proposed APF requirements with the APF provisions of ANSI Z88.2–1992 (''Respiratory Protection''). This consensus standard, published by the American National Standards Institute in 1992, is the only publicly available consensus standard that includes APFs. In most instances, the APFs being proposed by the Agency are identical to ANSI's APFs, however, some differences exist. Where OSHA has proposed an APF that differs from ANSI's, the Summary and Explanation provides the basis for that decision.

Environmental Impact Assessment

The Agency reviewed the proposed provisions according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council of Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). OSHA estimates that this proposed rule would have a direct impact on a relatively small number of respirator users and, in so doing , merely alter the type of respirator they are using. The Agency does not anticipate that this will significantly alter solid waste patterns, water quality, or ambient air quality. As a result of this review, OSHA concludes that the proposed provisions would have no significant environmental impact.

I. General

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Glossary

This glossary specifies the terms represented by acronyms, and provides definitions of other terms, used frequently in this proposal. This glossary does not change the legal requirements as proposed in this notice of proposed rulemaking, nor is it intended to propose new regulatory requirements or definitions. It is presented simply to assist the reader.

A. Acronyms

ACGIH: American Conference of Governmental Industrial Hygienists.
AIHA: American Industrial Hygiene Association.
ANSI: American National Standards Institute.
APF: Assigned Protection Factor (*see* definition in proposed regulatory text).
DOP: Dioctylphthalate (an aerosolized agent used for quantitative fit testing).
DFM: Dust/Fume/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.
LLNL: Lawrence Livermore National Laboratory.
MSHA: Mine Safety and Health Administration.
MUC: Maximum Use Concentration (*see* definition in proposed regulatory text).
NIOSH: National Institute for Occupational Safety and Health.
NRC: Nuclear Regulatory Commission.
OSHA: Occupational Health and Safety Administration.
PAPR: Powered air-purifying respirator (*see* definition below).
PEL: Permissible Exposure Limit (an occupational exposure level specified by OSHA).
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 (respirator selection guidance developed by NIOSH that contains a set of respirator protection factors).
REL: Recommended Exposure Limit (an occupational exposure level recommended by NIOSH).
SAR: Supplied-air 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 (an occupational exposure level recommended by ACGIH).
SWPF: Simulated Workplace Protection Factor (*see* definition below under ''Protection factor study'').

B. 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.

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:* A filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 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:* 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.

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:* 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 is generally accomplished by measuring the ratio of the concentration of an agent (*e.g.*, hazardous substance) outside the respirator (Co) to the agent's 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 tend to understate the protection that would be obtained if the respirator were being worn at all times.

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 correctly worn and used as part of a comprehensive respirator program. 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 subject 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:* 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:* An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

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

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

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

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (the ''OSHA Act'' or ''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), 29 U.S.C. 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), 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 must also 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)].

OSHA has discussed the nature of adverse health effects caused by exposure to airborne chemical hazards many times in previous rulemaking activities [*see,* for example, the preambles to any of OSHA's substance-specific standards codified in 29 CFR 1910.1001 to 1910.1052]. As discussed in the Significance of Risk section of the Respiratory Protection Standard, the health risk presented to workers can be represented by the risk that a respirator will not be properly selected or used, which increases the possibility that the user will be overexposed to a harmful air contaminant. The risks that are addressed by the Respiratory Protection Standard are not characterized as illness-specific risks but, instead, relate to a more general probability that when a respirator provides insufficient protection, the wearer may be exposed to a level of air contaminant that is associated with material impairment of the worker's health.

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 created with technology that can reasonably be expected to be developed [*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,* 453 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 must also 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 proposed APF and MUC provisions 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 where 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 the accidental release of airborne contaminants. The proposed amendments to OSHA's Respiratory Protection Standard, and the Agency's substance-specific standards, would 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. The proposed APF and MUC provisions provide additional guidance on the point at which an increase in the level of respiratory protection is necessary. The APF and MUC provisions will greatly enhance an employer's ability to select a respirator that will adequately protect employees. OSHA believes that in the absence of these proposed provisions, employers will be less certain about which respirators to select for adequate employee protection.

The Agency also developed the proposed provisions 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 VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble provides the benefits and costs of this proposal, and describes several other alternatives as required by section 205 of the UMRA (2 U.S.C. 1535). Based on this information, OSHA preliminarily concludes that the proposed APF and MUC provisions constitute the most cost-effective alternative for meeting its statutory objective of reducing risk of adverse health effects to the extent feasible.

III. Events Leading to the Proposed Standard

A. Regulatory History

Congress created 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 American Conference of Governmental Industrial Hygienists (ACGIH), the National Fire Protection Association (NFPA), and the American National Standards Institute (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). 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 needed 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, use of PAPRs, changing filter elements whenever an employee detected an increase in breathing resistance, and requirements referring employees with breathing difficulties to a physician trained in pulmonary medicine, either at fit testing or during routine respirator use [*see, e.g,* 29 CFR 1910.1025 (OSHA's Lead Standard)]. The respirator provisions in these substance-specific standards took into account advances in respirator technology and changes in related guidance documents that were state-of-the-art when OSHA published these substance specific standards and, in particular, recognized that effective respirator use depends on a comprehensive respiratory protection program that includes use of APFs.

OSHA's 1982 ANPR sought information on the effectiveness of its current Respiratory Protection Standard, the need to revise this standard, and suggestions on the nature of the revisions. The 1982 ANPR referenced the ANSI Z88.2–1980 standard on respiratory protection with its table of protection factors, the 1976 report by Dr. Ed Hyatt from the 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). Questions #2, #3, and #4 in the 1982 ANPR asked for comments on how OSHA should use protection factors. The Agency received responses from 81 interested parties. 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 the public comments received in response to 1982 ANPR, and OSHA's own analysis of revisions needed in the Respiratory Protection Standard to account for state-of-the-art respiratory protection. The Agency received 56 responses from interested parties (Ex. 36) which OSHA carefully reviewed in developing the proposal.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and provided public notice of an informal public hearing on the proposal (59 FR 58884). The Agency convened the informal public hearing on June 6, 1995. On June 15, 1995, as part of the public hearing, OSHA held a one-day panel discussion by respirator experts of APFs. Areas discussed included difficulties in measuring performance of respiratory protection in WPF and SWPF studies, statistical uncertainties regarding the distribution of data from these studies, and the problems associated with setting APFs for all respirators that protect all potential respirator users across a wide variety of workplaces and exposure conditions.

OSHA 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). That 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 it could resolve the complex issues regarding how to establish APFs, including what methodology to use in analyzing existing protection factor studies (*see* Section IV below for a more detailed explanation of the Nicas report and the comments made on it).

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 maximum use concentration (MUC) pending further rulemaking (see 63 FR 1182 and 1203). The Agency stated that, until a future rulemaking on APFs is completed:

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

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

History of Assigned Protection Factors

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

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

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

In 1972, NIOSH and the Bureau of Mines published new approval schedules for respiratory protection under 30 CFR Part 11. However, these new approval schedules did not include fit testing provisions as part of the respirator certification process.

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

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

5 for single-use respirators;

10 for half-mask respirators with DFM or HEPA filters;

50 for full facepiece air-purifying respirators with HEPA filters or chemical cartridges;

1,000 for PAPRs with HEPA filters;

1,000 for half-mask SARs operated in the pressure demand mode;

2,000 for full facepiece SARs operated in the pressure demand mode; and

10,000 for full facepiece SCBAs operated in the pressure demand mode.

ANSI's respiratory protection Subcommittee decided to revise Z88.2–1969 in the late 1970s. During its deliberations, the Subcommittee conducted an extensive discussion regarding the role of respirator protection factors in an effective respiratory protection program. As a result, the Subcommittee decided to add an APF table to the revised standard. In May 1980, ANSI published the revision as Z88.2–1980 (Ex. 10, Docket No. H049) and it contained the first ANSI Z88.2 respiratory protection factor table. The ANSI Subcommittee based the table on Hyatt's protection factors, which it updated using results from fit testing studies performed at LANL and elsewhere since 1973. For example, the protection factor for full facepiece air-purifying particulate respirators was 100 when qualitatively fit tested, or 1,000 when equipped with high efficiency filters and quantitatively fit tested. The table consistently gave higher protection factors to tight-fitting facepiece respirators when employers performed quantitative fit testing rather than qualitative fit testing. The ANSI Subcommittee concluded that PAPRs (with any respiratory inlet covering), atmosphere-supplied respirators (in continuous flow or pressure demand mode), and pressure demand SCBAs required no fit testing because they operated in a positive pressure mode. Accordingly, it gave these respirators high protection factors, limited only by IDLH values. The Subcommittee assigned protection factors of 10,000 and over to respirators used in IDLH atmospheres.

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

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

NIOSH stated that it may revise the 1987 RDL if warranted by subsequent WPF studies.

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 the 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 was 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 Z88.2 standard abandoned the 1980 standard's practice of giving increased protection factors to some respirators if quantitative fit testing was performed.

Tom 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, he reviewed the reasoning used by the ANSI Subcommittee in setting the 1992 ANSI APFs. He 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. The Z88.2 Subcommittee also reviewed the 1987 NIOSH RDL values, particularly the RDL's reduction of loose-fitting facepiece and PAPRs with helmets or hoods to an APF of 25 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 it decided to select 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 analogies (*i.e.*, same facepiece designs, operation at the same airflow rates) between these respirators and airline respirators. Nelson noted that a subsequent WPF report by Keys (Ex. 1–64–40) on PAPRs with helmets or hoods was consistent with an APF of 1,000. According to Nelson, the Subcommittee used WPF studies by Myers (Ex. 1–64–48), Gosselink (Ex. 1–64–23), Myers (Ex. 1–64–47), 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.

Tom Nelson 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 facepiece 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 to be consistent with the APF for SARs with helmets or hoods found in two earlier studies—a WPF study by Johnson (Ex. 1–64–36) and a SWPF study by Skaggs (Ex. 1–3803). The Subcommittee used the analogy between PAPRs and continuous flow supplied-air respirators to select the APF of 50 for half-mask pressure demand SARs and 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.''

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 88.2–1992 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 currently is reviewing the ANSI Z88.2–1992 standard, in accordance with ANSI policy specifying that each standard receive a periodic review. This review likely will result in revisions to the Z88.2 APF table based on WPF and SWPF respirator performance studies conducted since publication of the current standard in 1992.

B. Need for APFs

The proposed APF definition and regulatory text are important additions to, and an integral part of, OSHA's Respiratory Protection Standard because employers need this information to select appropriate respirators for employee use when engineering and work-practice controls are insufficient to maintain hazardous substances at safe levels in the workplace. Employers need the consistent and valid information contained in the proposed APF provisions to select respirators for employee protection, based on the type of hazardous substance and the level of employee exposure to that substance.

As noted in Table I of the proposed regulatory text, the proposed APFs differ for each class of respirator. In this regard, the proposed APF for a class of respirators specifies the workplace level of protection that class of respirator should provide under an effective respiratory protection program. Therefore, when the concentration of a hazardous substance in the workplace is less than 10 times the PEL, the employer must select a respirator from a respirator class with an APF of at least 10 for use by employees exposed to that substance. However, when the concentration of the hazardous substance is greater than 10 times the PEL, the employer must select a respirator that has an APF greater than 10 for this purpose. In addition, employers would derive MUCs from the APFs proposed for the different respirator classes. These MUCs determine the maximum atmospheric concentration of toxic gasses and vapors at which respirators equipped with cartridges and canisters can be used to protect employees.

In summary, when used in conjunction with the existing provisions of the Respiratory Protection Standard, especially the respirator selection requirements specified in paragraph (d), the proposed APF definition and regulatory text would provide employers with the information they need to select the appropriate respirators for reducing employee exposures to hazardous substances to safe levels. Accordingly, integrating the proposed APF provisions into the Respiratory Protection Standard will ensure that employees receive the optimum level of protection afforded by that standard.

C. Review of the Proposed Standard by the Advisory Committee for Construction Safety and Health (ACCSH)

The proposed provisions would replace the existing respirator-selection requirements specified by the Respiratory Protection Standard for the construction industry (29 CFR 1926.103). Accordingly, OSHA's regulation governing the Advisory Committee on Construction Safety and Health (ACCSH) at 29 CFR 1912.3 requires OSHA to consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees. On December 5, 2002, OSHA briefed the ACCSH membership on the proposed provisions and responded to their questions. On March 27, 2003, the APF proposal was distributed to the ACCSH membership for their review prior to their next regular meeting on May 22, 2003. OSHA staff discussed the APF proposal and answered questions from the ACCSH members during their meeting on May 22, 2003. The ACCSH then recommended that OSHA proceed with publishing the proposal.

IV. Methodology for Developing Assigned Protection Factors

This section contains an overview of the analyses performed for OSHA and summaries of the studies used in these analyses. OSHA entered the complete analyses and studies into Docket H049C as Exhibits 3, 4, and 5 and Exhibit 1–156 (Dr. Nicas' report). Studies and information supporting the APF for each class of respirator are discussed in Section VII of this document. The analyses discussed below assisted OSHA in determining its proposed approach to deriving APFs. Commenters expressed appreciation for the approach suggested by Dr. Nicas, but nearly all did not support implementation of his methods. However, his recommendations provided guidance to the Agency regarding the types of studies and data needed for determining APFs. Dr. Brown's complex statistical analyses demonstrated the widespread variability inherent in current workplace protection factor studies. However, he found in his final analysis that the performance of filtering facepiece and elastomeric half-mask respirators could not be differentiated, thereby supporting grouping of these two types of respirator under one APF.

A. Dr. Nicas' Proposal and Response From Commenters

During the June 1995 APF hearings, OSHA devoted a full day to a panel discussion on the uncertainties associated with sample statistics and their use for deriving APFs. Based on this discussion, OSHA contracted with Dr. Mark Nicas to develop a statistical method for deriving APFs. Nicas used two approaches to account for within-wearer and between-wearer variabilities. For penetration data collected from a specific cohort of respirator wearers, he used a one-factor lognormal analysis of variance. He used a two-factor lognormal analysis of variance to perform a meta-analysis of the data from studies of different cohorts of respirator wearers. Using these approaches, Nicas proposed assigning two different protection factors; he recommended one for chronic toxicants (*i.e.*, substances regulated by an 8-hour PEL), and the other for acute toxicants (*i.e.*, substances regulated by a STEL). Nicas also made recommendations regarding sampling data management and inclusion of studies in statistical analyses of respirator performance.

OSHA reopened the rulemaking record on November 7, 1995 (60 FR 56127) to request comment on Dr. Nicas' report titled ''The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors'' (Ex. 1–156). OSHA received 12 comments on the report. While some commenters expressed general support for Nicas' approach (*e.g.*, Ex. 1–182–4, American College of Occupational and Environmental Medicine), others had serious reservations about establishing APFs using this approach. The issues raised by these commenters are described below.

1. Lack of Valid and Reliable WPF Data

Two commenters stated that the available WPF data were of insufficient quality to permit a sophisticated statistical analysis. The 3M Company (3M) commended OSHA for ''attempting to use science to evaluate workplace studies for determining Assigned Protection Factors,'' but stated that insufficient valid data were available for such an evaluation, and that the data that were available were too variable (Ex. 1–182–5). In addition, Organization Resource Counselors, Inc. (ORC) stated: ''The use of existing, often flawed, workplace protection factor studies, is not a solution to the problem. * * * A reliance on sophisticated statistics in an attempt to compensate for a lack of reliable scientific data on respirator performance is both bad science and bad policy'' (Ex. 1–182–10).

2. Inappropriate Use of ANOVA Model

Three commenters believed that using Nicas' lognormal ANOVA model to analyze existing data was inappropriate (Exs. 1–174, 1–182–5, 1–182–1). Two of these commenters advocated using a simple analysis of the aggregate data instead (Exs. 1–174, 1–182–5). Thomas Nelson (Ex. 1–174) and 3M (1–182–5) expressed concern that the ANOVA model focuses primarily on within-wearer and between-wearer variability, while ignoring the potential variability contributed by other sources such as work site, respirator model, filter, and contaminant. Nelson stated: ''A simple analysis of the entire data (*i.e.*, geometric mean, estimates of percentiles and confidence intervals) includes these and other possible sources of variation and the within-person variability in the model.'' Two other commenters, Drs. Rappaport and Kupper [contractors for the Industrial Safety Equipment Association (ISEA)] believed that using an ANOVA model provided some benefits; however, they had concerns regarding the assumption of log-normality of penetration values, the lack of validation of the model, and errors that appeared in some of the equations. Therefore, they regarded ''implementation of Dr. Nicas' ideas as being problematic at this time,'' and encouraged the industry to develop improved methods and data for deriving APFs (Ex. 1–182–1).

3. ANOVA Model Fails To Account for Differences Between WPF Studies

Five commenters stated that the proposed analysis fails to account for important differences between studies that could affect WPF values. Thomas Nelson and 3M believed that the ANOVA model does not account for other sources of variability (Exs 1–174, 1–182–5). NIOSH stated that Nicas' report did not address the effect of the test subjects' work rates and other activities on a respirator's performance (Ex. 1–182–3), and did not account for employee training and program surveillance (Ex. 1–182–9). The Chemical Manufacturers Association (CMA) also commented on factors not considered in the Nicas report, ''including differences in training, experience, work site, work rate and sample collection'' (Ex. 1–182–7). ORC noted: '' The results of a WPF study are based on at least the following components: quality of the respirator chosen; quality of the training program; quality of the fit testing and selection program; nature of the work and ability to challenge the fit of a respirator (sedentary versus high exercise work)'' (Ex. 1–182–10).

4. Using a Conservative Criterion for Setting APFs

Five commenters stated that Nicas' criterion for setting APF values was overly conservative. The Dow Chemical Company (Dow) stated that the Nicas approach ''would result in protection factors which are very conservative'' (Ex. 1–182–2), while 3M believed that OSHA's use of Nicas's recommendation would result in a major change in the pattern of respirator use (Ex. 1–182–5). NIOSH commented that the approach may result in very low APF estimates because of high WPF variability, and that while the approach would derive more conservative (*i.e.*, more protective) APFs, its use for ''WPF studies with small sample sizes * * * could result in APF estimates less than or equal to 1.0 (APF values less than 1.0 are meaningless)'' (Ex. 1–182–3). Drs. Rappaport and Kupper stated that only weak precedence existed for Nicas' use of 95th percentiles to define APFs, and suggested that other percentiles (*e.g.*, the 90th percentile) would be more practical to implement (ISEA, Ex. 1–182–1). Finally, CMA believed that the proposed criterion rated ''all respirators on the lowest protection achieved by the lowest performing person'' (Ex. 1–182–7).

5. APFs Based on a Contaminant's Toxicity (Acute Versus Chronic Toxicants)

Dr. Nicas proposed that two APFs be assigned to a respirator, depending on its use against either a chronic toxicant or an acute toxicant. Four commenters remarked on the feasibility and effects of this approach. NIOSH commented that ''defining acceptable protection against short-term exposures is very complex * * *.'' (Ex. 1–182–3). 3M commented that dual APFs would be confusing to the user community and workers, and would make program management difficult (Ex. 1–182–5). CMA provided similar comments, and noted that many materials have both chronic and acute effects (Ex. 1–182–7). ORC believed that:

> * * * different APFs for different contaminants or types of exposure is not appropriate. Occupational exposure standards should have adequate safety factors which are based on the health outcome (*e.g.*, irritation, systemic toxicity, carcinogenicity) of exposure. (Ex. 1–182–10)

While Drs. Rappaport and Kupper stated that Nicas' argument about respiratory protection for substances with chronic effects was logical, they regarded the question of how to deal with acutely toxic substances as unresolved (Ex. 1–182–1).

6. Distribution of Contaminant Concentrations

Two participants believed that it was necessary to incorporate information on the variability of ambient exposure concentrations, as well as the maximum anticipated concentration, when discussing respirator selection. CMA stated that since an employee's exposures will vary from day to day, employers should select respirators with maximum use limits well above the mean exposure levels to ensure ''that there is less than 5% probability of exposures above the maximum use limit of the respirator'' (Ex. 1–182–7). In a related comment, ORC stated that many industrial applications typically have exposures only 2–3 times the acceptable exposure limit; therefore, ''selecting a respirator with an APF of 10 may mean there is only a remote chance of overexposure to a contaminant due to fit/wear variability'' (Ex. 1–182–10).

7. Other Concerns With Nicas' Method

The commenters raised several other issues with Dr. Nicas' methodology. For example, 3M (Ex. 1–182–5) and CMA (Ex. 1–182–7) believed that the relationship between outside concentration and WPF (*i.e.*, WPF increases with increasing Co) was poorly understood; therefore, a sophisticated analysis of the data is questionable. Other commenters noted errors in the equations of the proposed model (*e.g.*, Ex. 1–182–1) and with the distribution of the respirator penetration values (Ex. 1–182–1).

8. Miscellaneous Comments (*e.g.*, ANSI APFs)

In addition to responding to the Nicas report, a number of commenters supported using the APFs recommended in the ANSI Z88.2–1992 respiratory protection standard (Exs. 1–182–1, 1–182–2, 1–182–5, 1–182–7, 1–182–10). These commenters stated that the members of the ANSI Z88.2 committee were ''respected industrial hygiene and respirator experts'' (Ex. 1–182–5), that the ANSI Z88.2–1992 APFs were ''the appropriate values'' (Ex. 1–182–7), and that the ANSI APFs ''have been through the ANSI peer review process'' (Ex. 1–182–5). In advocating use of the ANSI APFs, none of the commenters described the process by which the ANSI Z88.2 committee derived its APFs, or identified the studies and other information on which that committee relied. Furthermore, several commenters (Exs. 1–182–7, 1–182–5, 1–182–10, 1–182–6, 1–182–8) noted that the ANSI Z88.2–1992 standard does not explicitly account for several factors in assigning APF values to different respirator classes, or the use of a respirator in different situations, which they indicated were necessary considerations. Moreover, some commenters (Exs. 1–182–11,1–182–12) recommended APFs that differ from those published by the ANSI Z88.2 Committee. Other commenters believed that it was OSHA's responsibility to show that the commonly used ANSI Z88.2 1992 APFs were erroneous (Ex. 1–182–2), and that the Agency should not use SWPF studies to derive APFs (Ex. 1–182–5). Several participants at the hearing for the final Respiratory Protection Standard stated that OSHA should issue a second NPRM to address the development of APFs (Exs. 1–182–1, 1–182–5, 1–182–10).

After carefully considering Dr. Nicas' model and the comments received in response to his report of the model, the Agency concluded that other possible approaches to deriving APFs should be investigated. Accordingly, the Agency identified and collected available data for this purpose. Of particular interest were data that OSHA could use to discriminate between the performance of different respirator classes. The Agency gathered information from both published and non-published papers and reports, and included WPF, SWPF, PPF, and EPF studies; Health Hazard Evaluations conducted by NIOSH; respirator performance data from manufacturers, such as SWPF data submitted to OSHA by Bullard (Ex. 3–8); and other material related to assessing respirator performance. This information is in Docket H049 as Exhibits 2, 3, and 4.

To assist in evaluating the data, OSHA employed Dr. Kenneth Brown (a statistician) and several respirator authorities: Mr. Harry Ettinger, Dr. Gerry Wood of LANL, and Drs. James Johnson, Kenneth Foote, and Arthur Bierman of LLNL. After the Agency reviewed all of the studies and information, it decided to attempt to analyze only WPF and SWPF studies since they address respirator performance exclusively. OSHA discusses the work and findings of these individuals below.

B. Analyses of WPF Studies

OSHA contracted with Dr. Brown to investigate possible approaches, other than those approaches proposed by Nicas, to evaluate respirator performance data from WPF studies. The following discussion is a general description of the analyses performed by Brown, as well as his overall conclusions. For a detailed explanation of the methodology and rationale used in the analyses, refer to Brown's reports in the docket (Exs. 5–1, 5–2).

OSHA reviewed the available WPF studies for possible inclusion in Brown's analyses. Early in this review process, the Agency decided to exclude WPF studies with a gas or vapor workplace challenge agent because: The preponderance of studies were conducted in workplaces with particulate challenges; gas/vapor studies did not provide any further insight or clarification regarding sources of variability in WPF studies (most likely, gas/vapor studies add variability to the data such as the effects of humidity on sampling media collection and desorption efficiencies); and pulmonary elimination differs between gases/vapors and particulates. Therefore, OSHA decided to analyze only WPF studies using particulate challenge agents. The Agency evaluated those studies initially selected for further analysis for compliance with the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134), as well as completeness of the data. The Agency compiled a list of review items to use in evaluating each study (Ex. 5–5).

OSHA then divided the remaining studies into two categories: Half-mask negative-pressure air-purifying respirators (APRs) and atmosphere-supplying respirators (PAPRs and SARs). This procedure resulted in 22 APR studies and 16 PAPR/SAR studies for analysis. OSHA placed a list of these studies, and their respective respirators, in the docket (Ex. 7–4). Brown subsequently identified 14 APR studies and 13 PAPR/SAR studies for further analysis (see Exs. 5–1 and 5–2 for more information on the evaluation criteria).

Brown's analyses divided the respirators used in these studies into separate respirator classes. The analyses divided APRs into 5 classes, listed below in Table 1. As this table shows, Brown's analyses separated filtering facepieces into four classes based on the characteristics listed under the Description column heading, with the fifth class comprised of elastomeric facepiece APRs.

TABLE 1.—HALF-MASK APR CLASSES

Class	Type	Description			
		Adjustable head straps	Exhalation valve	Double shell construction	Foam ring liner
1	Filtering facepiece				
2	Filtering facepiece	X		X	
3	Filtering facepiece	X	X	X	
4	Filtering facepiece	X	X	X	X
5	Elastomeric facepiece.				

In addition, Brown's analyses divided PAPRs into five classes and SARs into two classes, as shown in Table 2.

TABLE 2.—PAPR AND SAR CLASSES

Class	Type	Description
1	PAPR	Loose-fitting facepiece.
2	PAPR	Loose-fitting facepiece with hood and/or helmet.
3	PAPR	Hood and/or helmets—not loose-fitting.
4	PAPR	Tight-fitting half-mask face-piece.
5	PAPR	Tight-fitting full facepiece.
6	SAR	Loose-fitting.
7	SAR	Hood or helmet.

Later in the analyses, Brown further divided these classes according to class of respirator, study, and challenge agent (CLSA). This division resulted in 26 CLSAs for the APRs and 14 CLSAs for the PAPRs/SARs.

The data from the WPF studies consisted of simultaneous measurements of the challenge agent concentration inside the respirator facepiece (*i.e.*, concentration inside or Ci) and outside the respirator facepiece (*i.e.*, concentration outside or Co) in the ambient workplace atmosphere. Corresponding Co and Ci measurements can be used to calculate the workplace protection factor (WPF = Co/Ci) or penetration of the contaminant into the respirator (PEN = Ci/Co = 1/WPF). The APR studies had a total of 917 data pairs, while the PAPR/SAR studies provided 443 data pairs.

1. Half-Mask APRs

In the first phase of his analysis, Brown statistically analyzed the data for half-mask negative pressure APRs, both filtering facepiece and elastomeric APRs, using the following three approaches: (1) Pooled the data within classes, corrected the data for the positive relationship found between WPF values and increasing Co, and compared the differences in WPF statistics between classes; (2) conducted an intra-study analysis of the performance of two different classes of respirator used against the same contaminant under similar workplace conditions; and (3) divided the data into class-study-agent combinations, and evaluated WPF as a function of Co. The following sections discuss these approaches in detail.

Approach 1. Brown's initial approach was to determine if he could pool the data within each respirator class and estimate the fifth percentile WPF for that respirator class; he then tested for differences in WPFs between the respirator classes. He divided and analyzed the data by study, treating the data from each study as a homogeneous sample arising from the same parent distribution. Then he examined the data in each study for a Co effect, and constructed a scatterplot of ln(WPF) versus ln(Co) for each respirator class. In doing so, he treated extreme or poorly fitting data as outliers and removed them from the analysis. He subsequently derived a linear regression of ln(WPF) on ln(Co) for each study, and extrapolated from the observed range to the entire range of Co values in all of the data. The positive slopes, which he found for most classes, showed that ln(WPF) increased as ln(Co) increased. In addition, the regression lines were well mixed, indicating that studies within the same respirator class varied more than anticipated. This result indicated that variability occurring within respirator classes could obscure differences between respirator classes.

These studies collected data over different ranges of Co. Therefore, to compare the WPFs observed in the studies, Brown corrected the WPF values for all studies, using a common Co adjustment factor. He pooled the adjusted WPFs by class, and then plotted the cumulative distributions to determine if he could identify differences between respirator classes, despite intra- and inter-study differences. Finding no differences between respirator classes using the Co adjustment factor, he concluded that:

> Observed 5th percentiles for WPFs, and their lower confidence intervals when adjusted for the Co effect, showed no clear evidence that any class was preferable to another. In particular, there was no indication that Class 5 (elastomerics) performed better than four disposable classes. (Ex. 5–1, p. 8)

The results of these analyses prompted a more detailed examination of the data. To control for study-related and agent-related factors that may contribute to variability, Brown performed an intra-study analysis on two different respirator classes used against the same workplace challenge agent under similar workplace conditions (Approach 2).

Approach 2. The second approach attempted to determine respirator performance after controlling for study-to-study and agent-to-agent sources of variability. Among the half-mask APRs, the chance of detecting performance differences appeared to be greatest for comparisons between elastomeric and filtering facepiece respirators. In implementing this approach, Brown assumed that controlling for study and agent sources of variability would result in WPF differences attributable, in large part, to variability in respirator performance.

Four of the studies compared the performance of elastomeric and filtering facepiece respirators against the same challenge agent in the same workplace. After reviewing these studies, a study by Meyers and Zhuang (Ex. 1–64–51) was selected for further analysis because it was recent, followed a protocol patterned after other published WPF study protocols, and was well documented. Brown's statistical analyses of this study (see Ex. 5–1, Appendix C) indicated large sources of variability within the study, making comparison of the two respirator classes difficult and tenuous. Based on plots of the data and the occurrence of several outliers, it appeared that even data on the same agent, obtained under similar workplace conditions, may not have come from the same parent distribution. In addition, the variability of WPFs within the study (regardless of adjustment for the Co effect) was large. Therefore, the results of this second approach led Brown to state that, at least in this analysis, ''workplace studies may have too much intra-study variability for reasonably valid/accurate/reliable assessments and comparisons of respirator effectiveness.'' (Ex. 5–1, p. C–17)

Approach 3. Brown began the third statistical approach by dividing the data into units smaller than respirator class, *i.e.*, units based on class of respirator, study, and workplace challenge agent (class-study-agent or CLSA). This procedure resulted in 42 CLSA combinations. After removing deficient data (*e.g.*, no data on Co), he narrowed the data set to 26 combinations. Again, he tested the data for each CLSA to determine if WPF increases with Co and, if so, whether the effect held for all respirator classes. Data analyses of the 26 CLSAs indicated that WPF increased with Co; Brown then derived a common estimate (across all CLSAs) of the Co effect. He subsequently estimated the means for the CLSAs within each class of respirator, both with and without adjustment for Co effect. Brown compared the means of these CLSAs within and between respirator classes. For each respirator class, he grouped the CLSAs that had no significant difference between their means into common subclasses, and plotted both the adjusted and non-adjusted means [*i.e.*, mean of ln(PEN)] of the subclasses, as well as their associated confidence intervals. The results of the comparisons showed that: the estimated means of CLSAs vary so much within a class that the mean of one CLSA is likely to be a poor predictor of the mean of another CLSA within the same class; and it was not visually apparent from the plots that one class of respirator performed better than another class. In general, the comparison indicated that study outcomes, even within the same class of respirator, are highly heterogeneous.

Final analysis. Since the three approaches discussed above could not distinguish between respirator effectiveness within or across classes, the data were viewed, as a whole, from the relationship of Ci and Co. Brown pooled the data for all 26 CLSAs and derived several functional relationships from the pooled data. This approach showed that the majority of the observed data pairs achieved a WPF of 10. (See Ex. 5–1 for more details.)

After performing the above analyses, Brown made a number of observations and conclusions. He noted that the range of WPF values within a CLSA was typically wide, and that the observations were highly variable. In addition, he believed that variability in WPF studies can affect the accuracy, validity, and reliability of study results, as well as the ability to compare study results. Brown noted several possible sources of variability in WPF studies, including: (1) Study characteristics related to study design, execution, sample analysis, and data management and reporting; (2) measurements of Ci at different outside concentrations (Co effect), taken in conjunction with other poorly described factors (*e.g.*, particle size, temperature, humidity) that may affect the relationship of Ci and Co; (3) characteristics of the ambient agent itself (*e.g.*, possible effects of the agent occurring in a mixture with other agents); and (4) variations in data among studies related to using different study procedures (*e.g.*, repeated measurements on the same worker in some studies versus single measurements on each worker in other studies, random versus non-random selection of study participants). He also commented that the analyses assumed that the data were representative of workplace conditions; however, the data may not represent either current or future workplaces in which employees use respirators. Finally, Brown observed that studies with high Ci values, relative to Co, may have influenced his findings. He believed that these studies should be closely reviewed because some study weakness, unrelated to respirator performance, could be the reason for the high Ci values.

Brown also made some general observations about WPF studies. First, he believed that the role of WPF studies in assessing and comparing respirator effectiveness, and influencing APFs, should be reevaluated. He believed that a more refined instrument that is amenable to experimental design and control, such as chamber studies, is better suited for providing information during determination of assigned protection factors. Brown noted that the use of high concentrations of a challenge agent in chamber studies may minimize the uncertainty of extrapolating test results obtained at low outside concentrations to levels well above the observed range. Therefore, WPF studies would serve as a counterpart to chamber studies, *i.e.*, WPF studies would provide data on the respirator during actual use in the workplace, and identify workplace conditions in which a respirator may perform poorly. To improve comparability of results, he advocated using uniform procedures to: select the challenge agent; collect samples; record the data; and measure and interpret Ci and Co (Ex. 5–1, pp. 42–44).

Overall, the analyses led Brown to several conclusions. First, workplace studies have limitations for comparing respirator performance because of uncontrolled sources of variability. Support for this conclusion comes from the wide confidence intervals for the means of the CLSAs, and the wide range of those confidence intervals within the same respirator class. Second, Brown believed that the WPF has limits as a measure of respirator effectiveness because, in general, it tends to increase as Co increases. This relationship complicates comparisons of WPF values measured at different Co levels. Third, he found no clear evidence that one class of respirator is better than any other class, particularly between elastomeric half-mask and filtering facepiece respirators. In addition, the differing results between CLSAs within the same class of respirators indicated that the outcome of one CLSA may be a poor predictor for another CLSA in the same class.

2. PAPRs and SARs

Dr. Brown analyzed 13 studies to evaluate and compare the effectiveness of PAPRs and SARs. Ten of the studies were conducted with PAPRs, and three with SARs. Brown's analyses divided these ''high-performance'' respirators into seven classes (*i.e.*, five types of PAPR and two types of SAR) based on their design features (*see* Table 2), with subsequent separation of these respirator classes into 14 CLSAs.

Brown used the CLSAs to determine whether any differences in respirator effectiveness existed among the respirator classes. He analyzed the data for trends of WPFs, either upward or downward, as Co increases, and for homogeneity. Brown plotted all of the data, fitted lines to these plots, made comparisons of study results within each respirator class, and developed functions from the fitted lines. (For additional details on these statistical analyses and the data plots, *see* Ex. 5–2.)

On reviewing the data plots, Brown concluded that the data were consistent with a linear relationship between ln(Ci) and ln(Co). Also, the presence of outliers and/or an imbalanced distribution of the observations influenced the results. He recommended further investigation of the outliers, particularly those with unusually high Ci values, to determine if they resulted from characteristics of the respirator or other variables. He also recommended studying the imbalanced distributions to determine if they represented individual study biases caused, for example, by collecting data at different work sites or on different work shifts. Finally, Brown noted that the robust least trimmed squares line may be useful for estimating the relationship between ln(Ci) and ln(Co).

Fifth percentiles are commonly used as a benchmark for respirator performance. Brown's analyses showed that fifth percentile estimates differed considerably within respirator classes that contained more than one CLSA. The range of the fifth percentile estimates was 28–389 for the five CLSAs in Class 2, 17–107 for the two CLSAs in Class 4, 29–1779 for two CLSAs in Class 5, and 74–188 for the two CLSAs in Class 7. The fifth percentile estimates in Classes 3 and 6 were large, while the fifth percentile estimates were small in Classes 1, 4, and 7. Brown believed that, while some of these differences may be attributed to a real difference in respirator performance between classes, the sample sizes were too small and/or the sampling variability too large to obtain reliable estimates at low percentile levels. He noted that the fifth percentile estimates were variable, and were not predictable from one CLSA to another CLSA within the same respirator class. Thus, he concluded that the fifth percentile estimates of WPFs have limited utility for setting assigned protection factors. Table 3 lists the descriptive statistics for WPFs, for each class-study-agent combination.

TABLE 3.—DESCRIPTIVE STATISTICS FOR WPF, BY CLASS, STUDY AGENT

	CL1.26.Cd	CL2.22.Pb	CL2.23.Pb	CL2.24.Si	CL2.3.BAP	CL2.5.Asb	CL3.27.EBZ
Curve Label	1	2a	2b	2c	2d	No curves	3
Median	2,972.97	127.88	155.29	3,553.72	1,788.32	156.00	11,935.87
Range	25,186.05	1,040.75	6,131.76	95,518.07	8,203.89	537.00	4,746,673.83
Minimum	53.70	22.58	28.24	36.31	371.49	66.00	1,152.26
Maximum	25,239.75	1,063.33	6,160.00	95,554.38	8,575.38	603.00	4,747,826.09
No. Observations (N)	33	46	43	59	20	7	58
5th Percentile	280.25	27.82	35.03	92.07	388.70	70.50	1,797.79
10th Percentile	581.87	53.04	43.08	267.60	407.51	75.00	2,365.29
Reject Lognormality?	No	No	No	No	No	No	Yes
Geometric Mean	2,523.49	126.85	184.69	2,765.75	1,408.10	151.95	15,623.81
Geometric Stan. Dev	3.56	2.28	3.21	6.33	2.50	2.54	5.56
	CL4.21.Si	**CL4.6.Pb**	**CL5.18.Pb**	**CL5.21.Si**	**CL6.19.Si**	**CL7.25.Sr**	**CL7.28.Si**
Curve Label	4a	4b	5	No curves	6	7a	7b
Median	48.67	438.60	7,948.14	85.44	9,178.81	3,827.16	2,480.55
Range	176.27	2,310.33	73,081.90	189.92	34,735.48	87,137.82	33,384.67
Minimum	16.40	23.00	579.04	24.75	668.34	41.67	43.33
Maximum	192.67	2,333.33	73,660.94	214.67	35,403.82	87,179.49	33,428.00
No. Observations (N)	7	25	53	4	15	21	52
5th Percentile	17.20	107.06	1,779.12	29.10	1,407.60	74.07	188.14
10th Percentile	18.00	160.95	2,300.18	33.50	2,229.66	79.37	383.47
Reject Lognormality?	No	No	No	N too small	No	No	No
Geometric Mean	49.20	400.34	8,319.09	76.10	7,389.62	2,315.04	2,066.00
Geometric Stan. Dev	23.60	2.81	3.03	25.60	2.92	9.99	4.02

The objective of the review of these 13 WPF studies was to see what can be learned about the performance of each respirator class, and its relative effectiveness, based on the data for Co and Ci. He also attempted to determine how Ci changes as Co changes, and what factors affected this relationship.

Brown found too much unexplained variability between study outcomes, even within the same respirator class and within similar ranges of Co, to make valid and reliable comparisons. He noted that study outcomes for the same class of respirator may differ significantly, which raised concerns about interpreting the outcome for a class from a single study. More specifically, he questioned whether the results from one study would be similar to another study. He concluded that it is not possible to know to what extent the outcome of a study is attributable to characteristics of the respirator used.

Brown believed that the variability identified in this analysis was probably due to uncontrolled parameters in the workplace test situations, such as aerosol particle size distributions and densities, and work activities. Based on the data from these studies, he found that WPF tends to increase as Co increases (equivalently, penetration, or PEN., tends to decrease). He believed that the probability of a Co dependence for WPFs seemed to be established by his analyses.

C. Analyses of SWPF Studies

1. Bullard Models 77 and 88, Clemco Apollo Models 20 and 60, and 3M Whitecap II

In the mid-1980s, SWPF studies provided OSHA with information on the effects of temperature, relative humidity, airflow, and facial hair on respirator performance (LANL, 1988; Ex. 1–64–101, LLNL, 1986; Ex. 1–64–94). More recent SWPF studies provided additional information on the performance of the following abrasive blasting respirators: the Bullard Models 77 and 88 (Ex. 3–8–3), the Clemco Apollo Models 20 and 60 (Ex. 3–7–3), and the 3M Whitecap II (Ex. 3–9–2).

OSHA contracted with Mr. Harry Ettinger to review and comment on the study principles and protocols described in the five reports (Bullard, Clemco, 3M Whitecap, the LLNL study, and the LANL study). His report (Ex. 3–3) contained the following observations and conclusions.

Mr. Ettinger noted that while the reports do not satisfy the typical criteria for defining peer-reviewed publications, this was not a serious problem because the studies were conducted in national laboratories by knowledgeable and experienced investigators. Furthermore, the review procedures generally used by these national laboratories most likely provide a sufficient peer-review process. He noted that none of the reports provided sufficient detail to permit a statistical re-analysis of the data by OSHA. In addition, he observed that the studies of the Bullard, Clemco, and 3M respirators reported considerably higher fit factors than the 1986 and 1988 national laboratory studies. However, he believed that it was not appropriate to compare the results of recent studies with the older studies, but he noted that older respirators may not perform as well as newer designs.

Mr. Ettinger also noted that the tests of the Bullard, Clemco, and 3M respirators satisfied the established criteria of fit factors that exhibited only brief negative pressure spikes. He believed these results indicated that if these devices are used and maintained properly, they appear to have fit factors of at least 20,000. He believed that, using a safety factor of 20, a protection factor of 1,000 is attainable, assuming that the testing protocol is adequate.

Ettinger stated that he could not define clearly a relationship between the older and more recent study results. For example, he suggested that the additional exercises in the more recent study (ORC, 2001; Ex. 3–4–2) did not adequately represent normal or extreme work situations. Ettinger cautioned against assuming that all blasting helmets would achieve the high fit factors measured in the recent studies because performance is device specific, and indicated that older respirator designs may need to be reevaluated. Furthermore, he believed that quality control, human factors, minimum flow rate, and the sturdiness of respirator construction are important variables that should be evaluated in the testing protocol.

2. NIOSH N95 Study

In 1999, NIOSH conducted a chamber study of 21 N95 respirators (20 filtering facepiece, and 1 elastomeric, respirators) and statistically analyzed the respirators' performance (Ex. 4–14). At the request of OSHA, Drs. Johnson, Foote, and Bierman of LLNL undertook a review of this study to assist the Agency in evaluating APFs of half-mask respirators (Ex. 3–2). OSHA provided the raw data files from the study to LLNL for independent evaluation.

The NIOSH investigators used ambient (*i.e.*, room) aerosol as the challenge agent, and a PortaCount to measure respirator penetration. Use of ambient aerosol does not require aerosol generation equipment, thereby circumventing use of a possibly hazardous chemical. However, if this technique generates a low ambient particle concentration it is difficult to detect the reduced number of particles that penetrate the respirator; this effect results in an artificially low protection factor. In addition, an ambient aerosol that is varying in concentration during testing can cause error in the penetration measurements. Study participants can also produce aerosols ranging from 0.1 to 3 particles/cc through their breathing (*i.e.*, ''breathing'' background). Whenever the amount of challenge agent that penetrates the respirator is low (*i.e.*, on the order of particles/cc or less), the PortaCount cannot distinguish between particles in the breathing background and the challenge aerosol penetrating the respirator. The LLNL researchers believed that the breathing background can limit fit factor measurements to 1,000 and less when the challenge concentration is below 2,000 particles/cc (Ex. 4–15). They concluded that challenge aerosol concentrations can be better controlled in chamber studies than under this protocol.

When calculating faceseal leakage, the NIOSH authors assumed that all study participants have the same constant volumetric flow rate through the respirator. Using a filtration model developed by Rubow (Ex. 3–7–3), the LLNL reviewers determined media penetration that was approximately 5% less than the media penetration calculated by the NIOSH authors using the constant flow rate assumption. Since the method used by the NIOSH authors results in only a 5% error, and gives a conservative estimate of the filter penetration, the LLNL reviewers believed that the constant flow rate assumption is reasonable. The LLNL reviewers also discussed other considerations, including fluctuations in peak flows under various exercise conditions, and the correction factor for filter media penetration used by the NIOSH authors.

Investigating the possible effect of breathing background on the PortaCount fit factor measurement, the LLNL reviewers applied an estimated worst-case scenario to the data. The scenario consisted of the following two assumptions: (1) A challenge aerosol concentration of 3,000 particles/cc, and (2) a breathing background of 5 particles/cc. Applying these assumptions to the NIOSH data, the LLNL reviewers recalculated total penetrations, and adjusted the results for breathing background. They found that, when compared to the NIOSH results, 14 of the 21 respirators had more tests passing the 0.01 penetration criteria than before. The LLNL reviewers also calculated the 50th and 95th percentiles for the penetration data, both with and without applying the breathing background assumption. In view of their results, they believed that the original NIOSH analysis and findings result in a conservative estimate of the respirators' performance.

The LLNL reviewers also used the NIOSH raw data to reproduce values, geometric standard deviations, and the 95th percentile for total penetration, filter penetration, and face seal leakage. They then compared these results to total penetration and face seal leakage penetrations summarized in the NIOSH study (Exs. 4–1, Table 2; 4–14, Table I).

The few discrepancies were small, and could be attributed, for example, to rounding off values. The 95th percentiles in the NIOSH study were based on a formula using the geometric mean and geometric standard deviation, and assumed that the distribution was log normal. For comparison, the reviewers calculated the 50th and 95th percentiles based on the raw data alone (*i.e.*, assuming no distribution). Using this approach, the LLNL reviewers noted that, for many respirator models, the 50th percentile differed markedly from the geometric mean. They also saw differences between the 95th percentile calculated using a log normal distribution and the corresponding percentile determined directly from the data. LLNL reviewers stated that the NIOSH study demonstrated the advantages of SWPF studies for half-mask respirators. Their results confirm the quality of this important SWPF study of filtering facepiece and elastomeric half-mask respirators.

3. ORC Study of PAPRs and SARs

In 1997, ORC and a group of its member companies sponsored a study of 11 powered air-purifying and supplied-air respirators (PAPRs and SARs) to evaluate the protection that these respirators afforded to workers in the pharmaceutical industry. The study, ''Simulated Workplace Protection Factor Study of Powered Air Purifying and Supplied Air Respirators' (Ex. 3–4–1) was completed in 1998 by researchers at LLNL. OSHA requested Dr. Gerry Wood of LANL to evaluate ORC's LLNL study. He evaluated the study using the data received from ORC, as well as information on the study published in the American Industrial Hygiene Association Journal (Exs. 3–1, 3–4–2).

The raw data files from the study consisted of instantaneous (0.1 second) photometer aerosol measurements obtained before, during, and after 12 exercise periods (including four periods of normal breathing) performed by each study participant. The instantaneous penetration results for the 144 tests were plotted against time. Wood examined patterns of aerosol penetration into the respirator that occurred throughout testing, noting that certain exercises often exhibited penetration spikes. He found that running in place produced the most penetration spikes. However, he also noted other respirator/subject combinations result in spikes. Wood indicated that such non-random distributions of readings was not surprising, as different movements during an exercise should affect instantaneous penetrations differently.

Wood calculated 95% confidence limits for the average and maximum penetration values during each exercise. In doing so, he assumed that pre-test and post-test background, and chamber aerosol measurements were distributed normally, since no movement variables were present. He then calculated aerosol penetration. Wood found that the photometer reading averages and standard deviations that he analyzed for all 144 data sets were in agreement with the LLNL figures, and that rounding off figures accounted for any minor differences in average penetrations that he calculated.

In summary, Dr. Wood believed that the quality of the data, experimental protocol, measurements and data, and calculations applied to the data in the ORC–LLNL study were excellent. He agreed with the authors' conclusions that SWPF studies are useful for comparing respirators, and that the study protocol was reproducible.

D. OSHA's Overall Summary Conclusions

Prior to this current rulemaking, OSHA explored several procedures to evaluate and compare respirator performance across models, studies, agents, and testing protocols. The Agency thoroughly reviewed the available data on respirator performance to determine the current concepts, and possible methodologies, for deriving APFs. To evaluate the data, OSHA had to make several decisions.

For example, while OSHA was aware that particle size can affect concentration values, the Agency was unable to quantify this factor based on available information. Consequently, OSHA did not attempt to adjust for differences in particle size in the analyses. Furthermore, the Agency had to decide how to address sampling results that were below the limit of detection (LOD). Accordingly, whenever sampling results were below the limit of detection, OSHA set the Ci at a percentage of the LOD reported in the study. When the study reported extremely low Ci results as a percentage of the LOD, the Agency used the values provided by the authors.

OSHA was concerned that the analyses be those best able to account for parameter uncertainty, and be a measure of respirator effectiveness that is valid over a plausible range of concentrations for each of the agents against which the respirator is to be used. As discussed above, the Agency contracted with Drs. Nicas and Brown to independently evaluate the raw WPF data. As a result of these analyses, OSHA preliminarily agrees with Drs. Rappaport and Kupper, who indicated that, while some modeling may be useful, concerns remain regarding the lack of model validation (Ex. 1–182–1). Furthermore, OSHA finds merit in Thomas Nelson's comment that a simple analysis of the entire data may sufficiently cover the relevant sources of variation in these data (Ex. 1–174). Databases of the information used by the Agency in its analyses have been placed in the docket for review by interested parties (Exs. 5–3, 5–4, 5–5).

The Agency also recognizes that WPF and SWPF studies have their strengths and weaknesses. SWPF studies can control for a number of variables, thus providing less variable results across respirators classes than WPF studies. Also, SWPF studies can test respirators safely at the limits of their effectiveness. However, WPF studies evaluate respirators during use in the workplace. Therefore, the Agency believes that WPF or SWPF studies provide complementary information.

OSHA developed the proposed APFs using a multi-faceted approach. The Agency reviewed the various analyses of respirator authorities, available WPF and SWPF studies, and other APF literature. For example, OSHA reviewed Brown's analyses and noted no difference in performance between filtering facepiece and elastomeric half-mask APRs, and that few data pairs from the combined data sets analysis failed to achieve a WPF of 10. In addition, the data from WPF and SWPF studies, as well as a qualitative review of the available APF literature, supported an APF of 10 for all half-mask APRs. Therefore, OSHA is proposing an APF of 10 for half-mask APRs. The Agency used a similar approach in developing the remaining proposed APFs.

In conclusion, the APFs proposed by OSHA in this rulemaking represent the Agency's evaluation of all the available data and research literature; *i.e.*, a composite evaluation of all the relevant quantitative and qualitative information. The Agency seeks comment on this approach, as well as the proposed APFs developed using this approach.

E. Summaries of Studies

Researchers often determine the protection afforded by a respirator by conducting Workplace Protection Factor (WPF) studies and Simulated Workplace Protection Factor (SWPF) studies. A WPF study measures the effectiveness of respirators under workplace conditions. Workers participating in a WPF study wear respirators while performing their usual job tasks. The WPF is a measure of the reduction in exposure achieved while using respiratory protection and is the ratio of the concentration of the contaminant found in the workplace air to the concentration found inside the respirator facepiece. Similarly, a SWPF study measures the ratio of a contaminant's concentration both outside and inside the facepiece. However, researchers obtain these measurements in test chambers, which allows them to control some important variables (*e.g.*, outside concentration of the challenge agent). Rather than performing the actual job tasks found in a particular work setting, the study participants perform a series of exercises in the test chamber that simulate the actions of workers in general.

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

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

Study 1B. C.E. Coulton, H.E. Mullins, and J.O. Bidwell gave a presentation at the May 1994 American Industrial Hygiene Conference and Exposition (AIHCE) on worker protection afforded by the same respirator in two different environments and against two different contaminants (Ex. 1–64–13). At the first site, the authors determined exposure to cadmium dust for 18 workers in a plastic colorant manufacturing facility. They determined exposure to lead fume for 18 workers during ship breaking and recycling at the second site. At the colorant facility, cadmium-containing pigments were weighed, mixed with plastic resin, and fed into extruders for production of concentrated colorant. Samples were obtained from workers in the weighing, mixing, and extruding areas. Workers at the ship breaking facility used torches to cut an aircraft carrier into large sections that were then cut into smaller pieces on shore. Burners and firemen, on the ship and on shore, were sampled for lead. Work rate at the colorant facility was judged to be low, while the work rate of the ship breaking workers was assessed as being moderate. The respirator used in the study was a 3M 6000 series elastomeric half-mask equipped with either 3M 2040 or 3M 2047 HEPA filters (the 2047 HEPA filter has some activated charcoal for removal of nuisance levels of organic vapors). Employees normally wore the study respirator and were provided with training in its proper donning, fitting, and operation. In addition, the employees had to pass a saccharin qualitative fit test prior to study participation; they also had to be clean-shaven. The study was explained to the participants and they were observed on a one-on-one basis throughout the sampling periods.

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

Samples were analyzed by inductively coupled plasma (ICP) spectroscopy. For both cadmium and lead, the authors presented the range of outside concentrations, inside concentrations, and the associated geometric means and standard deviations. Three sets of WPFs were determined for cadmium and lead, based on three different methods for reporting inside samples that were below the limit of detection (LOD) (*i.e.*, calculating WPF using 70% of the LOD; calculating WPF using the LOD; or eliminating these samples from the WPF calculation database). No field blank adjustments were made (*i.e.*, no cadmium or lead detected), and no mention is made of adjusting the data for pulmonary retention of particles. In addition, samples were invalidated as a result of equipment and procedural problems, and if the outside filter weights were less than 100 times the limit of detection (or 101 times the field blank value). The authors reported a mean WPF of 353, with a fifth percentile of 34, for the cadmium samples, and a mean WPF of 135, with a fifth percentile of 15, for the lead fume samples. The authors noted a sizable difference in WPFs for cadmium and lead (using the same respirator), and discussed a number of possible reasons for the difference (*e.g.*, differences in particle size, work environment, work rate). The authors concluded that the ANSI Z88.2–1992 recommended APF of 10 for half-facepieces was appropriate.

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

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

Study 1D. Workplace performance of an elastomeric half-mask against exposure to lead was reported in 1984 by S.W. Dixon and T.J. Nelson for 11 workers in an unidentified work environment (Ex. 1–64–19). The participants' work rate was judged to be moderate to heavy. Workers viewed a training program and selected from three mask sizes of a Survivair 2000 elastomeric half-mask respirator, equipped with organic vapor/high-efficiency particulate filters. Participants were qualitatively fit tested with isoamyl acetate. Prior to participation, employees were quantitatively fit tested with a Dynatec/Frontier FE250A portable unit while wearing the Survivair with high-efficiency filters and performing six ANSI-recommended exercises. In addition, paired (before and after) quantitative fit tests were performed for about half of the WPF determinations to ascertain if quantitative fit tests can predict WPFs. Participants were instructed not to break the faceseal during sampling, and were observed throughout the sampling period.

Samples were collected on 25 mm 0.8 micron pore size polycarbonate filters, for 30 to 120 minutes (a complete job cycle) at a flow rate of 2 Lpm. Sampling trains were calibrated before and after each day's sampling, and respirators were disassembled, cleaned, and reassembled at the end of each day. The authors do not provide a more detailed discussion of the inside or outside sampling trains (*e.g.*, type of respirator probe, placement of outside sampling apparatus). Particle size analysis was performed using light microscopy and scanning electron microscopy.

Proton induced x-ray emission analysis (PIXEA) was used to analyze the samples. This method's limit of detection was 2 nanograms per sample. The authors provide an approximate particle aerodynamic diameter based on the particle size analyses. Inside-the-facepiece results were corrected for losses caused by the sample probe but were not corrected for lung deposition (which the authors believed caused only a small bias). Thirty-seven WPFs were determined; however, the individual data sets (*i.e.*, inside concentration, outside concentration, and associated WPF) were not provided. During the study, some participants were observed to break the faceseal to talk. The authors provide an overall range of WPFs achieved, GM, and GSD, for undisturbed facepiece samples and pooled disturbed and undisturbed facepiece samples. The authors reported a GM WPF of 3,400, and a best estimate of the fifth percentile of 390 when the facepiece was not disturbed, and a GM WPF of 2,400, and a best estimate of the fifth percentile of 160 when the facepiece was disturbed. The authors also found no correlation (at the 5% level) between WPF and outside concentration, or the relationship between WPF and quantitative fit factors for predicting workplace protection. The authors also estimated the program protection factor based on historical measures of air lead concentrations versus blood lead levels (a table and graph of this data was provided). They concluded that the half-mask respirator they tested provided WPFs that exceeded an APF of 10, and provided program protection factors (PPFs) that exceeded 10.

Study 2. Workplace protection against exposure to asbestos fibers (chrysotile and amosite) was reported at the 1985 AIHCE by T.J. Nelson and S.W. Dixon for 17 workers who removed asbestos-containing materials at two sites (Ex. 1–64–54). Six of these workers were removing asbestos fireproofing from a ceiling at the first site, while eleven workers at the second site were removing asbestos-containing pipe insulation. The participants' work rate was judged to be moderate, site temperatures ranged from 65–85 degrees Fahrenheit, and humidity was very high.

The following six brands of half-mask respirators were studied: 3M 8710 disposable dust/mist respirator; 3M 9910 disposable dust/mist respirator; American Optical R1050 disposable dust/mist respirator; Survivair 2000 elastomeric respirator with high-efficiency filters or DFM filters; MSA Comfo II elastomeric respirator with high-efficiency filters or DFM filters; and a North 7000 elastomeric respirator with high-efficiency filters. Participants were trained in respirator use by the investigators and were qualitatively fit tested using the saccharin fit test. Supplemental data indicate that participants wore one or more respirator brands. No mention is made of respirator donning and doffing procedures, or starting sampling trains in a clean area; however, the sampling procedures state pumps were stopped and cassettes removed in a dust-free area. Participants were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampling train was a 25 mm closed-face three-piece cassette with a ½-inch extender, containing a 0.8 micron pore size mixed cellulose ester filter. The cassette was attached directly to a tapered probe inserted into the respirator midway between the nose and mouth. In-mask samples were collected at a flow rate of 2.0 Lpm. The outside-the-facepiece sampling cassettes and probes were identical to the inside-the-facepiece sampling train and were fastened to the lapel of the subject. Outside samples were gathered at 0.5 to 1.0 Lpm. Sampling times ranged from 30 to 120 minutes, and the pumps were calibrated before and after each sampling period. The authors investigated uniform deposition of asbestos fibers across the filters; they noticed a slight trend for heavier deposition at the filter center using both methods. They also computed the precision of sample gathering using open- versus closed-face cassettes and found no difference between the methods.

Asbestos analysis was based on NIOSH method P&CAM 239 and NIOSH method 7400 (*i.e.*, the filter mounting and ''A'' counting rules). To increase analytical sensitivity, the methodology was modified by counting fibers in a minimum of 500 fields per inside-the-facepiece filter when less than 100 fibers were counted. The actual number of fibers counted in each sample was used to compute the airborne concentration. In addition, one microscopist performed all fiber counting. The distributions of fiber length and diameter were determined by transmission electron microscopy using lapel sample filters. The GM and GSD values for the fiber length, fiber diameter, and equivalent aerodynamic diameter at each worksite and the combined data from both sites were reported, but the values for fiber density and the length-diameter correlation coefficient were not provided. A total of 84 pairs of inside and outside fiber concentrations, and corresponding WPFs, were provided by participant, respirator brand, and sampling period in supplemental data tables. However, the authors considered seven WPF values measured for the American Optical respirator as suspect because the inside-the-facepiece filter samples contained glass fibers, originating from the respirator's filter matrix. These glass fibers have the same appearance as asbestos fibers under light microscopy. The authors did not adjust measured values for field blank values (*i.e.*, blanks were below the limit of quantification) or fiber retention in the respiratory tract (*i.e.*, the authors believed that pulmonary fiber retention resulted in only a slight change in concentration inside the facepiece).

The 3M 8710 results showed a GM WPF of 310, a GSD of 5.3, and a best estimate of the fifth percentile of 20. The 3M 9910 had a GM WPF of 580, a GSD of 4.2, and a best estimate of the fifth percentile of 55. The AO R1050 had a GM WPF of 52, a GSD of 4.2, and a best estimate of the fifth percentile of 5. The Survivair 2000 or MSA Comfo II equipped with DFM filters had a GM WPF of 240, a GSD of 6.3, and a best estimate of the fifth percentile of 12. With high-efficiency filters, the GM WPF was 94, the GSD was 3, and the best estimate of the fifth percentile was 16. For the North 7700 equipped with high-efficiency filters, the GM WPF was

250, the GSD was 6.9, and the best estimate of the fifth percentile was 11.

Since the WPFs for respirators equipped with DFM and high-efficiency filters were similar, and were well below the protection expected if filter efficiency alone was the determining performance factor, the authors concluded that ''* * * filter efficiency was not as significant a factor in determining the relative workplace performance against asbestos as the face fit''. The authors also noted comparable performance between disposable and elastomeric respirators. With regard to this, the authors noted that perspiration and wetting solutions led to the elastomeric facepieces slipping on the participants' faces, something that was not noted with the fibrous disposable respirators. The authors postulate that the effect of this slippage could be a reason why the two types of respirators had similar performance.

Study 3. In 1993, A. Gaboury and D.H. Burd performed a WPF study by measuring exposure to benzo(a)pyrene [B(a)P] on particles among 22 workers in a primary aluminum smelter (Ex. 1–64–24). The participants were rack raisers, stud pullers, and rod raisers on anode crews. The following three brands of elastomeric half-mask respirator devices were studied: Willson, Survivair, and American Optical. (**Note:** Respirator model numbers were not provided) The respirators were equipped with combination organic vapor/acid gas cartridges and DFM pre-filters, with the exception that dust/mist pre-filters were used on the American Optical respirator. The study also examined the performance of a powered air-purifying respirator (PAPR), but only the negative-pressure, air-purifying half-mask respirator data are presented here (the PAPR results are discussed below). The participants had used respirators for several years, had been previously trained in the use of the particular respirator under study, and had used it for more than six months. All participants in half-mask respirators were clean-shaven and were quantitatively fit tested using the TSI Portacount. The minimum acceptable fit factor was 100. Industrial hygiene technologists assisted participants with donning and doffing respirators, cleaned and maintained the respirators at the end of each work cycle, and observed participants on a one-to-one basis throughout the sampling period. Participants were directed not to tamper with the respirator or sampling equipment. Due to the high heat in the work area, the employer required that employees rest in a cool environment for one-half hour during each hour.

The inside-the-facepiece sampling train consisted of a closed-face three-piece cassette with a 25 mm organic binder free glass fiber filter, backed with a cellulose ester pad. The sampling cassettes were connected to a tapered Liu probe inserted into the respirator between the nose and mouth. The outside-the-facepiece sampling train was identical to the inside-the-facepiece sampling train; however, no mention is made of connecting the cassette to a Liu probe. All filters were pre-calcined at 400 degrees Centigrade for 24 hours. Both inside and outside samples were collected at a flow rate of 2 Lpm for approximately 300 minutes, or one-half of the 10-hour work shift. Respirators and sampling trains were worn and operated until the employee entered the rest area; they were donned and started prior to leaving the rest area for the next work cycle. Sampling cassettes were plugged when not in use and the respirators were cleaned after each work cycle. Field blanks were used to identify possible contamination due to handling. Sampling train airflow rates were checked at the beginning, middle (*i.e.*, after lunch), and end of the work day; on changing the cassettes; and when a problem was suspected. Sampling occurred over a five-day period. Only stud pullers and rod raisers used the elastomeric half-mask respirators.

B(a)P analysis followed the Alcan Method #1223–84. The ambient B(a)P particle size distribution was determined by collecting four samples, as close as possible to the workers, using an 8-stage Anderson cascade impactor (Model 296). Impactor samples were collected for two to five hours at a flow rate of 2 Lpm. The average percent of B(a)P mass (across four samples) per impactor stage (defined by an aerodynamic diameter cut point, in micrometers) was reported. About 93% of the B(a)P mass was associated with particles having diameters of less than 9.8 micrometers. A total of 18 pairs of inside and outside sample concentrations, with associated WPFs, were provided by brand of respirator and job category, but were not linked to specific participants. Overall GM, GSD, and 95% confidence interval on the mean were also provided for the inside and outside concentrations and WPF, along with an overall fifth percentile WPF. The authors stated that some employees participated more than once during the study. No mention is made of adjusting inside-the-facepiece concentrations for particle retention in the respiratory tract. The half-masks had WPF ranging from 13 to 410, with a GM of 47. The two-sided 95% confidence intervals were 30 and 74 for the dual cartridge respirators. The fifth percentile was 9. The authors found no significant relationship between B(a)P concentrations inside and outside the facepiece. Also, while the data were limited, the authors believed no correlation existed between WPF and quantitative fit factor. The authors concluded that the fifth percentile for the half-masks they tested were in agreement with the APF of 10 recommended by the NIOSH RDL.

Study 6. S.W. Lenhart and D.L. Campbell reported in 1984 on a WPF study in which they measured protection against exposure to particulate lead (Pb) for 25 primary lead smelter workers; seven of whom worked in the sinter plant and eighteen of whom were in the blast furnace area (Ex. 1–64–42). The predominant aerosol forms of lead were dust in the sinter plant and fume in the blast furnace. In both areas, lead comprised about 50% of the total aerosol particulate with composition of the remaining 50% being unknown. All participants wore an MSA elastomeric half-mask with high-efficiency filters. (**Note:** No respirator model number was provided) The study also examined the performance of an MSA PAPR, but only data for the negative-pressure, air-purifying half-mask respirator are presented here (the PAPR results are discussed below). The employees routinely used respirators; however, no mention is made of them with respirator training. Participants were quantitatively fit tested using an unspecified method, and had to achieve the employer's required fit factor of 250. Workers were instructed not to remove or manipulate the respirator during sampling, and were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampler consisted of a closed-face 37 mm cassette containing an AA filter and AP10 support pad. This cassette was connected to a tapered Liu probe that was inserted into the respirator between the nose and upper lip. In-mask samples were collected at 2 Lpm. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing an AA filter and AP 10 support pad; no tapered Liu probe was used. The outside sample cassette was attached to the worker's lapel. Outside samples were gathered at 2 Lpm. The authors collected samples for as much of each 8-hr work shift as possible. Respirators and sampling trains were donned and doffed, and samplers were started and stopped, in a lead-free area. Respirator facepieces were wiped clean inside prior to donning after each break and cleaned and sanitized after each shift. One WPF was measured for each employee. The ambient particle size distribution was determined using 19 Marple cascade impactor samples (11 in the sinter plant; 8 in the blast furnace area).

Lead analysis was by flame atomic absorption spectroscopy according to NIOSH Method S–341. Inside-the-facepiece samples that contained less than l0ug of lead were reanalyzed by graphite furnace atomic absorption (limit of detection = 0.2 μg). The ranges for the mass median aerodynamic diameters (in micrometers) and for the GSD values were reported. A total of 25 pairs of inside and outside half-mask values, and the corresponding WPFs, were provided by employee, job title, and job location. An overall GM and GSD of the WPFs, and various percentile WPFs, were provided. When samples contained lead below the level of detection, the authors reported concentration values ''* * * determined from the least amount of lead detectable by the analytical method and the sampled volume of air.''

In-mask values were not adjusted for particle retention in the respiratory tract (the authors imply retention probably had a non-significant effect on results, but could result in overestimated WPFs). No mention is made of the investigators using field blanks. They reported that approximately 98% of the WPFs would be expected to be at or above 10, 90% above 30, and 75% would be expected to be above 100. They concluded that an APF of 10 was appropriate for the half-mask negative pressure air-purifying respirator evaluated in this study. The authors also discussed two proportional methods of defining an APF.

Study 7. W.R. Meyers and Z. Zhuang conducted a 3-part workplace protection factor study in three different work environments. In addition to presenting the study findings, the authors also discuss their rationale for selecting exposure agents, study facilities, and workers; study procedures followed at the sites; and analytical methods. W.R. Meyers and Z. Zhuang in January, 1993 (Ex. 1–64–51) and W.R. Meyers, Z. Zhuang, and T.J. Nelson in 1996 (Ex. 3–12) reported on the first part of the study in which the authors determined protection against exposure to particulate lead (Pb), zinc (Zn), and total airborne mass (TAM) for 25 workers, on day and evening shifts, in three brass foundries (3, 9, and 13 participants, respectively). (**Note:** The reports mention 26 participants, but data were presented for only 25 participants.) Four brands of half-mask devices were studied: 3M 9920 disposable DFM respirator; American Optical 5-Star elastomeric respirator with DFM filters (R56A); MSA Comfo II elastomeric respirator with DFM filters (Type S); and Scott Model 65 elastomeric respirator with DFM filters (642–F).

Participants were selected from volunteers who normally wore respirators, were clean-shaven, and passed a fit test. Their work rate was subjectively determined by observing their work activities. Respirators were worn for the usual period. For the elastomeric half-mask respirators, the participants were quantitatively fit tested using a TSI Portacount; a fit factor of 100 or more constituted a pass. Disposable respirators were fit tested using the saccharin qualitative fit test. The investigators trained the participants in the proper donning and adjustment of the respirators, and instructed them not to remove or lift the respirator from their face in the work area. Readjustment of the respirator had to be accomplished by sliding the facepiece on their face. Workers were observed throughout the sampling period. Each participant wore two or more respirator brands, and one WPF was measured per employee for each brand worn.

The inside-the-facepiece sampling train was a 25 mm closed-face cassette attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. The cassette contained a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A 4.5 mm ring under the filter restricted airflow to an 18 mm circle in the center of the filter to keep deposition in an area that could be entirely covered by the proton beam used for sample analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. Sampled air was then drawn through a moisture trap using a personal sampling pump operating at 2 Lpm. The outside-the-facepiece sampling train was a 10 mm nylon cyclone attached to 25 mm closed-face cassette (the cassette was not connected to a flared mouth probe). The cassette contained a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A 4.5 mm ring under the filter restricted airflow to an 18 mm circle in the center of the filter. This sampling train was attached in the lapel area and samples were collected at a flow rate of 1.7 Lpm.

Two separate samples were gathered during the shift, one during the first half and another during the second half. Individual WPFs were based on monitoring times of approximately one to four hours. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. Elastomeric facepieces were cleaned and inspected at the end of each shift, but were not wiped out during the shift unless such wiping was a standard practice before the study (the authors noted that most of the time workers did not wipe out facepieces). Air-purifying filters (cartridges) and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing. In addition, the mouth of the in-mask probe was plugged whenever the respirator was not being worn. Working (field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators also washed the interior of the sampling cassettes to ascertain retention of sample particles on the cassette wall. The ambient particle size distribution was determined by PIXE 8-stage cascade impactor samples at several work locations in each foundry. These area samples were collected at roughly mid-chest to shoulder level of workers for approximately 1 hour, to prevent impactor overloading.

All samples were analyzed by proton induced X-ray emission analysis (PIXEA). The mass distribution of Pb, Zn, and TAM by particle aerodynamic diameter was graphically presented for all cascade impactor samples. Across the three foundries, 66 pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by job task, employee, brand of respirator, and analyte (Pb, Zn, and TAM). The authors did not adjust measured values for particle retention on sampling cassette walls since these losses appeared to be random, independent of collected mass, and of a negligible amount. No mention is made of correcting measured in-mask values for pulmonary particle retention. A foundry-specific average of the field blank loadings was used as a correction factor for estimating background and handling contamination for each foundry. Outside-the-facepiece samples were collected as respirable particulate, thereby providing respirable mass levels, while in-mask samples were collected as total particulate mass. The authors initially assumed that particles larger than 10 microns did not penetrate respirator faceseals; however, this was found to be incorrect after analyzing in-mask particle size. Therefore, to avoid comparison of dissimilar measurements, the investigators used particle size data obtained by ambient sampling to convert the respirable mass levels to total mass levels (using Chimera/TSI Disfit software). The reported levels represent these total mass values, and form the basis of the reported WPF values. The authors also provide data and discussion on a number of sampling analyses, including GM concentration of analyte by job task, GM concentration of analyte for in-mask and ambient concentrations, particle size distribution by job category, GM WPF estimates by job category, GM WPF by respirator type, within shift sampling variation, and variation between foundries. For the pooled data from the three foundries, the 3M 9920 filtering facepiece had a 50% WPF of 108, a GSD of 5.2, and a fifth percentile estimate of 7. The AO half-mask had a 50% WPF estimate of 98, a geometric standard deviation (GSD) of 5.8, and a fifth percentile WPF of 5. The MSA Comfo II half-mask had a 50% WPF of 163, a GSD of 3.1, and a fifth percentile WPF of 26. The Scott half-mask had a 50% WPF of 94, a GSD of 4.8, and a fifth percentile WPF of 7. For all respirators a 50% WPF of 114, a GSD of 4.6, and a fifth percentile estimate of 9 was reported. The authors concluded that ''* * * dust-fume-mist (DFM) half-facepiece respirators, when conscientiously used, worn, and maintained, provided effective worker protection.''

Study 8. W.R. Meyers and Z. Zhuang in January, 1993 (Ex. 1–64–51) and W.R. Myers, Z. Zhuang, and T.J. Nelson in 1996 (Ex. 3–12) reported on the second part of the three-part study, which evaluated protection against exposure to particulate iron (Fe) for 16 workers in the sinter plant and basic oxygen process (BOP) facility of a steel manufacturing plant. In addition, exposure to particulate calcium (Ca) in the BOP facility was determined for one worker. The five brands of half-mask respirators studied were: 3M 8710 disposable dust/mist respirator; Gerson 1710 disposable dust/mist respirator; American Optical 5-Star elastomeric respirator with dust/mist filters (R30); MSA Comfo II elastomeric respirator with dust/mist filters (Type F); and Scott, Model 65 elastomeric respirator with dust/mist filters (642–D).

In general, each participant wore two or more brands, and one WPF was measured per employee per brand worn. One employee had one WPF determined for only one respirator brand. For the elastomeric half-mask respirators, the participants were quantitatively fit tested. A fit factor of 100 or more constituted a pass. Disposable respirators were fit tested using the saccharin qualitative fit test. The overall study and sampling protocols were discussed by the authors in the foundry portion of the investigation (*see* Study 7 discussion above). While not specifically discussed, it is assumed that the same sampling parameters used in the foundry study were in place during this particular study, unless the authors stated otherwise. These assumptions include: composition of the sampling trains was unchanged; individual WPFs were based on monitoring times of one to four hours; elastomeric facepieces were cleaned and inspected at the end of each shift but the insides were not wiped during the shift such wiping was the employer's standard practice before the study; air-purifying filter cartridges and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing; and the in-mask probe mouth was plugged whenever the respirator was not being worn. In addition, it is assumed that the participants were clean shaven, normally used respirators, were trained in the proper donning and adjustment of the respirators, were instructed not to remove or lift the respirator from their face in the work area, and were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter to aid in PIXE analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. This cassette was attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. Sampled air was drawn through a moisture trap using a personal sampling pump operating at 1.5 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter. The cassette was not connected to a flared mouth probe. This sampling train was attached in the lapel area and samples were collected at a flow rate of 1.5 Lpm. (Note: Unlike the foundry portion of the study, outside samples were collected as total mass rather than respirable mass samples.) Sampling pump flows were calibrated before and after each sampling period and pumps were monitored at approximately 15–20 minute intervals. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. New cassettes were used for each sampling period. Working (*i.e.*, field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators also washed the interior of the sampling cassettes to determine retention of sample particles on the cassette wall. The ambient particle size distribution was determined by PIXE cascade impactor samples. Personal impactor samples, rather than area samples, were collected at the steel mill sites (*see* foundry sampling procedures discussed above in Study 7).

Analysis for Fe and Ca on inside-the-facepiece filters was by proton induced X-ray emission analysis (PIXEA). Due to filter overloading, analysis for Fe and Ca on outside-the-facepiece filters was by atomic absorption spectroscopy. The mass distribution of Fe by particle aerodynamic diameter was tabulated for all cascade impactor samples. A total of 54 individual pairs of inside- and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by shift and date, job category, employee, and brand of respirator. For 16 workers, the WPFs reported were based on the Fe data, while Ca data were used to calculate the WPF for one worker (flux unloader) in the BOP facility. Based on analytical information, the authors did not adjust measured values for particle retention on the walls of the sampling cassette. No mention is made of adjusting inside-the-facepiece values for particle retention in the respiratory tract. The average field blank mass loading was used as a correction factor for estimating background contamination. The 3M 8710 had a reported GM WPF of 377, a GSD of 3.7, and a fifth percentile WPF of 44. The Gerson 1710 had a reported GM WPF of 123, a GSD of 2.7, and a fifth percentile WPF of 24. The American Optical elastomeric half-mask had a reported GM WPF of 280, a GSD of 2.7, and a fifth percentile WPF of 56. The MSA Comfo II had a reported GM WPF of 427, a GSD of 4.3, and a fifth percentile WPF of 39. The Scott elastomeric half-mask had a reported GM WPF of 252, a GSD of 2.9, and a fifth percentile WPF of 45. The authors concluded that ''The 5th percentiles for the WPF distributions for each respirator or pooled data were greater than 20.''

The authors also provided data and discussion on a number of sampling analyses, including GM concentration of analyte and GM WPF by job task, GM concentration of Fe inside the facepiece and ambient and GM WPF by respirator brand, and particle size distribution by job category. The authors stated that ''* * * half-facepiece respirators (maximum use concentration 10 times the PEL) were a suitable selection for the tasks included in this study.''

Study 9. In January 1993, W.R. Meyers and Z. Zhuang reported on the third part of their investigation, in which they determined protection against exposure to particulate titanium (Ti), chromium (Cr), strontium (Sr) and total ambient mass (TAM) for 22 workers who spray painted aircraft on day, evening, and night shifts (Ex. 1–64–52). The three brands of half-mask elastomeric respirators studied were the: American Optical 5-Star, MSA Comfo II, and Scott Model 65. All respirators were equipped with combination high-efficiency filter/organic vapor cartridges.

Twelve participants each wore two brands of respirator with a WPF determined for each brand worn; nine participants wore one brand of respirator and had one WPF determined; and one employee had one WPF determined for one respirator brand and two WPFs determined for another brand. The participants were quantitatively fit tested and a fit factor of 100 or more constituted a pass. The overall study and sampling protocol was discussed by the authors in the foundry portion of the studies, summarized in Study 7 above (Ex. 1–64–51). While not specifically discussed, it is assumed that the same sampling parameters were in place during this particular study as in the foundry study, unless the authors stated otherwise. These assumptions include: composition of the sampling trains was unchanged; individual WPFs were based on monitoring times of one to four hours; elastomeric facepieces were cleaned and inspected at the end of each shift but were not the inside was not wiped during the shift, unless such wiping was the employer's standard practice before the study; filters and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing; and the mouth of the in-mask probe was plugged whenever the respirator was not being worn. In addition, it is assumed that the participants were clean-shaven, normally used respirators, were trained in the proper donning and adjustment of the respirators, were instructed not to remove or lift the respirator from their face in the work area, and were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter to aid in sample analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. This cassette was attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. Sampled air was then drawn through a moisture trap using a personal sampling pump operating at approximately 2 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter. The cassette was not connected to a flared mouth probe. This sampling train was attached in the lapel area, and samples were collected at a flow rate of 1 Lpm. (**Note:** Unlike the foundry portion of the study, outside samples were collected as total mass rather than respirable mass samples.) Sampling pump flows were calibrated before and after each sampling period and pumps were monitored at approximately 15–20 minute intervals. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. New cassettes were used for each sampling period. Working (*i.e.*, field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators did not wash the interior of the sampling cassettes to determine retention of particles on the cassette wall, since a simple alcohol wash would not have removed dried paint spray. Ambient particle size distributions were not characterized.

Analysis of all filters was by proton induced X-ray emission analysis (PIXEA). The average field blank mass loading was used as a correction factor for estimating background contamination. The authors did not mention adjusting inside-the-facepiece measured values for particle retention in the respiratory tract. A total of 36 individual pairs of inside-the-facepiece and outside-the-facepiece concentrations of each analyte (total airborne mass, titanium, chromium, strontium) were provided by shift and date, painting location on the plane (*i.e.*, top, side, or underside of the aircraft), employee, brand of respirator, and paint type (*i.e.*, top coat, primer). A total of 36 WPFs were reported by shift, task location on the plane, employee, and respirator brand; of the original 38 data sets, two sets were eliminated as outliers. For primer spraying, the reported WPFs were based on Cr data, while WPFs for spraying topcoat were based on Ti data. WPFs were not calculated for total airborne mass. The authors also provided data and discussion on a number of sampling analyses, including GM concentration of analyte (TAM, Ti, Cr) for both in-mask and ambient measurements by task location on the plane; GM WPF as a function of painting location on plane and paint type, and respirator brand; and GM WPF by respirator brand. The fifth percentile estimates for all WPF data were reported to be much greater than 10. The authors concluded that these half-facepiece elastomeric respirators, when properly worn and used in conjunction with existing controls provided effective worker protection.

Study 13. G. Wallis, R. Menke, and C. Chelton reported in 1993 on a WPF study in which they evaluated exposure to manganese dioxide dust for an unknown number of participants in several alkaline battery manufacturing plants (number of plants not provided) (Ex. 1–64–70). All participants wore the disposable 3M 8710 dust/mist respirator and performed their normal work activities. The participants were not trained by the investigators, but had been previously trained and routinely used respirators. It was not stated whether the participants had ever been fit tested for the 3M 8710 respirators. Prior to sampling, the participants washed their faces and were taken to a clean area, where the study was explained. The participants were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 37 mm cassette containing a 0.8 micron pore size mixed cellulose ester filter. The cassette was connected to a tapered Liu probe (made of nylon) which was inserted into the respirator midway between the nose and mouth. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing a 0.8 micron pore size mixed cellulose ester filter. The outside sampling cassette was attached to the employee's lapel. No mention is made of connection of the outside cassette to a tapered Liu probe. Inside- and outside-the-facepiece samples were collected at an airflow rate of 1.5 Lpm for 30 to 40 minutes. The authors chose a short sampling interval to prevent resistance across the inside-the-facepiece sampling filter due to a buildup of moisture from exhaled breath. Sampling pump flows were calibrated before, and rechecked after, each sampling period. Respirators were donned and doffed, and the sampling trains started (and assumed stopped), in the clean area. Field blanks were used to identify possible contamination of filters due to handling. The number of sample pairs collected per subject was not specified. The ambient manganese particle size distribution was determined by 6-stage Marple Cascade impactor equipped with an inlet cowl to prevent debris from entering the impactor. Samples were collected for several hours at a flow rate of 2 Lpm, and flows were calibrated before and after each sampling interval. Four samples were gathered: One in the powder drop area (Plant A) and three at the bag slitting operations (one in Plant A, two in Plant B).

Samples were analyzed for Mn by atomic absorption (AA) spectroscopy according to NIOSH Method 7300. The mass distribution of Mn by particle aerodynamic diameter was tabulated for all cascade impactor samples. Less than 30% of the mass was associated with respirable particles. A total of 70 individual pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by job activity (but not by employee or plant). No mention is made of adjusting measured values for particle retention in the respiratory tract or results of field blank analysis. A GM of 50 and a GSD of 3.5 was reported for all the WPF values measured. A calculated fifth percentile protection factor of 7.5 was also reported. The authors reported that their data indicated a systematic dependence of WPF on the concentration outside the respirator. In their discussion of this observation, the investigators refer to three possible causes presented by authors of other studies: Program protection factors tend to be low in low exposure settings since the workers, aware of the low exposure, exercise less care; low outside concentrations result in inside-the-facepiece concentrations so small that reliable quantification is difficult; and filter efficiency increases with loading, and low concentrations do not adequately load the filter. The authors discuss these causes relative to their study results, and postulate that another cause may be particle size selectivity (*i.e.*, smaller particles have a higher probability of entering the respirator). They conclude that it is important to characterize respirator performance in the environment where the respirator will be used.

Study 14. At the 1990 AIHCE, C.E. Colton, A.R. Johnston, H.E. Mullins, C.R. Rhoe, and W.R. Meyers presented a WPF study in which they measured protection against exposure to aluminum dust for five participants working as carbon changers in an aluminum smelter (Ex. 1–64–15). All participants wore the disposable 3M 9906 dust/mist respirator. The investigators trained the participants in donning the respirator and the participants were qualitatively fit tested, although the fit test method was not described. The total number of samples collected per employee was not specified, although it is stated that the five employees were sampled daily for five days. Participants were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. The cassette was connected to a tapered Liu probe, inserted into the facepiece in an unspecified location. In-mask samples were collected at an airflow rate of 2.0 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. Outside samples were gathered as respirable dust samples with the cassette being connected downstream from a cyclone apparatus. Sampling airflow rate was 1.7 Lpm. Sampler airflow rates were calibrated before and after each sample period. No mention is made of donning and doffing procedures. Field blanks were used to identify possible filter contamination caused by handling. The ambient aluminum particle size distribution was determined through 12 area samples (unspecified locations) collected by Marple personal cascade impactors. In addition, particulates that passed a cyclone selector were sized by optical microscopy.

Aluminum was determined by proton induced x-ray emission analysis (PIXEA). The mass distribution of aluminum by particle diameter and percent penetration to the collector was graphically presented. Final calculations used only those outside filter weights that were greater that 11 times the detection limit. A total of 24 time-weighted-average (TWA) inside-the-facepiece and outside-the-facepiece concentrations, with corresponding TWA WPFs, are provided in supplemental data (Ex. 1–146). The sample pairs are not linked to specific participants. No mention is made of adjusting sample results for particle retention in the respiratory tract. The mean blank value was zero, so no adjustment to measured values was made. The authors reported a GM of 27, a GSD of 1.5, and a fifth percentile of 13 for the 23 sample sets used. The report concluded that the respirator provided reliable WPFs of 10. Cumulative probability of achieving a particular WPF, and the effect of filter weight on WPF, were also graphically presented. The authors stated that the WPFs represented conservative estimates of protection since outside concentrations were measured as respirable dust. In the summary of this study (Ex. 1–146), submitted to OSHA along with the raw sampling data, the authors recommended that the study not be used to assess the ultimate APF for this class of respirator since they felt that the real WPF of the respirator was significantly underestimated.

Study 15. C.E. Colton, H.E. Mullins, and C.R. Rhoe presented a WPF study at the 1990 AIHCE in which they determined exposure to particulate Pb and Zn for 17 participants working in core making, mold making, pouring, and cleaning areas of a brass foundry (Ex. 1–64–16). All participants wore the disposable 3M 9970 high-efficiency respirator. The investigators trained the participants in the proper donning and fitting of the respirator, and participants were fit tested using the saccharin qualitative fit test method described in Appendix D of OSHA's Lead Standard (29 CFR 1910.1025). Sampling took place over five days.

The inside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter (open- versus closed-face was not specified). The cassette was directly connected to a tapered nylon Liu probe, inserted into the facepiece midway between the nose and mouth. The inside-the-facepiece samples were collected at a flow rate of 2.0 Lpm. The outside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. Outside samples were gathered as respirable dust samples, with the cassette being connected downstream from a 10 mm nylon cyclone. Samples were collected at a flow rate of 1.7 Lpm, and sampling pumps were calibrated before and after each sample. The authors do not mention using of field or manufacturer's blanks, respirator donning and doffing procedures, or methods of starting and stopping sampling trains in a clean area. The ambient Pb and Zn particle size distributions were determined by an unspecified number of Marple personal cascade impactor (Model 2401) samples.

Pb and Zn were determined by proton-induced x-ray emission analysis (PIXEA). The particle size data were not presented; however, the report stated that the Pb and Zn aerosols were present as both dust and fume. The range of outside-the-facepiece and inside-the-facepiece concentrations for Pb and Zn were provided. For the purpose of WPF calculation, inside-the-facepiece samples with non-detected concentrations were treated as containing analyte at the detection limit (This situation only arose with lead, not zinc). For the 62 sample sets taken for lead, the GM WPF was 415, the GSD was 4.4, and the fifth percentile WPF was 36. For zinc, the GM WPF was 681, the GSD was 5.6, and the fifth percentile WPF was 40. The authors believe they handled their results conservatively since outside concentrations were collected as respirable particulate, rather than total mass, and inside-the-facepiece samples with non-detected concentrations were given values of the analytical detection limit when calculating WPF. In the study summary, the authors concluded that when the respirator is properly selected, fit tested, and used, their results supported its use for concentrations up to 10 times the PEL.

Study 16. A.R. Johnston and H.E. Mullins reported at the 1987 AIHCE on a WPF study in which they measured exposure to particulate aluminum (Al), titanium (Ti) and silicon (Si) for three participants working in the polishing and grinding area of an aircraft components manufacturing facility (Exs. 1–64–34, 1–146, 1–133). Although WPFs were also measured for two other participants, one in the blasting area and one in the coating area, no data were presented for these employees. All participants wore the disposable 3M 8715 dust/mist respirator. Prior to testing, the investigators trained the participants in the proper fitting of the respirator, fit tested the employees using the OSHA Lead Standard's saccharin qualitative fit test method, and explained the study to them. Participants had previously worn respirators, but on an ''as needed'' or elective basis only. Employees were observed one-on-one throughout the sampling period. The number of WPFs measured per subject was not specified, although it appears that about six WPFs were measured per subject.

The inside-the-facepiece sampling train was a closed 25 mm three-piece cassette containing a polycarbonate filter. The cassette was connected to a tapered nylon Liu probe that was inserted into the facepiece at an unspecified location. Inside-the-facepiece samples were collected at a flow rate between 1.5 and 2 Lpm. The outside-the-facepiece sampling train was a closed 25 mm three-piece cassette containing a polycarbonate filter. The cassette was connected downstream from a tapered Liu probe. Outside samples were collected at a flow rate between 1.5 and 2 Lpm. Sampling times ranged from 35 to 235 minutes. Sampling pumps were calibrated three times a day—at the beginning of the shift, lunch, and the end of the shift. Sampling equipment was removed for breaks, which occurred multiple times in some instances. While no mention is made of using a clean area to don and doff respirators, and start and stop sampling trains, the authors noted that cassettes had to be removed in the work area. Field blanks were used to identify possible filter contamination due to handling. The ambient particle size distribution was not characterized.

Samples were analyzed by proton induced x-ray emission analysis (PIXEA). Sample results were adjusted for field blank values, but no mention was made of adjustments for particle retention in the respiratory tract. The authors rejected sample sets in which: the outside filter weight was less than 11 times the mean blank value; the inside filter weight was non-detectable, or less than the mean field blank value; or the measured WPF was determined to be an outlier (*i.e.*, too far above or below the geometric mean WPF using 5% confidence intervals). A total of 38 sample sets were accepted for Al (10), Ti (14), and Si (14). Pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, are provided in supplemental data (Exs. 1–146, 1–133), but were not linked to specific participants. Also, a table of GM WPF, GSD, and fifth percentile WPF, by analyte, was presented. The authors calculated WPF values for the 10 sample sets of Al, reporting a GM of 145, a GSD of 2.3, and a fifth percentile of 32. For the 14 sample sets measured for Ti, the GM was 59, the GSD was 1.7, and the fifth percentile was 24. For Si, using 14 sample sets, the GM was 172, the GSD was 3.1, and the fifth percentile was 24. The authors concluded that their study supports using this respirator for concentrations up to 10 times the PEL. In addition, the authors noted a positive correlation between filter weight and WPF. Two explanations put forth for this effect were that respirators work better with higher dust loadings, and that WPF measurements are more accurate at higher dust loadings. The authors favored the latter explanation, and believed that to assess true respirator performance capabilities, testing should be conducted at or near the respirator's APF, or a filter weight versus protection factor curve should be defined for predicting performance at higher concentrations. In a summary of this study submitted to OSHA (Ex. 1–146) the authors stated that:

> * * * the mass outside the respirator was very low. For this reason, the ability of the respirator to provide protection was not challenged. Therefore, this study should not be used for direct comparison to others in assigning protection factors as they are artificially low.

The authors also discussed sampling and analytical considerations for WPF studies, such as calibration reliability, sample cassette integrity, analytical sensitivity, and sample handling procedures.

2. WPF Study—Full Facepiece APR

Study 2A. C.E. Colton, A.R. Johnston, H.E. Mullins and C.R. Rhoe of the 3M Occupational Health and Environmental Safety Division in May,1989 gave a presentation at the AIHCE on their WPF study (Ex.1–64–14) performed with full facepiece air-purifying respirators worn in a secondary lead smelter. Air sampling for lead was conducted over 5 days in four areas of the plant; the blast furnace, reverberatory furnace, casting, and warehouse areas.

The respirator evaluated was the 3M 7800 Easi-Air full facepiece respirator used with 3M 7255 high efficiency filters. The respirator was equipped with a nosecup inside the facepiece. The sampling probe was inserted into the respirator in place of the speaking diaphragm to assure a gas tight seal and consistent probe location close to the breathing zone of the wearer. The respirators were equipped with sampling probes using a design by Dr. Ben Liu to minimize particle entry losses. Both the inside and outside sampling trains used the Liu designed probe for consistency.

Thirteen workers who normally wore full facepiece respirators in the plant qualified to participate in the study. They were trained in proper respirator use, the procedures to be followed for the study, and how to don and fit the 3M respirator. Quantitative fit testing was performed using the Portacount QNFT instrument and fit test operators followed the OSHA Lead standard exercise protocol for fit testing. The workers were fit tested wearing their normally required personal protective equipment (PPE), and care was taken to assure that this additional PPE did not interfere with facepiece fit. The criterion the authors used for passing the QNFT was a minimum fit factor of 500; 10 times the assigned protection factor of 50 given in the lead standard for a full facepiece negative pressure respirator. The 13 qualified workers were measured for face length and width, and all the workers except 1 were in Grids 1–4 of the Los Alamos Test Panel. The one remaining worker's his face was wider than those accommodated by the Los Alamos Test Panel.

Samples were analyzed by proton induced x-ray emission analysis (PIXEA) for lead. The authors reported that for PIXEA the sensitivity is good, typically 10 nanograms per sample. Area samples for particle size analysis were also collected, using Marple cascade impactors, in the reverberatory furnace, casting, and warehouse areas. Three particle size ranges were found; less than 1 μm (15% of the total aerosol), between 1 to 10 μm (20% of the total aerosol), and greater that 10 μm (65% of the total aerosol). The particle size distribution showed that both lead dust and lead fume were present.

The authors had pre-established that if the outside filter weights were less than 51 times the field blank value, the sample set would be rejected. The authors stated, ''You need at least this much differential between inside and outside samples if you want to prove or disprove that a respirator provides a PF of 50.'' None of the workplace samples were rejected for being less than 51x the field blank value. However, several sample sets were rejected for other reasons such as the inside sample coming loose from the probe, sample pump failure, *etc.* Field blanks were used, and were handled the same as other samples. Detectable amounts of lead were found on the field blanks. The mean value of the field blanks was used to correct the sample values by subtracting the mean field blank value from the inside and outside sample weights. WPFs were calculated by dividing the outside concentration (C_o) by its corresponding inside concentration (C_i), and checked for outliers. The authors reported that for the 20 samples collected the geometric mean WPF was 3929 and the GSD was 9.6, and the 5th percentile WPF estimate was 95. The outside concentrations ranged from 150 to 8380 μg/m³, and the inside concentrations ranged from 0.03 μg/m³ to 3.0 μg/m³. Sampling periods ranged from 30 minutes to 3 hours. The workers were under constant observation to ensure proper respirator use and wear and to ensure sample validity.

The authors looked at subsets of the data using multiples of the field blank mean values ranging from 1,000 times the field blank to 25,000 times the field blank value. The authors found a strong correlation between filter weight and workplace protection factor when they looked at the log of the mean filter weight and the log of the mean WPF. The authors stated that the data appeared to be close to the plateau region. The authors also stated that the quantitative fit factors measured during worker fit testing did not correlate with the WPFs measured in this study.

The authors concluded that '' * * * the results of this study indicate that this full facepiece respirator with high efficiency filters reliably provides workplace protection factors in excess of 50 against lead dust and fume aerosol.'' The authors stated that they would expect 95% of the workplace protection factors to be above 95. They also stated that ''The ANSI Z88.2 proposed Standard for Practices for Respiratory Protection has assigned a protection factor of 100 to this type respirator. These data support that recommendation.''

3. WPF Studies—Powered Air-Purifying and Supplied-Air Respirators Half-Mask PAPRs

Study 21. In 1983, W.R. Meyers and M.J. Peach of NIOSH reported half and full facepiece PAPR performance measurements for four workers during bagging of micro-crystalline silica (Si) in a silica processing plant (Ex. 1–64–46). The study examined several aspects of the respirator's performance. Prior to the workplace evaluation, dioctyl phthalate (DOP) was used to determine filter efficiency. A 4-hour Si dust chamber study was performed by mounting the PAPR on an anthropomorphic head, simulating worker breathing, and gathering inside- and outside-the-facepiece silica samples. Workers were provided with an unspecified brand of PAPR, with either a tight-fitting half-mask or full facepiece, and equipped with high-efficiency filters. Both styles of facepiece were made of natural rubber and had two exhalation valves. The sealing edge of the facepiece was either an internal roll (half-mask) or a flat edge with an inner flap (full facepiece). The filters were located downstream of the respirator's blower unit.

The PAPRs used in the study were identical to those already being used by the employees; the authors did not mention training the participants in proper use of the respirator. Respirators were placed on and removed from the participants by the investigators, as needed (*e.g.,* start of shift, lunch break, personal breaks, end of shift). Donning and doffing the respirator, and sampling train starting and stopping, occurred in a clean area. Samplers were started after the PAPR was donned and turned on, and were stopped before the PAPR was turned off for doffing. Facepiece interiors were examined for dust contamination after each removal (gross contamination was not observed), and the facepieces were cleaned by the investigators after each shift. In addition, each PAPR's volumetric air output (with the facepiece removed) was measured with a dry gas meter. Filters and batteries were changed according to the manufacturer's instructions. While no mention is made of fit testing the participants, the investigators instructed them not to manipulate, lift, or remove the facepiece during sampling. Participants were observed 100% of the time during donning and doffing, and about 80% of the time at their workstations. The authors used field blanks to assess contamination caused by handling.

The sampling train for the inside-the-facepiece samples consisted of a 37 mm two-piece cassette containing a 5 micron pore size FWS–B polyvinyl chloride filter. The cassette was attached directly to a modified Luer adaptor sampling probe, inserted into the facepiece between the nose and upper lip of the employee. The flow rate of the pump was 1.5 Lpm. The outside-the-facepiece samples were collected with a 37 mm two-piece cassette and a 5 micron pore size FWS–B polyvinyl chloride filter. The sampling airflow rate was 1.5 Lpm, and the cassette was attached to the subject's lapel. Outside samples were collected as total dust since previous sampling revealed 70% or more of the dust particles to be 10 microns or less in size (*i.e.,* respirable). Sample times ranged from 84 to 320 minutes, with cassettes being changed during the employees' lunch break. Overall PAPR performance (leakage) was determined by replacing the facepiece of two respirators with an air-filtering head containing a pre-weighed 76 mm glass fiber filter. The respirators were mounted in a free-standing stationary position, and run for 6–7 hours (with a battery change at 4 hours). The air output was measured, the filter weighed, and the ambient Si concentration estimated. Area samples were collected to determine particle size. An Anderson impactor was placed 4–8 feet from the participants and collected samples for about 3 hours at a flow rate of 1 cfm.

Samples were analyzed for free Si according to NIOSH P&CAM 259 (*i.e.,* gravimetric weight and x-ray powder diffraction for Si). Results were corrected for the average blank filter weight gain, but not for pulmonary retention (which the authors believed was negligible). Ten individual inside- and outside-the-facepiece concentrations, with associated WPFs, are tabulated by sample period, worker, type of facepiece, and sample time. The study reported that the half-mask PAPR did not provide the protection factor of 1,000 previously expected; instead, the protection factors ranging from 16 to 193. The authors also provided results for DOP filter penetration, aerodynamic mass median particle size and GSD, x-ray powder diffraction tests, and free-standing PAPR leakage measurements. The researchers discussed several parameters that could have affected results, including poor respirator use practices of the participants (which the authors believed they controlled and maintained at a minimal level); inside-the-facepiece sampling flow rate (which the authors believed was not a major source of error); and inherent PAPR leakage (however, the free standing PAPR results indicated minimal leakage). Also discussed as reasons for the low protection factors were possible leakage of Si past the blower housing grommet when employees bumped the PAPR during work (the effect of this was unknown) and leakage from inadequate facepiece fit (which the authors considered could be significant at moderate to heavy work rates).

Study 6. S.W. Lenhart and D.L. Campbell of NIOSH reported in 1984 on a WPF study in which they measured protection against exposure to particulate lead (Pb) for 25 primary lead smelter workers; 7 of the employees worked in the sinter plant, and 18 worked in the blast furnace area (Ex. 1–64–42). The predominant aerosol forms of Pb were dust in the sinter plant and fume in the blast furnace. In both areas, Pb comprised about 50% of the total aerosol particulate, with composition of the remaining 50% of particulates being unknown. All participants wore an MSA half-mask PAPR with high-efficiency filters (the authors provided no respirator model number in the report). The study also examined the performance of an MSA negative-pressure air-purifying respirator, which is discussed above in the half-mask air-purifying respirator study summaries. The participants routinely used respirators, but the investigators do not mention respirator training for the employees. The participants were not normally fit tested with the half-mask PAPR facepiece; however, for this study, they had to achieve a fit factor of at least 250 while wearing a negative pressure air-purifying respirator with the same half facepiece as the PAPR. Employees were instructed not to remove or manipulate the respirator during sampling, and were observed throughout the sampling period.

The inside-the-facepiece sampler consisted of a closed-face 37 mm cassette containing an AA filter and AP10 support pad. This cassette was connected to a tapered Liu probe that was inserted into the respirator between the nose and upper lip. In-mask samples were collected at 2 Lpm. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing an AA filter and AP 10 support pad (with no tapered Liu probe used). The outside sample cassette was attached to the worker's lapel. Outside samples were gathered at 2 Lpm. Samples were collected for ''as much of the 8-hr work shift as possible.'' Respirators and sampling trains were donned and doffed, and started and stopped, in a lead-free area. The inside of the respirator facepieces were wiped clean prior to donning after each break, and were cleaned and sanitized after each shift. The PAPR batteries were replaced after four hours of use (*i.e.,* according to manufacturer's instructions). Battery voltage was checked, and airflow rates were verified to exceed 15 Lpm before use. One WPF was measured for each participant. The ambient particle size distribution was determined by 19 Marple cascade impactor samples (11 in the sinter plant; 8 in the blast furnace area).

Analysis of Pb was by flame atomic absorption spectroscopy according to NIOSH Method S–341. Inside-the-facepiece samples that contained less than 10 μg of lead were reanalyzed by graphite furnace atomic absorption (limit of detection = 0.2 μg). The report provided ranges of the mass median aerodynamic diameters (in micrometers), as well as the GSD values. The authors provided a total of 25 pairs of inside- and outside-the-facepiece concentrations, and the corresponding WPFs, by employee, job title, and job location, as well as the overall GM and GSD of the PAPR WPFs and several percentile values. For samples containing Pb below the level of detection, the authors determined concentration values ''* * * from the least amount of lead detectable by the analytical method and the sampled volume of air.'' In-mask measured values were not adjusted for particle retention in the respiratory tract (the authors imply that retention had a non-significant effect on the results, but could cause WPF to be overestimated). No mention is made of using field blanks. Two approaches to defining an assigned protection factor (APF) were also discussed. These approaches are: Defining the APF in terms of a specific proportion of WPFs expected to exceed the APF, and defining the APF ''in terms of a one-sided lower tolerance limit above which we may predict with a specific confidence level that 95% of the workplace protection factors lie.''

The WPF for the PAPR had a GM of 380 and a GSD of 2.6, and the individual WPFs ranged from 23 to 1,600. Approximately 98% of the WPFs for the half-mask PAPR were above 50, 90% above 110, 75% above 200, 40% above 500, and only 25% above 1,000. The authors concluded that an APF of 50 was appropriate for the PAPR they tested, and that an APF of 500 was inappropriately high for the half-mask PAPR. A protection factor not in excess of 50 was recommended for half-mask PAPRs. The authors noted that the WPFs may be too high because the workers did not routinely undergo a quantitative fit test screen with negative pressure respirators before receiving their PAPR.

4. WPF Studies—Full Facepiece PAPRs

Study 21. W.R. Myers and M.J. Peach of NIOSH reported in 1983 on the performance of an unspecified brand of PAPR equipped with a tight-fitting elastomeric full facepiece and HEPA filters; four employees used the respirator in a silica bagging operation (A detailed description of the work setting, sampling methodology, and study protocol for this study is presented in the discussion of Study 21 in the section on half-mask PAPRs above) (Ex. 1–64–46). The full facepiece PAPR had a sealing edge consisting of a flat edge with an inner flap. The participants routinely used this PAPR and, therefore, the investigators did not train them in its use. Fit testing was not performed.

The investigators calculated WPFs for only three of the four employees because the sample for the fourth employee had an inside-the-facepiece concentration less than the limit of detection, making it unsuitable for WPF determination. The samples were evaluated for crystalline Si by x-ray diffraction. The full facepiece WPFs ranged from 25 to 215, which are low for a PAPR. In this regard, the authors reported that the employees routinely bumped and rubbed the belt-mounted motor blower housing and filter assembly during the bagging operation. They believed such action may have caused movement between the neck of the filter and the blower housing grommet; thereby resulting in the seal failing and allowing unfiltered air to bypass the filter. They reported some evidence to support this conclusion, but could not determine the contribution of this problem to the overall leakage into the facepiece. Although the blowers were checked to ensure each PAPR delivered a minimum 115 Lpm (4 cfm) airflow to the facepiece, the authors concluded that "* * * migration of contaminant into the facepiece of the PAPR system could be a significant source of leakage when the respirator is exposed to the wide ranging conditions that exist in the work environment." While the WPFs measured in this study were well below the level expected of a PAPR, the authors stated that these results "* * * represent a more accurate measure of the level of worker protection that can be expected from this type of PAPR system."

Study 18. At the 1990 AIHCE, C.E. Colton and H.E. Mullins presented a WPF study in which they assessed protection against exposure to lead fume and dust for 20 employees working in the blast furnace, reverberatory furnace, casting, and baghouse areas of a secondary lead smelter (Ex. 1–64–12). The employees were provided with a 3M Whitecap PAPR with a high-efficiency filter (TC–21C–456). The investigators trained the employees in the proper donning, fitting, and operation of the respirators. Using a TSI Portacount, the investigators conducted fit testing while the participants performed the exercise sequence contained in Appendix D of OSHA's Lead Standard; the required fit factor was 500. Participants were observed continuously throughout the sampling.

The inside-the-facepiece sampling train consisted of a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. The authors mounted the sampling cassette directly to an ABS Liu probe and inserted the probe into the facepiece in place of the speaking diaphragm. The outside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. The authors did not mention attaching the outside cassette to a probe or the location of the sampling cassette on the employee. Airflow rates of the sampling pumps were calibrated in-line before and after each sampling interval, but no sampling airflow rate was provided. Sampling was conducted for as much of the 8-hour shift as possible, with sampling intervals ranging from 1 to 4 hours. Field blanks were used, and area samples for particle size analysis were gathered with a Marple personal cascade impactor (Model 2401).

Sample and field blank analyses were performed using proton induced x-ray emission (PIXE) analysis. Particle size analysis by inductively-coupled plasma—mass spectrometry indicated particles in the dust and fume range. While the range of inside- and outside-the-facepiece concentrations were presented, individual inside and outside concentrations or results by employee or job classification were not provided. Similarly, the report presented an overall GM WPF, GSD, and fifth percentile WPF, but not individual WPFs. Of the 55 sample measurements, 34 of the inside-the-facepiece results were below the analytical limit of detection. In these instances, the authors used a conservative WPF calculation by setting the values at the limit of detection. No lead was detectable on the field blanks so no adjustments were made to sample weights. The authors do not mention adjusting inside-the-facepiece values for pulmonary particle retention. Final calculations used only those sample pairs with outside sample weights greater than 1,000 times the detection limit. The authors believed this procedure was necessary to determine that the respirator was capable of providing a protection factor of 1,000. The authors also analyzed the data for outliers (at the 99% confidence level). The overall data analysis resulted in a GM WPF of 8,843, a GSD 3.2, and a fifth percentile WPF of 1,335. The authors concluded that the data supported ANSI's proposed APF of 1,000 for full facepiece PAPRs. They also recommended that fit testing be performed on all tight-fitting respirators.

5. WPF Study—Helmet/Hood PAPRs

Study 27. At the 1990 AIHCE, D.R. Keys, H.P. Guy, and M. Axon reported on a 3-month WPF study in which they evaluated exposure to estradiol benzoate (a steroid) for an unspecified number of workers in a pharmaceutical facility (Ex. 64–40). They included three loose-fitting hood/helmet type PAPRs in the study: Racal Breathe Easy 10, Bullard Quantum, and 3M Whitecap II. All three PAPRs had double-bibbed capes, were equipped with HEPA filters, and did not have lift-up visors. A Tyvek hood was part of the Racal and Bullard PAPRs while the 3M had a hard helmet. PAPRs were previously used at the facility, so workers were already properly trained in their use and were familiar with wearing them. The investigators observed the participants continuously, one-on-one, during sampling. While the authors used field blanks, they did not mention determining particle size or using a clean area for donning and doffing or for starting and stopping the sampling train.

The inside- and outside-the-facepiece sampling trains consisted of a 37 mm two-piece cassette with a glass fiber filter, attached to a nylon Liu probe. Location of the inside-the-facepiece probe was not specified. Samples were gathered for ½–3 hours at a flow rate of 2.5–3.5 Lpm. Pumps were calibrated in-line before and after each sampling period.

The authors used radioimmunoassay (RIA), a very sensitive analytical technique, to analyze inside-the-facepiece samples, and HPLC to analyze outside samples; they rejected inside samples with weights below the limit of quantification. Also, the investigators rinsed the outside sample probes with methanol and analyzed the rinsate by HPLC to determine sample loss due to probe use. The authors did not provide any further analytical information.

Sixty valid sample sets were obtained from the study. Results were not adjusted for blank value (*i.e.,* all blank values were below 1 nanogram per filter) or probe loss (*i.e.,* the GM of 1% was not statistically significant). Individual inside and outside concentrations or WPFs were not reported. Instead, the authors presented the range of inside- and outside-the-facepiece concentrations. They determined an overall fifth percentile WPF for each respirator, along with the number of samples, the minimum and maximum WPF achieved, a GM WPF, and the GSD. In addition, the authors determined the percentage of WPFs that fell in selected ranges (*e.g.,* <1,000, 1,000–10,000) for each PAPR, and they briefly discussed the correlation between WPF and outside concentration (*i.e.,* they found WPF to be independent of outside filter loading in this study). The Racal Breathe Easy 10, with 29 sample pairs, had a GM WPF of 11,137, a GSD of 3.9, and a fifth percentile WPF of 1,197. The Bullard Quantum, with 9 sample pairs, had a GM WPF of 9,574, a GSD of 3.1, and a fifth percentile WPF of 1,470. The 3M Whitecap II helmet, with 22 sample pairs, had a GM WPF of 42,260, a GSD of 9.8, and a fifth percentile WPF of 997. The authors stated that they obtained WPFs above 10,000 for the three PAPRs at least 44% of the time, and that the three respirators provided WPFs above 1,000 throughout the study. The authors concluded that the results of their study agreed with the then-proposed ANSI Z88.2–1992 APF of 1,000 for PAPRs with hoods or helmets.

6. WPF Studies—Loose-Fitting Helmet/Hood PAPRs & Loose-Fitting Facepiece PAPRs

Study 23. W.R. Meyers, M.J. Peach, K. Cutright, and W. Iskander reported in 1984 on a study in which they examined lead (Pb) exposure of 12 workers in a secondary lead smelter (Ex. 1–64–47). The job classifications studied were furnace operator, helper, and pig caster. They selected two employees from each classification on two shifts. The PAPRs used in the study were the 3M W–344 and the Racal AH3; each employee wore both respirators twice. Pre-shift quantitative fit testing was performed each day. The investigators trained the participants, but did not describe the training; they monitored the employees continuously during sampling.

The authors referred to a companion paper for a description of the sampling protocol used in this study; therefore, they provided no information is provided on sampling or analytical methodologies in this report. Eight impactor samples were collected at each work activity to determine particle size distribution. Samples were collected for the full shift, but the investigators did not provide specific sampling times. The authors also provided the range of inside-the-facepiece concentrations, with associated GM and GSD, for both brands of respirator; they measured these concentrations with the PAPRs placed on manikins which were located at the worksites where employees in the three job classifications worked.

For each respirator, the study provided 24 individual inside- and outside-the-facepiece (front and rear) concentrations, along with associated WPFs and each employee's fit factor. It also provided the overall GM, GSD, and 95% confidence level on the mean for the inside-the-facepiece concentrations, WPFs, and fit factors. The authors tabulated the data by day, shift and work activity. For both respirators, two samples were discarded due to sampling pump failure, giving 22 usable measurements for each respirator. The WPFs measured on the Racal AH3 ranged from 42 to 2,323, with a GM of 205 and a GSD of 2.83. The 3M W–344 had WPFs that ranged from 28 to 5,500, with a GM of 165 and a GSD of 3.57. The two-sided 95% confidence limits around the mean of the WPFs were 128 and 325 for the Racal AH3, and 94 and 292 for the 3M W–344. The authors provided a detailed discussion of their statistical analyses of the data; they also discussed several potential sources of variation in the workplace performance of PAPRs, including: a possible relationship between fit factor and WPF; a possible relationship between fit factor and inside-the-facepiece concentration; day of the week; shift; leakage into the facepiece due to ambient air currents; and worker activity. The only sources found to be potentially significant were leakage into the facepiece due to ambient air currents and worker activity. The authors stated that ''* * * using the pooled 3M and Racal WPF data and a probability of 0.95 the assigned protection factor calculated by this method for these PAPRs would be 26.'' They recommended a reduction in the RDL's APF of 1,000 for loose-fitting PAPRs with helmets and HEPA filters.

Study 5. W.H. Albrecht, G.R. Carter, D.W. Gosselink, H.E. Mullins, and D.P. Wilmes reported at the 1986 AIHCE on a study they conducted that evaluated protection against exposure to asbestos fibers for 12 workers who manufactured asbestos-containing brake shoes for trucks (Ex. 1–64–23). The employees performed six operations at the facility: mixing brake shoe components, weighing mixed formulation, pre-forming molding press charges, molding the shoe, grinding the brake shoe surface, and drilling shoe mounting holes. The investigators sampled at each operation. The PAPR studied was the 3M Airhat with high-efficiency (HEPA) filters. The participants and supervisory staff were shown an audio slide presentation explaining how to fit respirators and the procedures for saccharin fit testing; they then received the saccharin qualitative fit test (since the authors do not specifically mention fit testing the PAPR, it is assumed that only the half-mask respirators studied were fit tested). Fit testing was not conducted prior to each study test. The PAPR was fitted and worn according to the manufacturer's instructions. Each employee was observed on a one-on-one basis during testing to assure that they properly donned and used the respirator and that sampling train integrity was maintained.

The inside-the-facepiece sampling train was a closed-face filter cassette connected to a tapered Liu probe, inserted into the respirator between the nose and mouth. The outside-the-facepiece sampling train was a closed-face filter cassette connected to a Liu probe attached in the employee's lapel area; the authors do not mention cassette size. Samples were collected for 30 minutes, but other sampling times were occasionally used; sampling pump flow rates were 2 Lpm (inside-the-facepiece) and 0.5 Lpm (outside-the-facepiece). The report does not mention modifying the inside-the-facepiece probe location (midway between the nose and mouth) or the sampling flow rate for the PAPR versus that used for the half-mask respirators studied.

Sampling trains were calibrated before the shift, at lunch, and at the end of the shift; average airflow rate was used to calculate sampled air volume. The investigators did not mention determining the PAPR's airflow rate.

Asbestos analysis was based on NIOSH method 7400, with 500 fields counted per inside sample filter and 100 fields counted per outside sample filter. The distributions of fiber length and fiber diameter were not characterized. The authors stated that blanks were submitted for fiber counting; however, no further mention is made of the blank results or how they were addressed. None of the PAPR samples were comparison counted by Phase Contrast Microscopy (PCM) and Scanning Electron Microscopy (SCM). A total of seven PAPR WPFs were reported (5 employees). Individual pairs of inside and outside concentration values were not provided. Individual WPFs were reported for each of the seven sampling intervals, but were not linked to specific participants or jobs. The authors provided an overall GM, GSD, and fifth percentile for the Airhat PAPR; a range of asbestos concentrations and the associated GM and GSD were also reported by job. An inside-the-facepiece fiber count of 1,000 was used in calculating the WPF when the sampling result was at or below the limit of detection (*i.e.*, 1,000 fibers per filter). The investigators did not mention adjusting inside-the-facepiece values for fiber retention in the respiratory tract. In addition, the authors determined that sampling results were not affected, at the 95% confidence level, by sampling flow rate or open-versus closed-face sampling cassette. The mean breathing zone concentration of asbestos for the Airhat PAPR was 4.14 fibers/cc, with a mean breathing zone concentration range of 1.23 to 8.05 fibers/cc. The authors reported a GM WPF for the PAPR of 199, with a GSD of 2.36 and a fifth percentile of 42. Five employees tested the PAPR, resulting in a total of nine sample sets, including two unusable sets of data. The authors noted that respirators that had the highest GM and fifth percentile WPFs (*i.e.*, the 3M Airhat and 3M 9920 DFM respirators) were also tested at higher breathing zone fiber concentrations. They believed that this factor probably led to these respirators' increased performance measurements.

Study 22. In 1986, W.R. Meyers, M.J. Peach, K. Cutright, and W. Iskander reported on a study in which they evaluated exposure to lead (Pb) dust and mist for 12 workers on two lead acid plate production lines of a battery manufacturer (Ex. 1–64–48). They sampled the pasting operator and two slitter operators on each line for two different shifts. The respirators studied were the Racal Airstream AH5 and the 3M W–3316, equipped with a helmet, visor enclosure, and dust/mist filters. Participants were clean-shaven, and each employee wore both types of respirator twice. The AH5 provided a seal between the employee's face and the face shield by using two flexible face seals; air was exhausted at the chin. The size of the faceseal (*i.e.*, large or small) was selected based on the appearance of best fit and wearer comfort. The 3M's soft flexible face seal gave a loose-fitting seal between the face and face shield, with air exhausted at the temples. Prior to field testing, randomly-selected filters underwent silica dust penetration testing. The investigators put on and removed the respirators from the employees in a clean area, except when the employees took personal breaks (in which case, the employees donned and doffed the respirator in the work area). Employees were not fit tested, but were instructed in the proper use of the PAPR and directed not to remove the helmet, lift the face shield, or tamper with the sampling equipment without notifying the investigators. The investigators continuously monitored donning and doffing and work activities. Respirator helmets and visors were cleaned between each use, and volumetric air output was periodically checked (usually at the beginning of the shift, lunch, and shift's end). The authors replaced the batteries according to manufacturer's instructions, and when low airflow occurred. They also installed new filters at the beginning of each shift. The investigators started the sampling pumps after the employees donned the respirators and the PAPR blower was functioning; they stopped the pumps before turning off the PAPR blower.

Sampling trains were identical and consisted of a closed-face 37 mm two-piece cassette, containing a 0.45 micron pore size cellulose ester filter and back-up pad. Inside-the-facepiece sample cassettes were attached directly to a modified Luer adapter sampling probe, inserted through the face shield about one to two inches in front of the employee's mouth. Outside-the-facepiece sample cassettes were located at the front lower right side of the facepiece, away from the PAPR's exhaust airflow; they located a second cassette located the employee near the PAPR's filter, to determine the filter's contaminant challenge. All samples were collected as total dust at a flow rate of approximately 2 Lpm over the full shift (The report did not provide actual sample times). Sampling pumps were calibrated in the laboratory, and the flow rates confirmed at the worksite. Performance of the PAPR filtration system was checked by placing operating respirators on manikins (without simulated breathing), located about 4 feet from the subjects. Two filter blanks were used for each shift. Particle size distribution was determined through using a Marple cascade impactor operating at a flow rate of 3 Lpm.

Inside-the-facepiece samples were analyzed by graphite furnace using a modified NIOSH P&CAM 214 method, with perchloric acid in the wet ashing step. Outside-the-facepiece samples were analyzed by atomic absorption spectroscopy (NIOSH Method S–341 with the perchloric acid wet ashing step modification). Forty-seven individual inside- and outside-the-facepiece (*i.e.*, front and rear) time-weighted-average (TWA) measurements, with associated TWA WPFs, were provided (AH5 = 24; W–316 = 23). These results were tabulated by day, shift, and work activity. Overall GM and GSD were also given for the concentration measurements and WPFs. All blanks were below the analytical limit of detection; the authors did not mention adjustments for pulmonary retention. Particle size (large) and stationary manikin filter efficiency (98%–99.9%) were briefly discussed. The WPFs for the Racal AH 5 ranged from 23 to 1,063, with a GM of 120 and a GSD of 2.64. The WPFs for the 3M W–316 ranged from 31 to 392, with a GM of 135 and a GSD of 1.89. Since the authors found no statistical difference between the performance of the respirators, they pooled the data for both respirators; they then graphically plotted the percent of WPFs less than specific values. The pooled data for the two PAPRs resulted in a distribution with a GM of 127 and a GSD of 2.28. The authors stated that, at a 0.95 probability level, this class of PAPRs would receive an assigned protection factor of 25. The authors also stated that the results ''* * * strongly suggest that the respirator user community not view current generation powered air-purifying respirators equipped with helmets as positive pressure respiratory devices.''

Study 3. A. Gaboury and D.H. Burd (Ex. 1–64–24) and A. Gaboury, D.H. Burd, and R.S. Friar (Ex. 1–64–348) reported in 1993 on the WPF study they performed in a primary aluminum smelter. Exposure to benzo(a)pyrene [B(a)P] on particles was measured for 22 employees who worked as rack raisers, stud pullers, and rod raisers on anode crews. The employees used a Racal Breathe-Easy 1 (BE1/AP3), a loose-fitting helmeted PAPR. The PAPR came equipped with one-piece non-woven flame-retardant face seals, visor locking clips, and combination organic vapor and HEPA filters. (The authors also tested the performance of several negative-pressure, air-purifying half-mask respirators; see Study 7 above). The employees previously received training on this PAPR, and used it for more than six months prior to the study. Forty percent of the employees had beards (*i.e.*, more than two weeks growth), but the investigators did not find a significant difference between bearded and non-bearded participants. No fit testing was performed on the employees, but previous quantitative fit testing showed fit factors ''greater than 1000 in all cases.'' Industrial hygiene technologists assisted participants with donning and doffing respirators, cleaned and maintained the respirators at the end of each work cycle, and observed participants on a one-to-one basis throughout the sampling period. The investigators directed the employees not to tamper with the respirator or sampling equipment. Due to high heat levels in the work area, the employer required employees to rest in a cool environment for one-half hour during each work hour.

The inside-the-facepiece sampling train consisted of a closed-face three-piece cassette with a 25 mm organic-binder-free glass fiber filter, backed with a cellulose ester pad. Inside sampling cassettes were connected to a tapered Liu probe, which was inserted through the PAPR's visor and into the employee's breathing zone. The outside-the-facepiece sampling train was identical to the above; however, the investigators did not mention connecting the cassette to a Liu probe. The outside cassette was mounted on a bracket at the top of the visor. All filters were pre-calcined at 400 degrees Centigrade for 24 hours. Both inside and outside samples were collected at a flow rate of 2 Lpm for approximately 300 minutes, or one-half of the 10-hour work shift. Respirators and sampling trains were worn and operated until the employee entered the rest area; they donned and turned on the respirators prior to leaving the rest area for the next work cycle. The authors plugged the sampling cassettes when not in use, and cleaned the respirators after each work cycle. Field blanks were used to identify contamination due to handling. Sampling train airflow rates were checked at the beginning, middle (*i.e.*, after lunch), and end of the work day; upon changing cassettes; and when a problem was suspected. PAPR turbo-unit flow rate was checked every two hours to assure flow was greater than six cubic feet per minute (cfm). Sampling occurred over a five-day period.

B(a)P analysis followed Alcan Method #1223–84. The ambient B(a)P particle size distribution was determined by collecting four samples, as close as possible to the workers, using an 8-stage Anderson cascade impactor (Model 296). Impactor samples were collected for two to five hours at a flow rate of 2 Lpm. The average percent of B(a)P mass (across four samples) per impactor stage (defined by an aerodynamic diameter cut point, in micrometers) was reported. About 93% of the B(a)P mass was associated with particles having diameters of ≤9.8 micrometers. A total of 20 pairs of inside and outside sample concentrations, with associated WPFs, were provided by job category (but not for individual employees), and whether the employee had a beard. An overall GM, GSD, and 95% confidence interval on the mean were also provided for the inside and outside concentrations and WPFs, along with an overall fifth percentile WPF. The authors stated that some employees participated more than once during the study. They did not mention adjusting inside-the-facepiece values for particle retention in the respiratory tract. The authors found no significant relationship between B(a)P concentrations inside and outside of the facepiece, but they did find a correlation between WPF and outside B(a)P concentrations. The authors stated that, while the data were limited, they recommended testing PAPRs at relatively high concentrations to obtain an accurate measure of their performance. The inside B(a)P concentration ranged from 0.006 to 0.072 μg/m^3, with a GM of 0.012 μg/m^3. The outside B(a)P concentration ranged from 246 to 111.48 μg/m^3 with a GM of 16.73 μg/m^3. WPFs ranged from 371 to 8658, with a GM of 1,414. The two-sided 95% confidence interval limits around the overall GM WPF were 918 and 2,173; the fifth percentile was 275. The authors cautioned that these results WPFs achieved under conditions of good worker compliance and tight administrative control; however, without these conditions, WPFs may be less because: close surveillance of workers is not usually performed; cleaning during rest periods is not done prior to returning to the workplace; visor locking clips are not routinely used; and no respirator is used 100% of the time while in the workplace.

Study 26. At the 2001 AIHCE, D.V. Collia, *et al.* presented a study on the workplace performance of a PAPR against exposure to cadmium (Cd) for seven workers, over three days, in a nickel-cadmium battery manufacturing facility (Ex. 3–5). The respirator studied was the 3M Breathe-Easy 12 (BE–12), a loose-fitting facepiece PAPR equipped with high-efficiency filters; the employees were using this PAPR prior to the study. During a preliminary visit, the investigators discussed the study with the union, management and workers. The authors also evaluated the worksite and took area samples to identify areas with the highest exposures. Prior to sampling, they informed the employees about their role in the study, as well as the study's purpose and procedures. The investigators continuously observed the employees during sampling, and used field blanks to identify contamination from handling. The study contained no additional information on sampling protocols (*e.g.*, donning and doffing procedures).

Inside-the-facepiece samples were gathered using 25 mm three-piece cassettes containing an unspecified membrane filter and a porous plastic back-up pad. A nylon Liu probe was used, and the samplers were positioned directly across from the midline between the employee's nose and mouth. Outside-the-facepiece samples used 25 mm three-piece cassettes containing an unspecified membrane filter, backed with a cellulose pad. Outside samples were positioned close to the employee's breathing zone (the investigators provided no further details). All samples were collected at 2 Lpm for approximately one and one-half hours (range: 67–156 minutes).

Inside-the-facepiece samples and blanks were analyzed by flame atomic absorption spectroscopy and heated graphite furnace atomizer (AAS–HGA). Analysis of outside-the-facepiece samples was by AAS. The analytical methodology used OSHA's method for Cd in workplace atmospheres (OSHA ID–189). The authors provided the mean mass for inside and outside blanks, but made no mention of data adjustments for blanks or pulmonary retention. They also reported minimum and maximum concentrations of inside- and outside-the-facepiece samples for each employee. Supplemental data contained 41 individual measurements of inside and outside concentrations, tabulated by employee, job area, sample period and set, sample time, pump flow rate, and sampled air volume.

WPFs were calculated for 33 of the sample sets (8 of the 41 inside-the-facepiece samples had no detectable Cd). The calculated GM WPFs ranged from 1,460 to 9,440. The fifth percentile WPF was calculated in three different ways: the traditional approach yielded a fifth percentile WPF of 315; an analysis of variance (ANOVA) model, yielded a fifth percentile of 280; and the Monte Carlo simulation model approach resulted in a fifth percentile of 220 when the non-detected inside values had a value of 0.002, a fifth percentile of 303 with the non-detected values excluded, and a fifth percentile of 103 with Employee C excluded. The authors concluded that the BE–12 PAPR provided a level of protection consistent with an APF of 25.

Study 24. D.W. Stokes, A.R. Johnston, and H.E. Mullins determined exposure to silica (Si) dust for five workers in a roofing granule production plant (Ex. 1–64–66). The participants were involved in cleanup of silica dust byproduct by sweeping, brushing walls, and shoveling. The respirator studied was the 3M Airhat, a loose-fitting PAPR with helmet, equipped with dust/mist or high-efficiency filters, and worn with and without a Tyvek shroud. The investigators assisted the participants were assisted with donning the sampling equipment; however, they did not mention training the employees. They observed the employees during sampling, and used field blanks to determine the effects of handling on sample contamination. They did not mention determining the particle size of the contaminant.

Inside-the-facepiece samples were collected through a Liu probe inserted into the faceshield (they did not provide the probe's specific location). A 25 mm cassette containing a 0.8 micron pore size polycarbonate filter was used, and sampling airflow rate was 1.5 Lpm. Outside-the-facepiece samples were gathered as both total and respirable dust. Respirable dust samples were collected at 1.8 Lpm using a 37 mm 0.8 micron pore size polycarbonate filter placed in a cyclone that attached to the employee's lapel. Total dust samples also used a 37 mm 0.8 micron pore size polycarbonate filter. Sampling airflow rate was 2 Lpm, with the sampling cassette attached to the employee's lapel. The investigators calibrated the sampling pumps each day, and checked proper airflow rate three times throughout the day. They collected samples over a four-day period, with sampling times ranging from 30 minutes to 1 hour. At the beginning and end of each sample, the authors confirmed that each PAPR's airflow rate was in excess of 6 cfm.

The authors used proton induced x-ray emission (PIXE) to analyze the samples. They adjusted the inside- and outside-the-facepiece concentrations by subtracting the mean blank value, but did not mention adjustments for pulmonary retention of particles. They also did not provide individual inside-and outside-the-facepiece concentrations and WPFs. They presented results in two tables showing respirable dust samples with values 25 times the mean blank level, and total dust samples with values 100 times the mean blank level. The investigators provided tables reporting sample size and overall GM, GSD, and fifth percentile WPF by type of filter (*i.e.*, dust/mist, HEPA) and the presence or absence of a shroud (*i.e.*, dust/mist with shroud, dust/mist without shroud). Using the respirable dust samples that were 25 times the mean blank value, the authors combined the sampling results of the PAPR with dust/mist filters (*i.e.*, with and without a shroud) and found an overall GM WPF of 2,480 and a fifth percentile of 95. The combined respirable dust results of the HEPA-filtered PAPR gave an overall GM WPF of 5,730 and a fifth percentile of 762.

Atmosphere-Supplying (Supplied-Air) Respirators

Atmosphere-supplying respirators, also referred to as supplied-air respirators (SARs) or airline respirators, operate in one of three modes: Demand, continuous flow, and pressure demand. Demand and pressure demand respirators can be equipped with half or full facepieces. Continuous flow respirators can also be equipped with a helmet, hood, or loose-fitting facepiece.

7. WPF Studies—Loose-Fitting Atmosphere-Supplying Respirators With Hood or Helmet

Study 28. A.R. Johnston, *et al.* in 1987 conducted a WPF study evaluating exposure to silica (Si) among four shipyard workers who wore a 3M Whitecap II loose-fitting, continuous flow SAR with hood/helmet while sandblasting paint from the flat top of a barge (Ex. 1–64–36). The respirator was comprised of a W–8100 abrasive blasting helmet, a W–5114 breathing tube, a W–2862 air / temperature control valve, 50 feet of W–9435 air hose, and a W–8054 extended length shroud. To permit evaluation of the respirator at its low and high range of airflow rates, air pressure was maintained at 60 or 80 psi, resulting in an in-helmet airflow rate of either 6.4 or 14.4 cfm. The investigators informed the employees of the purpose and protocols of the study, and instructed them in the proper donning and use of the respirator. They also directed the employees not to adjust or remove the respirator after sampling began. Sampling trains were connected and disconnected in a clean area when possible. Sampling pumps were started after confirming proper operation and donning of the respirator, as well as airflow rate into the helmet. Pumps were stopped before the helmet was disconnected from the air supply and removed. The authors maintained continuous one-on-one observation of the employees during sampling, and used several field blanks during each day of sampling.

The authors collected inside-the facepiece samples on 25 mm cassettes containing 0.8 micron pore size polycarbonate membrane filters. They attached the cassettes directly to a Liu probe inserted through the center of the faceshield, about midway between the nose and mouth; the probe extended about 3 mm into the helmet. The flowrate for the inside samples was approximately 2 Lpm. The authors collected outside-the-facepiece samples as both total and respirable dust, using a 37 mm cassette with a 0.8 micron pore size polycarbonate membrane filter. They used a Bendix or SKC cyclone, operating at 1.7 Lpm airflow rate, to gather the respirable dust samples and obtained total dust samples at flow rates ranging between 0.5 and 2 Lpm. Both outside-the-facepiece sample cassettes were located on the employee's lapel. The investigators calibrated the sampling pumps at least three times a day, and sampling periods ranged from 10 to 60 minutes to prevent filter overloading.

The authors analyzed all samples using PIXE. They found Si on all 18 blanks. Of 68 initial sample sets, they discarded 16 (11 due to test malfunctions and 5 due to outside loadings less than 10 times the mean blank level and inside loadings at or below the blank level). They corrected the remaining 52 sample sets for blank value, and then tabulated by inside and outside filter weights, inside and outside sample volume, and associated WPFs. Since nearly all of the dust was of respirable size, the authors did not report results for the total dust samples. Comparing the sampling results with the mean blank levels, the investigators stated that the analytical confidence limits of the data were poor, with only 11 samples being better than plus or minus 25%. The authors considered samples with inside concentrations greater than 1,000 times the mean field blank to be an accurate indicator of the respirator's performance capability; seventeen sample sets met this criteria, but they removed two samples WPF calculation database as outliers. For the remaining 15 samples, the GM WPF was 4,076, the GSD was 2.3, and the fifth percentile WPF was 1,038.

The authors concluded that WPFs generated from sample sets with light outside dust loadings significantly underestimated respirator performance; higher outside sample loadings appeared to be less influenced by non-respirator variables. The investigators judged WPF estimates derived from data subsets with higher outside filter loadings as providing a better indication of respirator performance capability. The authors also discussed an apparent correlation between WPFs and outside filter loadings (*i.e.*, a higher loading equaled higher a WPF until reaching a plateau about 600 times the mean blank value); however, the correlation between WPFs and outside concentrations was not statistically significant. In addition, the effect of higher versus lower helmet airflow rate on sample results and WPFs was not significant. They also discussed the daily and overall WPFs achieved when using time-weighted-averages for the calculations. They concluded that their data supported the ANSI Z88.2 proposed APF of 1,000 for loose-fitting SARs with hoods or helmets.

Study 20. At the 1989 AIHCE, A.R. Johnston, C.E. Colton, D.W. Stokes, H.E. Mullins, and C.R. Rhoe presented a WPF study on a 3M W–8000 Whitecap II SAR with a helmet, and equipped with a breathing tube (W–5114), a compressed air hose (W–9435), and either a vortex cooling assembly (W–2862) or air regulating valve (W–2907) (Ex. 1–64–37). They evaluated exposure to iron (Fe) dust and silicon (Si) dust for six workers involved in grinding iron parts at a foundry. Air supply pressure was 60 psi with the vortex cooler or 25 psi with the regulating valve, thereby maintaining a helmet airflow rate of 6.7 cfm throughout the test. They did not mention employee selection procedures, previous use of respiratory protection, provision of training, or respirator donning and doffing procedures. They verified air supply pressure; valve settings; and integrity of the respirator, connections, and sampling train before starting the sampling pumps. They stopped the samplers before disconnecting the respirator from the air supply; they then took the participants to a clean area to remove the sampling cassette. The investigators observed the employees on a one-on-one basis during sampling, and used field blanks to evaluate possible contamination due to sample handling.

The inside-the-facepiece sampling train consisted of a 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. The authors attached the cassette to a Liu probe installed into the faceshield approximately midway between the nose and mouth; it extended a few millimeters into the helmet. They collected inside-the-facepiece samples at an airflow rate of 2 Lpm. The outside-the-facepiece sampling train also used 25 mm cassettes containing 0.8 micron pore size polycarbonate filters. The investigators collected outside samples as respirable dust using a MSA or Bendix cyclone operating at an airflow rate of 1.7 Lpm; however, they did not mention the location of the outside sample cassette. They collected area samples for particle size analysis using cellulose acetate filters and a personal sampling pump operating at 2 Lpm. They calibrated the sampling pumps at least three times a day, but did not mention specific calibration times.

The authors analyzed the samples for Fe and Si using proton induced x-ray emission (PIXE) analysis. Having detected Fe and Si on the field blanks, they used the mean blank value to correct inside- and outside-the-facepiece sample weights. They used optical microscopy to determine mean particle size range from 6 area samples. The investigators presented no data for individual inside- and outside-the-facepiece concentrations, and associated WPFs; however, they did provide the range of outside sampling measurements, and the overall average outside concentration, for both analytes. While they presented the range of inside-the-facepiece concentrations, they did not report the average inside concentrations. Outside samples averaged 1,500 μg/m^3 for iron dust, and ranged from less than 100 to 2,800 μg/m^3. Outside samples for silicon averaged about 1,000 μg/m^3, with a range from less than 100 to 1,500 μg/m^3. Inside concentrations were at or near the detection limits for both elements. For the 39 samples with values greater than 25 times the field blank, the authors reported a GM WPF of 273, a GSD of 5.7, and a fifth percentile of 39. For samples with outside filter weights greater than 750 times the field blank, they reported a GM WPF of 1,012, a GSD of 2.6, and a fifth percentile of 199. The investigators found a significant correlation between mean filter weights and WPFs; this correlation did not plateau at higher filter loadings. The authors stated that their measurements never reached a level at which the protection factors were independent of the outside filter weight. They concluded that the relatively low sample loadings resulted in WPFs that significantly underestimated the respirator's performance. They stated that, in the case of SARs, the researchers:

* * * should attempt to target outside loadings of at least 1000 times the anticipated analytical detection limit. If we do not, the data we get is likely to reflect limitations of our sampling and analysis procedures, rather than the respirators we are testing.

Study 19. At the 1993 AIHCE, C.E. Colton, H.E. Mullins, and J.O. Bidwell of 3M presented a WPF study on the 3M Snapcap W–3256 airline respirator (TC 19C–70) with a loose-fitting hood, fitted with a W–3258 hard hat, W–5114 breathing tube, W–2862 vortex tube air regulating valve, and 50–100 feet of W–9435 compressed-air hose (Ex. 1–64–17). They measured exposure to silica (Si) for four workers involved in furnace teardown at a foundry. The respirators were operated at an air pressure of 75 psi, with the participants were permitted to regulate the airflow rate to a comfortable level. The authors later determined that this level was 8–9 cfm. The job task consisted of using pneumatic chippers to remove the furnace wall and bottom. Pieces of wall and bottom either fell into or were shoveled into a barrel for removal. The employees then vacuumed of the furnace bottom. The job consumed most of the eight-hour shift. Since the furnace was warm and the work was physical, the employees worked in pairs for about one hour before switching with other employees; therefore, sampling times varied over the two separate days of the study. Participants normally wore air-line respirators. The investigators informed them of the study's purpose, procedures, and their role, and provided them with instruction on the proper donning, fitting, and operation of the respirator; however, the authors did not mention fit testing the participants. The investigators observed the employees on a one-on-one basis during sampling. The employees donned and doffed the respirators and sampling trains in a clean area, and the investigators checked the integrity of the respirator and sampling train before the respirator was connected to the air supply. The authors started the sampling pump after connecting the respirator to the air line, and stopped the pump before disconnecting the respirator from the air supply. They used field blanks to evaluate the possibility of contamination from handling the samples.

Inside- and outside-the-facepiece samples were collected in 25 mm three-piece cassettes containing 0.8 micron pore size polycarbonate filters and porous plastic back-up pads. Inside-the-facepiece cassettes were attached to the inside of the hood, directly across from the employee's mouth, with the cassette pointed toward the employee. A nylon Liu probe was attached to the inside cassette, and a sample line ran through the elasticized inner shroud and out to the sampling pump; the inside sampling flow rate was 2 Lpm. Outside-the-facepiece samples were collected as respirable dust through use of a 10 mm nylon cyclone; the outside sampling flow rate was 1.7 Lpm. The authors do not mention the location of the outside sampling cassettes, or what method they used to conduct particle size sampling.

The investigators used PIXE to analyze collected samples for Si; however, overloading of many of the outside-the-facepiece samples prevented PIXE analysis, requiring analysis of these samples by Inductively Coupled Plasma (ICP) spectroscopy. The authors made no field blank adjustments to the measured sample weights (*i.e.*, Si was not detected on the field blanks). The investigators intended to invalidate sample pairs with an outside filter weight less than 1,001 times the field blank value, or limit of detection if the field blank value was zero; all outside sample weights were more that 10,000 times the detection limit. In addition, they rejected sample pairs with inside sample weights that were less than the mean blank value. They did not mention correcting inside-the-facepiece values for pulmonary retention of particles, or how they managed sample results that were below the analytical detection limit. Particle size analysis showed the contaminant to be ''a dust with over 50 percent of the mass greater than 10 μm.'' The authors established a correlation between the PIXE and ICP analytical methods by analyzing 37 samples using both methods. They developed a linear regression equation that permitted PIXE equivalents to be predicted from the ICP results. They reviewed the WPF results using: The ICP results for the outside concentrations, and PIXE results for the inside concentrations; and the regression to predict PIXE equivalents for the outside concentrations, and PIXE results for the inside concentrations.

The authors calculated WPFs and checked the resulting values for outliers at the 99% confidence level. They did not provide individual inside- and outside-the-facepiece concentrations, but instead reported an overall range of inside and outside concentrations, along with the ranges' associated GM and GSD. In addition, the authors did not provide individual WPF values, but presented calculated WPFs as an overall fifth percentile WPF, GM, and GSD for each of the 2 days, based on both methods discussed above (*i.e.*, ICP and PIXE equivalent). They found that the two methods gave similar results. Using the equivalent PIXE values (*i.e.*, calculated from ICP values), and the

PIXE in-facepiece values, the GM WPF was 10,344, the GSD was 2.5, and the fifth percentile WPF was 2290. The authors stated that the loose-fitting hood performed differently than a loose-fitting PAPR, and this difference should be reflected in the APF assigned. In addition, they briefly discussed a comparison of the study results with the results of several other PAPR and air-line respirator studies.

Study 25. In 2001, T.J. Nelson, T.H. Wheeler, and T.S. Mustard published a WPF study of a supplied-air hood (Ex. 3–6). They measured exposure to strontium (Sr) for 19 painters and helpers involved in sanding and painting operations on several types of aircraft. They judged the work rate to be light to moderate. Prior to sampling, they informed the employees about the study, and instructed them to remain connected to the air supply during calibration and sampling. The participants used a 3M H–422 series supplied-air hood, equipped with an outer bib with an inner shroud and hard hat, H–420 hood, W–3258 hard hat, W–2878 suspension, 50 feet of W–9435 hose, and either the W–2862 vortex cooling assembly or the W–2863 vortex heating assembly. The investigators regulated the supply air pressure to between 60 and 80 psi. Employees donned the hoods in the work area, but investigators did not attach the sampling cassettes until after the employees connected the hood to the air supply and airflow began. They used field blanks to identify possible contamination due to handling, storage or shipment. In addition, they used manufacturer's blanks to detect contamination from manufacture of the filter, and a system blank to determine if contamination was present in the air supply.

The investigators collected inside- and outside-the-facepiece samples using 37 mm or 25 mm three-piece cassettes containing mixed cellulose ester filters. The first 19 samples (*i.e.*, collected during sanding) utilized 37 mm cassettes/filters, but half of the outside samples had no detectable Sr. To increase analytical sensitivity, they collected the remaining 18 samples with 25 mm cassettes and filters. Once the employee was connected to the air supply, they attached a sampling cassette inside the hood at a point midway between the nose and mouth, and to the side of the face. They then uncapped the cassette and connected a Liu probe to the cassette inlet. The authors placed the outside cassette in the lapel area and pointed it forward and down. They started the sampling pumps simultaneously, and performed in-line calibration. They collected samples at an airflow rate of 2 Lpm, for a period consisting of 2 hours for sanding and 90 minutes for painting. At the end of sampling period, they in-line calibrated the pumps, stopped the pumps, capped and removed the cassettes, and the employees disconnected and doffed the hood. They collected the system blank by mounting a cassette in an operating hood that was located away from the work area, and sampled air from inside the hood at 2 Lpm for 2 hours The authors did not mention making a particle size determination.

The investigators analyzed the outside-the-facepiece samples and one of the manufacturer's blanks using NIOSH Method 7300. They used PIXE analysis for the inside-the-facepiece samples, field blanks, system blank, and the other manufacturer's blank. They tabulated the sampling results by date, activity, employee, sample time, inside and outside sampled volumes, inside and outside concentrations, and WPF. The authors reported thirty-one individual inside- and outside-the-facepiece concentrations. However, the results of the outside samples obtained during sanding operations were only 30 times greater than the inside sample values. Therefore, the authors did not consider the data from the sanding operations to be a very useful indicator of respirator performance, and they did not calculate WPFs for the initial 19 sanding samples. Of the remaining 18 painting samples, they calculated WPFs for only 15 samples, after discarding 3 samples due to sampling errors. The Sr levels measured outside of the respirator ranged from 340 to 24,529 μg/m^3, but the investigators found no detectable amounts of Sr on any inside-the-facepiece sample. Therefore, the authors could not directly determine WPFs for the respirator. However, they estimated WPFs by substituting the limit of detection for the inside concentration values. This procedure resulted in estimated WPFs that ranged from more than 920 to 52,000. The authors concluded that their study was ''* * * consistent with other simulated and WPF studies in that the ANSI Z88.2 WPF of 1000 is supported.''

8. SWPF Studies—Type CE Abrasive Blasting Respirators

Bullard: 1995 LLNL Evaluation. During the development of the Interim Final Standard for Lead (Pb) in Construction (1926.25; 1996) and the Final Respiratory Protection Standard (63 FR 1152; 1998), the E.D. Bullard Company (Bullard) expressed concern about the APF of 25 for Type CE respirators. The concern was that the interim final lead rule, as issued, went far beyond the HUD guidelines by assigning a different and lower protection factor to Type CE respirators than the HUD guidelines, which incorporated the general industry standard at 29 CFR § 1910.1025. Bullard maintained that its Model 77 and 88 respirators provide much greater protection, and sought to have the APF for these models elevated to 1,000 in the Lead in Construction Standard. OSHA agreed to provide Bullard with the relief sought only if it contracted with an acceptable third party to design, monitor, and interpret the results of a simulated workplace study of these models under an appropriate and acceptable test protocol. As a condition for granting that relief, the study had to demonstrate that the abrasive blasting respirators achieved, at a minimum, a protection factor rating of at least 20,000 and maintained positive pressure throughout the testing.

Bullard contracted with Lawrence Livermore National Laboratory (LLNL) which designed, conducted, and interpreted the results of the SWPF study, based on a protocol that was acceptable to OSHA. The LLNL informal report resulting from the testing indicated (based on computerized data backed up by strip chart recordings) that the two Bullard abrasive blast respirators achieved a minimum protection factor of 40,000 and maintained positive pressure throughout the testing.

Therefore, the SWPF study conducted by LLNL demonstrated that, if used properly, the Bullard respirators were acceptable for lead exposures that are less than or equal to 1,000 times the PEL (50,000 μg/m^3). In an August 30, 1995 memo to its Regional Administrators, OSHA recognized that the SWPF study results indicated that an APF greater than 25 was appropriate for the Bullard Model 77 and Model 88 respirators, and the Agency granted these models an interim APF of 1,000 when used for lead in construction (Ex. 3–8–4; memo to RAs dated 8/30/95). However, the memo also noted that the Agency was aware of other data and at least one field study showing that in the workplace these respirators may provide considerably less protection when used in ways that do not conform to the manufacturer's specifications (*e.g.*, the air supply hose is too long; the hose diameter is incorrect; the manufacturer's specified air pressure is not maintained) or that do not comply with the requirements of paragraphs (b), (d), (e) and (f) of 1910.134 (*e.g.*, the respirator is not inspected frequently enough for possible deterioration). The memo further stated that respirators will provide less protection than they are capable of, when used improperly (*e.g.*, donning and doffing the respirators while still in containment; disconnecting the air hose prior to leaving the exposure area). In addition, these respirators are used in extreme conditions during construction activities (*e.g.*, substantial and, sometimes rapid, deterioration caused by high-speed ''bounceback'' of the abrasive blasting material; very high levels of exposure). The impact of ''bounceback'' on the integrity of the respirator was not evaluated in the LLNL SWPF study since the study challenge agent was a liquid, not a particulate (which is typically the type of contaminant found in workplaces). Also, because these respirators may, at times, be used near the limits of their protective capability, workers wearing these respirators in abrasive blasting operations could receive acute exposures if the respirators do not perform properly. Therefore, performance consonant with the elevated APF can only be assured when the respirators are properly used.

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

Clemco Apollo Models 20 and 60 and 3M Whitecap II. With the assistance of the Industrial Safety Equipment Association (ISEA), other respirator manufacturers of Type-CE, continuous-flow, abrasive blasting respirators covered by the Lead in Construction Standard were contacted. By participating in a similar study, these manufacturers were provided with an equal opportunity to obtain the same relief afforded to Bullard. The Clemco Apollo Models 20 and 60 and the 3M Whitecap II were tested under conditions similar to the Bullard Model 77and 88 study. Based on the results of the studies, OSHA granted the respirators the interim APF of 1,000, and developed the same enforcement policy for Clemco (Ex. 3–7–4; memo to Regional Administrators dated 03/31/97) and 3M (Ex. 3–9–3; memo to Regional Administrators dated 12/08/98). Again, the interim APF was contingent on the final APF for these respirators being determined through this rulemaking.

9. SWPF Studies—N95 Air-Purifying Respirators

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

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

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

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

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

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

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

10. SWPF Studies—PAPRs and SARs

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

The experimental protocol used in the study was developed by the Organization Resources Counselors' respirator task force, LLNL investigators, participating respirator manufacturers, and representatives from NIOSH and OSHA. The study included a simulated workplace exercise protocol consisting of 12 exercises: normal breathing, twisting the head from side-to-side, moving the head up and down, touching toes, raising arms above the head, twisting at the waist, running in place, normal breathing, hand scooping of pebbles, normal breathing, building a concrete block wall, and normal breathing. Two exercises, hand scooping of pebbles and building a concrete block wall, were included to simulate tasks in the pharmaceutical industry. Seventeen subjects participated in the evaluation of five powered air-purifying respirators (PAPRs) and six supplied-air respirators (SARs). Twelve tests were conducted for each respirator, with the study being performed in the LLNL respirator test facility.

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

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

TABLE 4.—SUMMARY OF SIMULATED WORKPLACE PROTECTION FACTOR RESULTS

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

TABLE 4.—SUMMARY OF SIMULATED WORKPLACE PROTECTION FACTOR RESULTS—Continued

Device	Range of SWPFs	Median SWPF	5th percentile SWPF
SAR 6	160,000–>250,000	>250,000	>250,000

List of Respirators

Powered Air-Purifying Respirators With Hoods/Helmets

(PAPR1) 3M Whitecap helmet with chinstrap with GVP blower (hard plastic helmet with bib).
(PAPR 2) 3M Snapcap hood with chinstrap with GVP–100 blower (Tyvek hood with bib).
(PAPR 3) Racal BE–5 (clear PVC hood with bib).
(PAPR 4) Racal BE–10 (Polycoated Tyvek hood with bib and head suspension).

Loose-Fitting Powered Air-Purifying Respirator

(PAPR 5) Racal BE–12 (Polycoated Tyvek loose-fitting facepiece).

Supplied-Air Respirators

(SAR 1) 3M Whitecap helmet with chinstrap (hard plastic helmet with bib).
(SAR 2) 3M Snapcap hood with chinstrap (Tyvek hood with bib).
(SAR 3) MSA VERSA-Hood with #5–613–1 direct hose connection for 3/8'' hose system (Tyvek hood).
(SAR 4) North Model 85302 TB (Tyvek hood with ratchet head suspension and bib).
(SAR 5) North Model 85302 T (Tyvek hood with ratchet head suspension).
(SAR 6) Bullard CC2OTIC with 2ORT suspension and 2ONC chinstrap (Tyvek hood with bib).

Note: All PAPRs tested with high-efficiency filters.

The study report was finalized in 1999, and ORC requested that OSHA consider assigning an interim final APF of 1,000 to the study's high-performing respirator models, with provisions for an APF as high as 5,000 based on programmatic and environmental factors (Ex. 3–4–3, 1999 communication with OSHA). ORC also recommended that, because the current NIOSH respirator certification procedures are not capable of distinguishing between high-performing PAPRs and SARs (and that some respirators may not provide adequate protection), the study methodology should be the basis for determining APFs for all respiratory protective equipment regulated by OSHA.

In 2000, ORC renewed its requests. They pointed out that the study demonstrated that the PAPRs tested, including the loose-fitting facepiece PAPRs, were capable of achieving protection factors of 6,000 to 10,000 (rather than the APF of 25 assigned by NIOSH and adopted by OSHA), and that the tested SARs achieved protection factors of 3,000 to 10,000. However, one tested SAR model did not provide a protection factor of 25, demonstrating to the Agency the importance of testing specific equipment being considered for an increased APF to assure the expected protection.

ORC asserted that new APFs for the models tested in the study were warranted. They believed that the study results justified a re-evaluation of the methods for assessing the ability of PAPRs and SARs to provide protection against airborne particulates, and asked OSHA to issue a directive or similar document assigning an interim APF of 1,000 for the SARs and PAPRs that tested successfully in the study. ORC believed that SWPF testing of PAPRs and SARs was beneficial, and strongly supported use of a collaborative approach as was pursued in developing the study.

OSHA permitted use of an interim APF of 1,000 for 9 of the 11 respirators tested and developed an enforcement policy similar to that followed for the Bullard, Clemco, and 3M respirators (Ex. 3–4–4; 2002 memo to RAs). Again, the interim APFs are subject to a final APF determination resulting from this rulemaking. OSHA requests comments on all aspects of this study.

LLNL/OSHA PAPR Study. OSHA requested that LLNL conduct two additional PAPR studies using the protocol of the 1995–96 ORC study. The raw data from the two evaluations were then compared with the ORC SWPF study data.

A modified SWPF protocol was used to test two additional PAPRs, an MSA OptimAir and a Neoterik, selected by OSHA. The testing employed the same exercise protocol as the ORC study; however, only three test subjects participated in the evaluation. The three test subjects each performed four separate donnings of each respirator model. The 50th and 95th percentiles of the penetration and protection factors for the two respirators are shown in Table 5.

TABLE 5

Respirator model	Penetration		Protection factor	
	50th percentile	95th percentile	50th percentile	95th percentile
MSA OptimAir	1.67×10^{-6}(a)	4.08×10^{-5}	250,000(a)	24,510
Neoterik	2.74×10^{-5}	1.43×10^{-3}	36,563	698

For the Neoterik, SWPFs of 100 and somewhat less were observed for the running in place and the moving bricks (building a concrete block wall) exercises. The Neoterik demonstrated SWPFs near 1,000 and somewhat less for the twisting head side to side, moving the head up and down, and touching toes exercises. For the MSA OptimAir, SWPFs approaching 100 for the running in place exercise were observed, while all of the other exercises resulted in SWPFs of 10,000 or greater. Penetration levels by type of exercise were compared between the OSHA PAPR analyses and the ORC results. In general, the comparison indicated that the same exercises triggered increased penetration values. That is, sources of penetration were ''running-in-place'' (for both respirators) and ''moving bricks'' (for the Neoterik PAPR).

V. Health Effects

In a number of previous rulemakings, OSHA discussed the serious health effects caused by exposure to airborne chemical hazards (*see, e.g.*, Appendix A of the Hazard Communication Standard at 29 CFR 1910.1200, and the preambles to any of the Agency's substance-specific standards codified at 29 CFR 1910.1001 to 1910.1052). When OSHA promulgates a new or revised PEL for a chemical air contaminant, (*e.g.*, Arsenic, 29 CFR 1910.1018; Asbestos, 29 CFR 1910.1001; Benzene, 29 CFR 1910.1028; Lead, 29 CFR 1910.1025; Ethylene Oxide, 29 CFR 1910.1047), it determines at what level of exposure to the contaminant employees develop serious health effects (*e.g.*, exposure to the contaminant is life-threatening, causes permanent damage, or significantly impairs employees' ability to perform their jobs safely).

As discussed in Section VI, ''Summary of the Final Economic Analysis,'' of the final Respiratory Protection Standard (63 FR 1171), OSHA estimated that improvements and clarifications made to the previous Respiratory Protection Standard would prevent, each year, between 843 and 9,282 (best estimate, 4,046) work-related injuries and illnesses, and between 351 and 1,626 (best estimate, 932) work-related deaths from cancer and chronic diseases such as cardiovascular disease. To support this estimate, OSHA used its Integrated Management Information System database to identify several substances that had a wide range of adverse effects, as well as documented workplace exposures that exceeded the PELs for these substances. The health effects associated with exposure to these substances include:

- Sudden death or asphyxiation (*e.g.*, from exposure to carbon monoxide, carbon dioxide);
- Loss of lung function (*e.g.*, from exposure to wood dust, welding fumes, manganese fumes, copper fumes, cobalt metal fumes, silica);
- Central nervous system disturbances (*e.g.*, from exposure to carbon monoxide, trichloroethylene);
- Cancer (*e.g.*, from exposure to chromic acid, wood dust, silica); and
- Cardiovascular problems (*e.g.*, from exposure to carbon monoxide).

Furthermore, most of the airborne contaminants measured as part of the workplace protection factor studies considered during development of this proposal cause serious health effects. For example, acute lung, skin, and eye irritation occur as a result of occupational exposures to styrene, lead, strontium, benzo(a)pyrene, and silica. Longer-term exposures to other substances sampled in these studies cause bone and blood effects (lead particulates), neurological effects (mercury fumes), chronic lung damage (cotton dust), and cancer (asbestos fibers and chromium particulates).

The risk that an employee will experience an adverse health outcome while exposed to a hazardous airborne substance is a function of the toxicity or hazardous characteristics of the substance, the concentrations of the substance in the air, the duration of exposure, the physiology of the employee, and workplace conditions. These factors combined assist in determination of the type of respirator selected to reduce an employee's exposure below the PEL for the hazardous substance. Under many workplace-exposure conditions, prevention of serious health effects depends substantially on the protection afforded to employees by a respirator.

Employers need the APFs provided in this proposal to select appropriate respirators for employee use when engineering and work-practice controls are insufficient to maintain hazardous substances at safe levels in the workplace. In this regard, the proposed APFs will permit employers to select respirators for employee protection based on the type of hazardous substance and the level of employee exposure to that substance, among other factors. OSHA strongly believes that proper respirator selection using the proposed APFs will protect employees from overexposure to hazardous substances, thus preventing the serious health effects that result from such overexposure.

While APFs are an important factor in respirator selection, employers must consider other factors as well. In this regard, simply applying an APF to the level of an airborne contaminant in a workplace will not ensure that employees receive adequate protection. Throughout the preamble of the final Respiratory Protection Standard, OSHA demonstrated that adequate fit testing, proper respirator use, employee training, and thorough inspection and maintenance of respirators are some of the other factors essential to an effective respiratory protection program. The Agency believes that failure to comply with any of these program requirements substantially increases the chance that the respirator selected by the employer will not protect employees against hazardous air contaminants because of respirator malfunction, excessive leakage, improper use, or some combination of these problems. Therefore, employers should expect respirators to provide effective employee protection against the serious health effects of hazardous airborne substances only when they use the respirators in the context of a comprehensive respiratory protection program. If respirators are to provide employees with at least the minimum level of exposure protection listed in the proposed APF table, employers must comply with the other respiratory protection requirements specified under OSHA's Respiratory Protection Standard at 29 CFR 1910.134.

In this rulemaking, OSHA also is proposing to supersede the existing APF requirements in its substance-specific standards. By superceding these requirements, the Agency expects that the benefits estimated for the proposed APFs under the Respiratory Protection Standard would be available to employers who must select respirators for employee use under the substance-specific standards. In addition, OSHA would be harmonizing the APF requirements in the substance-specific standards with the APF requirements proposed for its Respiratory Protection Standard. The Agency believes that harmonization would reduce confusion among the regulated community and aid in uniform application of APFs, while maintaining employee protection at levels at least as protective as the existing APF requirements.

VI. Summary of the Preliminary Economic and Regulatory Flexibility Screening Analysis

A. Introduction

OSHA's Preliminary Economic and Regulatory Flexibility Screening Analysis (PERFSA) addresses issues related to the costs, benefits, technological and economic feasibility, and economic impacts (including small business impacts) of the Agency's proposed Assigned Protection Factors (APF) rule. The Agency preliminarily 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 PERFSA presents OSHA's full economic analysis and methodology. The Agency entered the complete PERFSA into the docket as Exhibit 6–1. The remainder of this section summarizes the results of that analysis.

The purpose of this PERFSA is to:

- Identify the establishments and industries potentially affected by the rule;
- Evaluate the costs employers would incur to meet the requirements of proposed 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 proposed 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 proposed 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 section 6(b)(5) substances). The proposed 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 recent NIOSH–BLS survey of respirator use and practices [1] (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.[2] As shown in Table VI–1, an estimated 291,085 establishments reported respirator use in industries covered by OSHA's proposed 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 nonpowered 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 VI–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 nonpowered 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).

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[1] 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.

[2] 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 VI-1

Estimated Number of Establishments With Respirator Users, by Type

			Nonpowered Air-Purifying				Supplied-Air	
SIC	Title	All Respirator Types	Filtering Facepiece	Half-mask	Full-face	PAPR	Total	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

Table VI-1

Estimated Number of Establishments With Respirator Users, by Type

SIC	Title	All Respirator Types	Nonpowered Air-Purifying: Filtering Facepiece	Nonpowered Air-Purifying: Half-mask	Nonpowered Air-Purifying: Full-face	PAPR	Supplied-Air: Total	Supplied-Air: SCBA
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 VI-2

Estimated Number of Respirator Users, by Type

SIC	Title	Nonpowered Air-Purifying: Filtering Facepiece	Nonpowered Air-Purifying: Half-mask	Nonpowered Air-Purifying: Full-face	PAPR	Supplied-Air: Total	Supplied-Air: 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	9,190	128,159	4,124	1,267	1,215	0
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
43	United States Postal Service	6,536 **	2,347 **	1,905 **	1,064 **	1,207 **	605 **
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

Table VI-2

Estimated Number of Respirator Users, by Type

		Nonpowered Air-Purifying				Supplied-Air	
SIC	Title	Filtering Facepiece	Half-mask	Full-face	PAPR	Total	SCBA
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
	State and local governments	53,692 ***	35,756 ***	15,683 **	7,173 **	10,742 **	4,491 **
	Totals	2,319,745	1,542,809	677,569	304,186	434,565	192,824

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.

The proposed 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 VI–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 section 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 VI–3).

Table VI-3A

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments with Respirators [a,b]	Arsenic		Asbestos		Cadmium		Lead		Cotton Dust [a]		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. "Respirator Use and Practice." Bureau of Labor Statistics Press Release, March 20, 2002.
[a] Estimates for supplied-air respirators provided by ERG consultant Jeffrey Stull of International Personal Protection, Inc.
[b] Establishment estimates as reported by NIOSH. These may differ from establishment estimates shown in Table VI-1 that have been benchmarked to the to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

Table VI-3B

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments with Respirators [a,b]	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.
[a] The 2001 NIOSH/BLS Survey of Respirator Use and Practices. "Respirator Use and Practice." Bureau of Labor Statistics Press Release, March 20, 2002.
[b] Establishment estimates as reported by NIOSH. These may differ from establishment estimates shown in Table VI-1 that have been benchmarked to the to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

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C. Compliance Costs

The proposal does not raise issues of technological feasibility because it requires only that employers use respirators already on the market. However, costs of the proposed APFs result from requiring some users to switch to more protective respirators than they currently use. When the proposed 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 would be safe to wear in atmospheres up to 50 times the PEL, consistent with similar requirements regarding respirator use found in existing standards for section 6(b)(5) chemicals.

For each respirator type, OSHA compared the proposed and current APF requirements, including existing APFs for section 6(b)(5) substances, and identified an incrementally more protective respirator model. To be adequate, the more protective respirator must have a proposed 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 proposed 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 proposed to lower the APF 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. 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.

The Agency estimated distributions of exposures above the PELs based on reports from its Integrated Management Information System describing workplace monitoring of section 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 1 and 5 times the PEL, 13.1 percent found exposures between 5 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. 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 nonpowered, 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.[3] 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.[4]

3. Aggregate Compliance Costs

For each respirator type affected by the proposed 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 VI–4 shows estimated compliance costs for OSHA's proposed APF rule of $4.6 million. The proposed rule would require 1,918 users of nonpowered 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

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

[4] 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.

$0.4 million. Industry-specific compliance costs vary according to the number of respirator users and the proportion of these users affected by the proposed rule. Industries with relatively large compliance costs include SIC 17, Special trade contractors ($0.8 million), and SIC 80, Health services ($0.8 million). Potentially offsetting these costs are a limited number of cases where employers would be allowed to shift to a less expensive respirator.

As discussed previously, however, the Agency believes the actual costs of the proposal 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, OSHA estimates over 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, however, 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.

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Table VI-4

Summary of Costs by Respirator Class

SIC	Industry	Nonpowered Air-Purifying Respirators: Users [a]	No. Upgrading	Cost	Powered Air-Purifying Respirators: Users [a]	No. Upgrading	Cost	Supplied-Air Respirators: Users [a,b]	No. Upgrading	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	141,472	12	$11,280	1,267	52	$5,395	1,215	27	$2,722	$19,397
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
43	United States Postal Service	10,789	6	$5,212	1,606	80	$9,677	1,443	25	$2,204	$17,093
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

Table VI-4

Summary of Costs by Respirator Class

SIC	Industry	Nonpowered Air-Purifying Respirators			Powered Air-Purifying Respirators			Supplied-Air Respirators			Total Cost
		Users [a]	No. Upgrading	Cost	Users [a]	No. Upgrading	Cost	Users [a,b]	No. Upgrading	Cost	
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
	State and local governments	105,131	60	$56,002	10,094	525	$53,472	7,568	133	10,662	$120,137
	Totals	4,540,123	1,918	$1,796,299	436,498	22,848	$2,345,407	325,898	5,110	$429,315	$4,571,022

Source: OSHA estimates based on preliminary results from the 2001 NIOSH/BLS Survey of Respirator Use and Practices, in press.

[a] Includes users who use more than one type of respirator. For this reason, some respirator users may be double counted, and the totals may exceed the number of users for the respirator class.

[b] Excludes employees exclusively using SCBAs.

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D. Benefits

The benefits that would accrue to respirator users and their employers take several forms. The proposed 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 proposed in this rulemaking help ensure these benefits are achieved, as well as provide an additional degree of protection. The proposed APFs would reduce employee exposures to several section 6(b)(5) chemicals covered by standards with outdated APF criteria, thereby reducing exposures to chemicals such as asbestos, lead, cotton dust, and arsenic.[5] While the Agency did not quantify these benefits, it estimates that 29,655 employees would have a higher degree of respiratory protection under the proposed 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 would result from the harmonization of APF specifications, thereby making compliance with the respirator rule easier for employers. Employers also would 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 the proposed 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.

The proposed 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 would fall in this group (*i.e.*, shift to a less expensive 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 F2d 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 proposed APFs, OSHA then assessed the proposal's economic feasibility for all affected establishments, *i.e.*, those covered by the proposal.

The Agency assumed that establishments falling within the scope of the proposal 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. Absent 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 the proposed APF standard on before-tax profits and sales shown in Table VI–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 proposed standard could lead to significant impacts on all affected establishments. The actual impact of the proposal 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.

[5] 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 proposed rulemaking directly addresses the APF provisions of the substance-specific standards; therefore, this proposal would affect directly the respirators used by employees covered by these standards.

Table VI–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.[6] 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.[7] Based on the data for establishments in all industries shown in Table VI–5, OSHA concludes that the APF proposal is economically feasible for the affected establishments.

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

[7] 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 proposal in some industries. See the full PEA (Ex. 6–1) for further details.

Table VI-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	0.00%	0.02%
08	Forestry	$2,533,391	2,689	$942.1	10.30%	$97,040	261	9.7%	$0.00	0.00%	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	0.00%	0.01%
15	General building contractors	$354,383,931	197,940	$1,790.4	4.00%	$71,614	19,071	9.6%	$2.79	0.00%	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	0.00%	0.01%
17	Special trade contractors	$351,559,520	433,522	$810.9	4.00%	$32,438	40,823	9.4%	$19.41	0.00%	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	0.00%	0.00%
21	Tobacco products	$36,626,849	185	$197,983.0	4.02%	$7,953,335	30	16.2%	$4.18	0.00%	0.00%
22	Textile mill products	$81,180,135	6,464	$12,558.8	2.77%	$347,644	720	11.1%	$25.63	0.00%	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	0.00%	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	0.00%	0.01%
25	Furniture and fixtures	$61,269,677	12,388	$4,945.9	3.51%	$173,603	2,053	16.6%	$4.84	0.00%	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	0.00%	0.01%
27	Printing and publishing	$209,740,895	63,986	$3,277.9	3.80%	$124,545	124	0.2%	$0.00	0.00%	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	0.00%	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	0.00%	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	0.00%	0.00%
31	Leather and leather products	$10,125,106	1,922	$5,268.0	2.20%	$115,725	14	0.7%	$119.63	0.00%	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	0.00%	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	0.00%	0.00%
34	Fabricated metal products	$231,787,815	39,399	$5,883.1	4.55%	$267,453	7,374	18.7%	$7.07	0.00%	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	0.00%	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	0.00%	0.00%
37	Transportation equipment	$522,250,748	13,210	$39,534.5	3.74%	$1,479,823	3,788	28.7%	$30.26	0.00%	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	0.00%	0.01%
39	Miscellaneous manufacturing industries	$52,171,899	18,711	$2,788.3	3.80%	$106,073	3,140	16.8%	$24.34	0.00%	0.02%
40	Railroad transportation	$36,900,000	4,802	$7,684.3	11.08%	$851,036	846	17.6%	$24.34	0.00%	0.00%
41	Local and interurban passenger transit	$18,741,822	20,067	$934.0	4.51%	$42,101	809	4.0%	$10.45	0.00%	0.02%
42	Trucking and warehousing	$197,132,918	135,874	$1,450.9	3.91%	$56,783	4,090	3.0%	$17.08	0.00%	0.03%
43	United States Postal Service	$56,600,000	33,613	$1,683.9	NA	NA	1,012	3.0%	$0.00	0.00%	NA
44	Water transportation	$34,059,390	9,392	$3,626.4	7.48%	$271,426	50	0.5%	$5,755.39	0.16%	2.12%
45	Transportation by air	$175,932,797	13,694	$12,847.4	3.62%	$465,132	48	0.4%	$427.74	0.00%	0.09%
46	Pipelines, except natural gas	$7,830,792	971	$8,064.7	6.55%	$528,055	252	25.9%	$1.47	0.00%	0.00%
47	Transportation services	$39,490,484	52,884	$746.7	3.39%	$25,322	8	0.0%	$0.00	0.00%	0.00%
48	Communications	$343,904,510	46,030	$7,471.3	5.58%	$416,833	100	0.2%	$0.00	0.00%	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	0.00%	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	0.00%	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	0.00%	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	0.00%	0.00%
53	General merchandise stores	$334,801,710	36,481	$9,177.4	2.70%	$248,028	687	1.9%	$4.27	0.00%	0.00%
54	Food stores	$424,619,077	179,120	$2,370.6	1.41%	$33,443	2,394	1.3%	$0.77	0.00%	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	0.00%	0.01%
56	Apparel and accessory stores	$117,838,184	126,658	$930.4	1.85%	$17,181	308	0.2%	$28.16	0.00%	0.16%

Table VI-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
57	Furniture and homefurnishings stores	$138,532,297	117,939	$1,174.6	2.28%	$26,812	2,769	2.3%	$2.62	0.00%	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	0.00%	0.00%
60	Depository institutions	$626,235,388	115,268	$5,432.9	10.80%	$586,749	1,372	1.2%	$0.00	0.00%	0.00%
61	Nondepository institutions	$208,902,233	53,365	$3,914.6	15.05%	$589,102	299	0.6%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$267,894,402	50,032	$5,354.5	13.32%	$712,970	278	0.6%	$0.00	0.00%	0.00%
63	Insurance carriers	$977,328,464	41,776	$23,394.5	6.82%	$1,596,288	442	1.1%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$76,085,799	132,265	$575.3	6.83%	$39,261	744	0.6%	$0.00	0.00%	0.00%
65	Real estate	$191,986,451	257,248	$746.3	13.31%	$99,329	1,541	0.6%	$0.00	0.00%	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	0.00%	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	0.00%	0.02%
72	Personal services	$53,965,771	208,546	$258.8	5.86%	$15,151	9,743	4.7%	$1.90	0.00%	0.01%
73	Business services	$538,701,000	410,246	$1,313.1	4.79%	$62,857	13,517	3.3%	$2.80	0.00%	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	0.00%	0.03%
76	Miscellaneous repair services	$39,030,526	68,439	$570.3	5.44%	$31,000	3,375	4.9%	$10.45	0.00%	0.03%
78	Motion pictures	$72,351,766	46,844	$1,544.5	5.14%	$79,355	17	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$94,816,288	99,642	$951.6	4.28%	$40,728	1,612	1.6%	$3.47	0.00%	0.01%
80	Health services	$824,840,187	505,878	$1,630.5	6.17%	$100,610	16,486	3.3%	$50.94	0.00%	0.05%
81	Legal services	$124,335,948	170,271	$730.2	17.50%	$127,789	61	0.0%	$22.44	0.00%	0.02%
82	Educational services	$136,669,596	50,146	$2,725.4	8.14%	$221,895	564	1.1%	$22.44	0.00%	0.01%
83	Social services	$95,229,314	165,519	$575.3	4.44%	$25,535	6,668	4.0%	$0.42	0.00%	0.00%
84	Museums, botanical, zoological gardens	$6,636,189	5,466	$1,214.1	21.45%	$260,421	235	4.3%	$0.00	0.00%	0.00%
86	Membership organizations	$111,881,925	249,022	$449.3	7.21%	$32,400	533	0.2%	$0.00	0.00%	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	0.00%	0.01%
89	Services, n.e.c.	$20,335,429	17,650	$1,152.1	6.80%	$78,346	6	0.0%	$0.00	0.00%	0.00%
	State and local governments	$763,300,000	167,788	$4,549.2	NA	NA	6,893	4.1%	$17.43	0.00%	NA
	Totals	$19,043,065,527	7,060,972	$2,696.9	4.87%	$131,423	291,085	4.1%	$15.70	0.00%	0.01%

Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

F. Economic Impacts to Small Entities

OSHA also estimated the economic impacts of the proposed rule on affected entities with fewer than 20 employees, and for affected small entities as defined by the Small Business Administration (SBA). Table VI–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 VI–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 proposed rule on small entities.

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 proposed regulation would not have a significant impact on a substantial number of small entities.

Table VI-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	104,822	$271.5	6.02%	$16,339	6,514	6.2%	$0.09	0.00%	0.00%
08	Forestry	$1,005,916	2,225	$452.1	10.30%	$46,566	212	9.5%	$0.00	0.00%	0.00%
09	Fishing, hunting, and trapping	$934,691	2,327	$401.7	5.80%	$23,313	0	0.0%	NA	NA	NA
13	Oil and gas extraction	$9,568,821	13,330	$717.8	8.65%	$62,093	622	4.7%	$0.94	0.00%	0.00%
15	General building contractors	$140,742,413	185,770	$757.6	4.00%	$30,305	17,656	9.5%	$1.06	0.00%	0.00%
16	Heavy construction, except building	$25,680,517	29,075	$883.3	4.00%	$35,330	2,526	8.7%	$0.20	0.00%	0.00%
17	Special trade contractors	$156,222,049	395,090	$395.4	4.00%	$15,816	35,004	8.9%	$4.09	0.00%	0.03%
20	Food and kindred products	$13,034,058	10,852	$1,201.1	3.46%	$41,599	504	4.6%	$8.59	0.00%	0.02%
21	Tobacco products	$36,982	58	$637.6	4.02%	$25,614	6	10.6%	$0.00	0.00%	0.00%
22	Textile mill products	$2,804,537	3,026	$926.8	2.77%	$25,655	96	3.2%	$0.00	0.00%	0.00%
23	Apparel and other textile products	$7,444,651	16,162	$460.6	2.56%	$11,784	258	1.6%	$0.00	0.00%	0.00%
24	Lumber and wood products	$15,544,934	29,353	$529.6	3.90%	$20,648	430	1.5%	$2.22	0.00%	0.01%
25	Furniture and fixtures	$4,131,575	8,093	$510.5	3.51%	$17,919	401	5.0%	$2.45	0.00%	0.01%
26	Paper and allied products	$2,406,977	1,922	$1,252.3	4.50%	$56,366	43	2.2%	$0.00	0.00%	0.00%
27	Printing and publishing	$22,196,893	47,557	$466.7	3.80%	$17,734	26	0.1%	$0.00	0.00%	0.00%
28	Chemicals and allied products	$8,762,403	5,616	$1,560.3	4.49%	$69,995	1,610	28.7%	$6.89	0.00%	0.01%
29	Petroleum and coal products	$2,213,850	650	$3,405.9	2.99%	$101,816	92	14.2%	$10.74	0.00%	0.01%
30	Rubber and misc. plastics products	$7,183,667	7,483	$960.0	4.02%	$38,638	382	5.1%	$6.79	0.00%	0.02%
31	Leather and leather products	$570,806	1,223	$466.7	2.20%	$10,253	2	0.2%	$0.00	0.00%	0.00%
32	Stone, clay, and glass products	$6,351,359	8,423	$754.0	4.93%	$37,150	538	6.4%	$0.00	0.00%	0.00%
33	Primary metal industries	$2,848,236	2,530	$1,125.8	4.52%	$50,860	273	10.8%	$0.00	0.00%	0.00%
34	Fabricated metal products	$17,077,020	22,251	$767.5	4.55%	$34,890	3,378	15.2%	$0.95	0.00%	0.00%
35	Industrial machinery and equipment	$24,064,335	39,977	$602.0	4.05%	$24,354	4,188	10.5%	$1.41	0.00%	0.01%
36	Electronic and other electric equipment	$8,356,375	9,070	$921.3	5.59%	$51,514	1,134	12.5%	$1.52	0.00%	0.00%
37	Transportation equipment	$5,835,684	7,727	$755.2	3.74%	$28,269	2,022	26.2%	$3.55	0.00%	0.01%
38	Instruments and related products	$5,684,460	7,207	$788.7	5.06%	$39,918	616	8.6%	$3.63	0.00%	0.01%
39	Miscellaneous manufacturing industries	$6,908,160	14,575	$474.0	3.80%	$18,031	1,973	13.5%	$2.80	0.00%	0.02%
40	Railroad transportation	NA	NA	NA	NA	NA	NA	NA	ERR	NA	NA
41	Local and interurban passenger transit	$3,052,031	13,557	$225.1	4.51%	$10,148	576	4.2%	$0.49	0.00%	0.00%
42	Trucking and warehousing	$42,301,497	104,401	$405.2	3.91%	$15,858	3,298	3.2%	$1.72	0.00%	0.01%
44	Water transportation	$4,501,041	7,061	$637.5	7.48%	$47,711	40	0.6%	$4.00	0.00%	0.01%
45	Transportation by air	$3,397,447	5,352	$634.8	3.62%	$22,982	21	0.4%	$0.00	0.00%	0.00%
46	Pipelines, except natural gas	$64,316	21	$3,062.7	6.55%	$200,536	4	17.2%	$16.05	0.00%	0.01%
47	Transportation services	$12,815,924	38,195	$335.5	3.39%	$11,378	6	0.0%	$0.00	0.00%	0.00%
48	Communications	$9,283,329	14,256	$651.2	5.58%	$36,330	26	0.2%	$0.00	0.00%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	8,938	$1,211.0	10.37%	$125,641	1,335	14.9%	$3.53	0.00%	0.00%
50	Wholesale trade--durable goods	$467,174,837	228,351	$2,045.9	2.54%	$52,056	8,636	3.8%	$0.94	0.00%	0.00%
51	Wholesale trade--nondurable goods	$321,562,895	126,151	$2,549.0	4.46%	$113,768	3,944	3.1%	$2.56	0.00%	0.00%
52	Building materials and garden supplies	$37,776,200	46,450	$813.3	2.37%	$19,289	1,511	3.3%	$0.00	0.00%	0.00%
53	General merchandise stores	$3,346,901	8,796	$380.5	2.70%	$10,283	50	0.6%	$0.00	0.00%	0.00%
54	Food stores	$57,468,235	111,162	$517.0	1.41%	$7,293	439	0.4%	$0.00	0.00%	0.00%
55	Automotive dealers and service stations	$149,337,410	116,015	$1,287.2	1.45%	$18,609	5,083	4.4%	$0.84	0.00%	0.00%
56	Apparel and accessory stores	$18,706,435	50,308	$371.8	1.85%	$6,867	36	0.1%	$0.00	0.00%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	78,842	$575.7	2.28%	$13,142	1,660	2.1%	$0.00	0.00%	0.00%

Table VI-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
58	Eating and drinking places	$61,841,796	293,318	$210.8	3.00%	$6,322	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$119,265,615	258,538	$461.3	2.49%	$11,479	448	0.2%	$0.00	0.00%	0.00%
60	Depository institutions	$15,538,559	14,378	$1,080.7	10.80%	$116,718	163	1.1%	$0.00	0.00%	0.00%
61	Nondepository institutions	$13,454,697	21,262	$632.8	15.05%	$95,230	103	0.5%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$19,644,662	27,262	$720.6	13.32%	$95,949	140	0.5%	$0.00	0.00%	0.00%
63	Insurance carriers	$9,416,333	5,668	$1,661.3	6.82%	$113,357	63	1.1%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$33,660,359	116,075	$290.0	6.83%	$19,792	543	0.5%	$0.00	0.00%	0.00%
65	Real estate	$108,609,341	221,549	$490.2	13.31%	$65,246	1,047	0.5%	$0.00	0.00%	0.00%
67	Holding and other investment offices	$35,174,755	21,022	$1,673.2	24.01%	$401,733	102	0.5%	$0.00	0.00%	0.00%
70	Hotels and other lodging places	$12,241,793	40,186	$304.6	6.96%	$21,204	783	1.9%	$0.76	0.00%	0.00%
72	Personal services	$27,470,741	168,826	$162.7	5.86%	$9,527	7,156	4.2%	$0.23	0.00%	0.00%
73	Business services	$108,448,938	307,737	$352.4	4.79%	$16,869	7,651	2.5%	$0.74	0.00%	0.00%
75	Auto repair, services, and parking	$52,027,411	160,544	$324.1	4.39%	$14,236	22,900	14.3%	$1.01	0.00%	0.01%
76	Miscellaneous repair services	$18,035,716	60,601	$297.6	5.44%	$16,178	2,626	4.3%	$7.32	0.00%	0.05%
78	Motion pictures	$13,026,870	29,959	$434.8	5.14%	$22,341	8	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$26,704,545	79,317	$336.7	4.28%	$14,410	1,159	1.5%	$0.00	0.00%	0.00%
80	Health services	$167,087,490	385,533	$433.4	6.17%	$26,742	11,346	2.9%	$0.22	0.00%	0.00%
81	Legal services	$54,265,197	156,877	$345.9	17.50%	$60,534	41	0.0%	$0.00	0.00%	0.00%
82	Educational services	$8,902,333	30,770	$289.3	8.14%	$23,555	367	1.2%	$0.00	0.00%	0.00%
83	Social services	$22,228,579	99,911	$222.5	4.44%	$9,874	3,696	3.7%	$0.13	0.00%	0.00%
84	Museums, botanical, zoological gardens	$1,283,445	4,300	$298.5	21.45%	$64,023	164	3.8%	$0.00	0.00%	0.00%
86	Membership organizations	$43,669,772	222,292	$196.5	7.21%	$14,167	396	0.2%	$0.00	0.00%	0.00%
87	Engineering and management services	$90,405,763	254,295	$355.5	6.39%	$22,720	6,189	2.4%	$0.18	0.00%	0.00%
89	Services, n.e.c.	$5,728,501	15,743	$363.9	6.80%	$24,744	3	0.0%	$0.00	0.00%	0.00%
	Totals	$2,781,206,926	4,930,213	$564.1	5.00%	$28,183	174,264	3.5%	$1.71	0.00%	0.01%

Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

Table VI-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%	$0.14	0.00%	0.00%
08	Forestry	$1,496,747	2,400	$623.6	10.30%	$64,235	233	9.7%	$0.00	0.00%	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%	$22.40	0.00%	0.01%
15	General building contractors	$234,203,450	195,315	$1,199.1	4.00%	$47,964	17,540	9.0%	$1.12	0.00%	0.00%
16	Heavy construction, except building	$68,664,092	35,618	$1,927.8	4.00%	$77,112	3,314	9.3%	$3.53	0.00%	0.00%
17	Special trade contractors	$270,401,924	426,477	$634.0	4.00%	$25,361	34,756	8.1%	$15.67	0.00%	0.06%
20	Food and kindred products	$104,629,113	15,992	$6,542.6	3.46%	$226,600	1,781	11.1%	$10.88	0.00%	0.00%
21	Tobacco products	$1,255,255	91	$13,794.0	4.02%	$554,130	10	11.1%	$0.00	0.00%	0.00%
22	Textile mill products	$20,377,246	4,845	$4,205.8	2.77%	$116,423	458	9.4%	$3.49	0.00%	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	0.00%	0.00%
24	Lumber and wood products	$58,343,756	35,076	$1,663.4	3.90%	$64,854	1,278	3.6%	$2.23	0.00%	0.00%
25	Furniture and fixtures	$26,295,821	11,217	$2,344.3	3.51%	$82,285	1,540	13.7%	$2.05	0.00%	0.00%
26	Paper and allied products	$31,334,277	4,057	$7,723.5	4.50%	$347,629	249	6.1%	$12.01	0.00%	0.00%
27	Printing and publishing	$85,620,541	57,018	$1,501.6	3.80%	$57,055	91	0.2%	$0.00	0.00%	0.00%
28	Chemicals and allied products	$59,010,014	8,227	$7,172.7	4.49%	$321,776	1,955	23.8%	$84.99	0.00%	0.03%
29	Petroleum and coal products	$13,950,653	1,047	$13,324.4	2.99%	$398,317	118	11.3%	$120.02	0.00%	0.03%
30	Rubber and misc. plastics products	$58,709,872	13,043	$4,501.3	4.02%	$181,167	1,627	12.5%	$6.74	0.00%	0.00%
31	Leather and leather products	$4,003,751	1,675	$2,390.3	2.20%	$52,509	184	11.0%	$4.92	0.00%	0.01%
32	Stone, clay, and glass products	$34,254,470	11,791	$2,905.1	4.93%	$143,127	1,393	11.8%	$20.47	0.00%	0.01%
33	Primary metal industries	$36,511,582	4,806	$7,597.1	4.52%	$343,213	1,023	21.3%	$26.50	0.00%	0.01%
34	Fabricated metal products	$113,752,781	34,250	$3,321.2	4.55%	$150,988	4,015	11.7%	$3.72	0.00%	0.00%
35	Industrial machinery and equipment	$127,178,710	52,548	$2,420.2	4.05%	$97,917	4,176	7.9%	$3.78	0.00%	0.00%
36	Electronic and other electric equipment	$69,499,940	14,355	$4,841.5	5.59%	$270,705	1,292	9.0%	$7.11	0.00%	0.00%
37	Transportation equipment	$41,544,504	10,653	$3,899.8	3.74%	$145,974	1,984	18.6%	$12.89	0.00%	0.01%
38	Instruments and related products	$33,908,725	10,190	$3,327.6	5.06%	$168,410	787	7.7%	$10.59	0.00%	0.01%
39	Miscellaneous manufacturing industries	$30,627,905	17,837	$1,717.1	3.80%	$65,322	2,267	12.7%	$13.48	0.00%	0.02%
40	Railroad transportation	$2,897,433	541	$5,355.7	12.89%	$690,234	95	17.6%	$71.75	0.00%	0.01%
41	Local and interurban passenger transit	$7,690,615	16,537	$465.1	4.51%	$20,964	540	3.3%	$1.62	0.00%	0.01%
42	Trucking and warehousing	$79,888,400	114,623	$697.0	3.91%	$27,278	3,166	2.8%	$3.08	0.00%	0.01%
44	Water transportation	$14,075,608	8,051	$1,748.3	7.48%	$130,855	46	0.6%	$4.33	0.00%	0.00%
45	Transportation by air	$15,156,218	6,386	$2,373.4	3.62%	$85,925	22	0.3%	$0.00	0.00%	0.00%
46	Pipelines, except natural gas	$986,979	39	$25,307.2	6.55%	$1,657,050	5	13.9%	$10.64	0.00%	0.00%
47	Transportation services	$19,513,397	40,529	$481.5	3.39%	$16,327	6	0.0%	$0.00	0.00%	0.00%
48	Communications	$41,125,079	17,482	$2,352.4	5.58%	$131,244	28	0.2%	$0.00	0.00%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	8,938	$1,211.0	10.37%	$125,641	1,323	14.8%	$3.03	0.00%	0.00%
50	Wholesale trade--durable goods	$837,107,306	258,492	$3,238.4	2.54%	$82,401	9,740	3.8%	$9.88	0.00%	0.01%
51	Wholesale trade--nondurable goods	$637,454,650	143,751	$4,434.4	4.46%	$197,917	4,455	3.1%	$53.66	0.00%	0.03%
52	Building materials and garden supplies	$37,776,200	46,450	$813.3	2.37%	$19,289	1,368	2.9%	$0.00	0.00%	0.00%
53	General merchandise stores	$3,346,901	8,796	$380.5	2.70%	$10,283	85	1.0%	$0.00	0.00%	0.00%
54	Food stores	$101,566,550	123,572	$821.9	1.41%	$11,595	852	0.7%	$0.00	0.00%	0.00%
55	Automotive dealers and service stations	$149,337,410	116,015	$1,287.2	1.45%	$18,609	5,043	4.3%	$0.93	0.00%	0.00%
56	Apparel and accessory stores	$18,706,435	50,308	$371.8	1.85%	$6,867	63	0.1%	$0.00	0.00%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	78,842	$575.7	2.28%	$13,142	1,494	1.9%	$0.00	0.00%	0.00%

Table VI-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
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	0.00%	0.00%
60	Depository institutions	$15,538,559	14,378	$1,080.7	10.80%	$116,718	186	1.3%	$0.00	0.00%	0.00%
61	Nondepository institutions	$13,454,697	21,262	$632.8	15.05%	$95,230	117	0.6%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$19,644,662	27,262	$720.6	13.32%	$95,949	157	0.6%	$0.00	0.00%	0.00%
63	Insurance carriers	$5,850,805	4,967	$1,177.9	6.82%	$80,375	73	1.5%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$47,083,678	119,907	$392.7	6.83%	$26,800	616	0.5%	$0.00	0.00%	0.00%
65	Real estate	$142,479,284	230,304	$618.7	13.31%	$82,340	1,139	0.5%	$0.00	0.00%	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	0.00%	0.00%
70	Hotels and other lodging places	$24,876,889	47,698	$521.5	6.96%	$36,302	1,070	2.2%	$1.00	0.00%	0.00%
72	Personal services	$36,957,629	176,477	$209.4	5.86%	$12,262	7,222	4.1%	$0.35	0.00%	0.00%
73	Business services	$188,061,601	337,126	$557.8	4.79%	$26,703	9,637	2.9%	$0.98	0.00%	0.00%
75	Auto repair, services, and parking	$66,003,052	167,057	$395.1	4.39%	$17,356	22,771	13.6%	$1.16	0.00%	0.01%
76	Miscellaneous repair services	$25,861,556	63,328	$408.4	5.44%	$22,198	2,756	4.4%	$7.17	0.00%	0.03%
78	Motion pictures	$13,026,870	29,959	$434.8	5.14%	$22,341	9	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$47,922,810	90,742	$528.1	4.28%	$22,604	1,231	1.4%	$0.00	0.00%	0.00%
80	Health services	$243,370,668	413,561	$588.5	6.17%	$36,312	11,837	2.9%	$0.21	0.00%	0.00%
81	Legal services	$54,265,197	156,877	$345.9	17.50%	$60,534	47	0.0%	$0.00	0.00%	0.00%
82	Educational services	$25,677,552	40,592	$632.6	8.14%	$51,502	398	1.0%	$0.00	0.00%	0.00%
83	Social services	$50,553,841	117,544	$430.1	4.44%	$19,088	3,960	3.4%	$0.22	0.00%	0.00%
84	Museums, botanical, zoological gardens	$2,928,264	4,912	$596.1	21.45%	$127,873	186	3.8%	$0.00	0.00%	0.00%
86	Membership organizations	$78,452,141	242,081	$324.1	7.21%	$23,371	429	0.2%	$0.00	0.00%	0.00%
87	Engineering and management services	$151,671,072	271,169	$559.3	6.39%	$35,745	8,091	3.0%	$3.20	0.00%	0.01%
89	Services, n.e.c.	$8,169,059	16,395	$498.3	6.80%	$33,882	4	0.0%	$0.00	0.00%	0.00%
	State and local governments	$101,000,000	17,289	$5,841.9	NA	NA	509	2.9%	$24.07	0.00%	NA
	Totals	$5,200,213,260	5,383,168	$966.0	4.68%	$45,203	191,389	3.6%	$7.53	0.00%	0.02%

* "Small entity" as defined by the Small Business Administration (Ex. 6-6).
Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

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VII. Summary and Explanation of the Proposed Standard

This section of the preamble provides a summary and explanation of each proposed revision to OSHA's Respiratory Protection Standard involving assigned protection factors.

A. Revisions to the Respiratory Protection Standard

This section addresses the revisions proposed for paragraphs (b), (d)(3)(i)(A), (d)(3)(i)(B), and (n) of OSHA's exiting Respiratory Protection Standard at 29 CFR 1910.134).

Paragraph (b)—Definitions

Revisions to this paragraph would add two important definitions''—assigned protection factor'' and ''maximum use concentration''—to OSHA's Respiratory Protection Standard. The following sections explain these proposed definitions in detail.

1. Assigned Protection Factor

As part of its 1994 proposed rulemaking for the Respiratory Protection Standard, OSHA proposed a definition for assigned protection factors (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 Respirator Decision Logic (RDL) (59 FR 58901–58903). However, NIOSH subsequently decided not to publish a list of APFs as part of its 42 CFR part 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, Dr. 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 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 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). The American National Standards Institute (ANSI) developed a definition for 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 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 dropped 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 workplace protection factor (WPF) studies. In this regard, five percent represents the fifth percentile of the geometric distribution of protection factors for individual participants in a WPF study. Each participant's protection factor is the concentration of challenge agent outside the respirator (C_o) divided by the concentration of that agent inside the participant's respirator (C_i), or C_o/C_i); therefore, the fifth percentile is the threshold for specifying the APF for the respirator tested under those workplace conditions. Using the fifth 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). Most WPF studies adopt the fifth-percentile threshold as the conventional standard, recognizing that about five percent of respirator users will not attain the APF determined for the respirator or class of respirators even when they receive proper fit testing and use the respirator correctly as part of 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.

The Agency's review of the available data on respirator performance, as well as findings from the personal protective equipment surveys (Exs. 6–1, 6–2), indicate that the existing definitions of APF are confusing to the respirator-using public. Accordingly, OSHA believes that the proposed definition would 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 Agency revised the terms in the ANSI APF definition to improve clarity. OSHA's proposed 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 29 CFR 1910.134.

The revisions made to the ANSI APF definition in developing this proposed APF definition include 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 requirement that employers must select a respirator in the context of a comprehensive respiratory protection program. Accordingly, the APFs in Table I of this proposal do not apply when any of the program elements required by OSHA's Respiratory Protection Standard are absent from an employer's respirator program, including fit testing, maintenance, selection, use, training, and other specified elements. This wording is necessary because the level of employee protection afforded by the proposed APFs depends on the other elements of a comprehensive respiratory protection program being in place continuously, and operating effectively. Employers and employees cannot expect to achieve an APF reliably unless employers ensure that their employees use respirators in accordance with a continuing, effective respiratory protection program.

The proposed APF definition is an important addition to the Respiratory Protection Standard because it informs employers how the APF constrains respirator use. The APF can only be achieved by a respirator or class of respirators that are functioning properly in accordance with paragraphs (b) and (j) of the Respiratory Protection Standard. This means that the respirator must be capable of performing its function of reducing employee exposures to airborne contaminants by being in correct working order. Accordingly, employers must maintain the respirator properly, with no defects such as cracked or distorted facepiece seals, missing exhalation valves, broken straps, or any other defect that would cause leakage into the respirator or prevent proper operation. For air-purifying respirators, the filters must be appropriate for the airborne contaminant, and provide an adequate service life.

Employers must properly fit and train employees for respirator use, which addresses the requirements in paragraphs (f) and (k) of the Respiratory Protection Standard. Therefore, employers must fit employees with the size and model of respirator they will be using in the workplace. They must then wear that same size and model of respirator in the workplace, and follow the training they receive for performing respirator seal checks, inspections for correct respirator operation, and proper donning and wearing the respirator.

2. Maximum Use Concentration

Employers use MUCs to select appropriate respirators, especially for use against organic vapors and gases since the MUC specifies 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. MUCs are a function of the assigned protection factor (APF) determined for a respirator (or class of respirators) and the exposure limit of the hazardous substance.

Ed Hyatt in the 1976 LASL report on Respiratory Protection Factors (Ex. 2) recounted the early history of maximum use concentration (MUC), starting with the MUC recommendations of the joint American Industrial Hygiene Association and American Conference of Governmental Industrial Hygienists committee in 1961. This committee recommended that, for highly toxic compounds, full facepiece respirators with high-efficiency filters should use a maximum limit of 100 x the threshold limit value (TLV). In 1961, in the United Kingdom, Hyatt noted that Letts recommended that half-mask dust respirators provided effective protection against airborne contaminants no greater than 10 x the TLV.

In 1974, NIOSH and OSHA started the Standards Completion Program to develop standards for substances with existing permissible exposure limits (PELs). This process resulted in the development of NIOSH Criteria Documents, each of which provided technical information and recommendations for specific airborne contaminants. These documents also recommended MUCs for different types of respirators; NIOSH obtained the information for these MUCs 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 for 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.

Several commenters to the 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 MUC requirements in paragraph (d)(3)(i)(B) for future rulemaking.

Employers use MUCs to select appropriate respirators, especially for use against organic vapors and gases. In this regard, the MUC specifies the maximum concentration of a toxic vapor or gas at which a respirator will provide protection to an employee who uses the respirator. Accordingly, in this proposed rulemaking, OSHA defines 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.

Under this proposed 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 assigned protection factor (APF) determined for a respirator (or class of respirators) and the exposure limit of the hazardous substance.

The last sentence in the proposed definition describes this function 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.[8] The term ''usually'' in this sentence is consistent with paragraph (d)(3)(i)(B)(*2*), which is part of the proposed MUC requirements (see section below titled ''Regulatory Text for Maximum Use Concentrations.'') This proposed paragraph reads, ''Employers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.'' Therefore, while employers would use the proposed calculation to determine most MUCs, they would have to use MUCs determined by respirator manufacturers when these MUCs are lower than the MUCs determined using the proposed calculation. As noted below in the explanation of proposed paragraph (d)(3)(i)(B)(*2*), OSHA believes that this requirement would provide employees with a necessary added measure of protection from hazardous substances in the workplace.

Importantly, the last part of the proposed definition specifies exposure limits as ''permissible exposure limit (PEL), short-term exposure limit (STEL),

[8] For example, when the hazardous substance is nitrobenzene (with a PEL of 1 ppm), and the respirator used by employees has an APF of 10, then the calculated MUC is 10 ppm (*i.e.*, 1ppm x 10).

ceiling limit (CL), peak limit, or any other exposure limit used for the hazardous substance.'' The exposure limits are consistent with the terms used in the Z tables in 29 CFR 1910.1000 and the substance-specific standards in 29 CFR parts 1910, 1915, and 1926.

The phrase ''any other exposure limit used for the hazardous substance'' refers to exposure limits other than the exposure limits specified in the OSHA Z tables or in its substance-specific standards; employers use the other exposure limits to provide additional protection to employees or to comply with OSHA's general-duty clause (Section 5(a)(1) of the OSH Act; 29 U.S.C. 654 where OSHA has no standard). Employers may adopt such exposure limits from existing consensus standards (*e.g.*, the ACGIH TLVs), or develop them specifically for the unique hazardous substances found in their workplaces.

Paragraph (d)(3)(i)(A)—APF Provisions

1. Introduction

As early as 1976, respirator scientists were classifying respirators into distinct groups based on the level of protection they provided. These early respirator classes are similar to the classes now in use, as well as the classes developed by OSHA for this proposal. In the following parts of this section, the Agency describes the historical development of APFs for specific classes of respirators, and then explains OSHA's proposed APF for each of these respirator classes.

In addition to basing the APFs proposed in this rulemaking on the studies and previous APF standards described in this section, the Agency contracted with Dr. Kenneth Brown to conduct statistical analyses of the original data reported in most of the WPF studies reported below. Dr. Brown's quantitative analyses justify combining data for filtering facepiece and elastomeric half-mask respirators in determining an APF for these two respirator classes, and using a qualitative analysis of the data for identifying APFs separately for powered air-purifying respirators, supplied-air respirators, and self-contained breathing apparatuses. (Note that insufficient WPF data were available for Brown to include full facepiece air-purifying respirators in his analyses.) OSHA discusses the procedures and results of these statistical analyses in section IV of this preamble. The Agency believes that the APFs developed through the procedures discussed below are consistent with the results of the analyses performed by Dr. Brown.

2. Half-Mask Air-Purifying Respirators

Historical development of APFs for half-mask air-purifying respirators. In 1976, Ed Hyatt of LANL tested eight commercially available Bureau of Mines (the Federal agency then designated to approve respirators) half-mask respirators (Ex. 2). Based on quantitative fit testing results obtained from a respirator test panel,[9] Hyatt assigned six of these respirators an APF of 10; the remaining two respirators performed less effectively than the other six, thereby achieving an APF of less than 10. Hyatt did not use data from the two poor performing respirators to set the APF of 10 for the class because, as he stated in his report, ''For practical purposes, the remaining two models are not available.''

In 1980, the ANSI Z88.2 Respiratory Protection Standard (*i.e.*, ''the 1980 ANSI standard;'' Ex. 10, Docket H049) required fit testing to identify grossly misfitting half-mask respirators. That standard assigned an APF of 10 to half-mask air-purifying respirators when employers performed qualitative fit testing, and an APF as high as 100 when they performed quantitative fit testing (Ex. 10, Table 5, p. 21, Docket H049). ANSI based the latter APF on the results of studies that quantitatively fit tested a panel of respirator users, much as Hyatt did in 1976 (Ex. 2).

NIOSH developed its RDL in 1987 (Ex. 1–54–437Q), which assigned an APF of 5 to single-use and quarter mask air-purifying respirators, and an APF of 10 to half-mask respirators, including disposable half-mask respirators. In developing these APFs, NIOSH used results from quantitative fit-test studies performed on its own respirator test panel, several LANL quantitative fit-test studies (including Hyatt's 1976 study), and several WPF studies that it conducted in the early 1980s (Exs. 1–64–42, 1–64–47).

The 1992 Z88.2 ANSI Respiratory Protection Standard (*i.e.*, ''the 1992 ANSI standard''; Ex. 1–50) retained an APF of 10 for half-mask air-purifying respirators, including quarter masks, disposable half-masks, and half-masks with elastomeric facepieces. In determining these APFs, a committee of respirator experts convened by ANSI reviewed and discussed available APF studies, and then arrived at a final decision using a consensus process.

The following table summarizes the previous APFs assigned to half-mask air-purifying respirators, beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

Half-mask air-purifying respirators	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Single use (no longer available)[1]	5		5	
Filtering facepiece			10 (disposable)	10
Half-mask (elastomeric)	10	10 (with QLFT) 100 max. (with QNFT).	10	10

[1] Filtering facepieces replaced single-use respirators.

OSHA's proposed APFs for half-mask air-purifying respirators. Respirator manufacturers construct elastomeric half-masks using malleable compounds (*e.g.*, silicon, natural or synthetic rubber) that readily conform to the respirator user's face, thereby effectively sealing the inside of the mask against penetration by airborne hazardous substances. Filtering facepieces also are available in a variety of designs and materials that affect their fit to a user's face. For example, the design of the ''fold flat'' filtering facepiece allows employees to fold them for easy carrying and storage; when employees need this respirator for protection, they unfold the mask and place the fabric filter over their mouth and nose and then position the attached elastic headbands or straps around their head.

Half-mask respirators, including the subclasses of elastomeric and filtering facepiece respirators, vary widely in

[9] LANL developed a respirator test panel consisting of 25 men and women selected to have face sizes representing about 95% of the U.S. working population (Ex. 7, docket H049).

design and construction; these characteristics could result in different fitting characteristics which, in turn, can affect the level of employee protection afforded by the respirators. In this regard, an important question is whether available WPF and SWPF studies demonstrate sufficient variability in protection between and among filtering facepiece and elastomeric respirators to warrant different APF levels.

OSHA reviewed available WPF and SWPF studies that determined APFs for separate models of half-mask respirators based on each respirator's performance. These studies usually determine a protection factor for each respirator user (*e.g.*, an employee in a WPF study, or a member of a panel of respirator users in a SWPF study) who participates in the study, with each of these values expressed as the concentration of challenge agent outside the respirator (C_o) divided by the concentration of that agent inside the respirator (C_i), *i.e.*, C_o/C_i. After collecting these values, a statistical analysis determines the geometric distribution of the values; the overall APF for the respirator is the estimated value that lies at the fifth percentile of the geometric distribution. Listed in the table below are the WPF studies on filtering facepiece and elastomeric respirators reviewed by the Agency.

WPF studies for filtering facepieces (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Cohen (Ex. 1–64–11):				
Prototype Mercury (disposable respirator)	26	28		5
Albrecht *et al.* (Ex. 1–64–23):				
3M 8710	13	81	1.99	25
3M 9910	13	107	2.50	20
3M 9920	10	223	2.38	45
Nelson and Dixon (Ex 1–64–54):				
3M 8710	18	310	5.3	20
3M 9910	14	580	4.2	55
AO R1050	7	52	4.2	5
Reed *et al.* (Ex. 1–64–61):				
3M 9910	19	18	3.1	3
Johnston and Mullins (Ex. 1–64–34):				
3M 8715 (with aluminum particulate)	10	145	2.3	32
3M 8715 (with titanium particulate)	14	59	1.7	24
3M 8715 (with silicon particulate)	14	172	3.1	24
Colton *et al.* (Ex. 1–64–15):				
3M 9906	23	27	1.5	13
Colton *et al.* (Ex. 1–64–16):				
3M 9970 (with lead particulate)	62	415	4.4	36
3M 9970 (with zinc particulate)	62	681	5.6	40
Myers and Zhuang (Ex. 1–64–51) (conducted in a brass foundry):				
3M 9920 (with zinc particulate)	20	108	5.2	7
Myers and Zhuang (Ex. 3–14) (conducted in a steel mill):				
3M 8710 (with iron particulate)	10	377	3.7	44
Gerson 1710 (with iron particulate)	11	123	2.7	24
Colton and Mullins (Ex. 1–146):				
3M 9920 and 3M 9925	32	147	2.5	33
Wallis *et al.* (Ex. 1–64–70):				
3M 8710	70	50	3.5	7.5
Lenhart and Decker (Ex. 1–64–56):				
3M 9920	5			12
3M 9970 (two separate studies)	2			86 and 98
Gaboury and Burd (Ex. 1–64–24):				
AO, Willson, Survivair	18	47	2.5	9
Gavin *et al.* (Ex. 1–64–22):				
North 7709 (with OV cartridge)	63	75	3.1	11.7
Weber and Mullins (Ex. 3–15):				
3M 5000 (with OV cartridge)	46	39.7	2.14	11
Myers and Zhuang (Ex. 1–64–51) (conducted in a brass foundry):				
AO 5-Star (with DFM filter)	6	98	5.8	5
MSA Combo II (with DFM filter)	9	163	3.1	26
Scott 65 (with DFM filter)	6	94	4.8	7
Myers and Zhuang (Ex. 3–14) (conducted in a steel mill):				
AO 5-Star (with DM filter)	11	280	2.7	56
MSA Combo II (with DM filter)	8	427	4.3	39
Scott 65 (with DM filter)	11	252	2.9	45
Myers and Zhuang (Ex. 1–64–52) (conducted in a paint-spraying facility):				
AO 5-Star (with HEPA or OV filter)	38	2,211		171
MSA Combo II (with HEPA or OV filter)	38	4,580		437
Scott 65 (with HEPA or OV filter)	38	6,630		1,121
Lenhart and Campbell (Ex. 1–64–42):				
MSA Combo (with HEPA filter)	25	180	4.1	18
Albrecht *et al.* (Ex. 1–64–23):				
3M Easi-Air 7000 (with HEPA filter)	8	56	1.35	31
3M Easi-Air 7000 (with DM filter)	6	68	1.66	28
Dixon and Nelson (Ex. 1–64–54):				
Survivair 2000 and MSA Combo II (with DFM filter)	17	240	6.3	12

WPF studies for filtering facepieces (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Survivair 2000 and MSA Combo II (with HEPA filter)	14	94	3.0	16
North 7700 (with HEPA filter)	14	250	6.9	11
Dixon and Nelson (Ex. 1–64–19):				
Survivair 2000 (with HEPA or OV filter)	37	3,400	3.8	390
Colton *et al.* (Ex. 1–64–13):				
3M 6000 (with HEPA filter and cadmium particulate)	25	333	4.18	32
3M 6000 (with HEPA filter and lead fume)	31	129	3.15	19
Colton and Bidwell (Ex. 4–10–4):				
3M 7000 (with 7255 HEPA mechanical filter)	21	1,006	4.65	80
3M 7000 (with 2040 HEPA electrostatic filter)	22	562	3.5	71

OSHA found only one SWPF study on half-mask air-purifying respirators. In 1987, Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) of LANL performed a SWPF study that included laboratory testing of the MSA Comfo II half-mask air-purifying elastomeric respirator. The geometric mean fit factors they measured during simulated work exercises ranged from 800 to 5,700 for this half-mask. These results appear to complement the WPF results discussed in the following paragraph.

The summary statistics for WPF studies of filtering facepieces and elastomeric half-masks presented in the previous tables show little difference between these two major subclasses of half-mask respirators. Most importantly, the estimated protection factors for these two subclasses evidence considerable overlap. In addition, both tables show that many respirators in each class received estimated protection factors above 10, while a few respirators performed below that level. Accordingly, the WPF studies overall support assigning an APF of 10 for this respirator class (*i.e.*, half-masks), which consists of quarter masks, filtering facepieces, and elastomeric half-mask respirators. OSHA could find no studies on the performance of quarter masks, but just as in the 1992 ANSI standard (Ex. 1–50) has included quarter masks with half-masks.

The statistical analyses of these studies performed by Dr. Kenneth Brown (see section IV above) corroborate these conclusions. These analyses could not differentiate between filtering facepieces and elastomeric half-masks, which justifies combining the study data for these two subclasses into a single class for a subsequent APF determination. This determination showed that nearly 96% of the WPF data in these combined studies were at or above an APF of 10.

3. Full Facepiece Air-Purifying Respirators

Historical development of APFs for full facepiece air-purifying respirators. In 1976, 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 standard listed an APF of 100 for full facepiece air-purifying respirators with DFM filters. 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 the respirator users received quantitative fit testing.

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, and an APF of 10 when using DFM filters. NIOSH developed the lower APF of 10 for respirators equipped with DFM filters after it tested the efficiency of these filters. In the absence of workplace protection factor studies of full facepiece respirators, NIOSH based these APFs on results from earlier quantitative fit testing performed by LANL on panels of respirator users.

The 1992 ANSI standard retained the 1980 ANSI standard's APF of 100 for full facepiece air-purifying respirators, but required that respirator users perform fit testing and achieve a minimum fit factor of 1,000 prior to using the respirators; in this regard, quantitative fit testing was necessary because no qualitative fit test could achieve a fit factor of 1,000. The ANSI standard kept this APF because the ANSI committee found that no new WPF or SWPF studies had been performed for this respirator class since it last issued APFs in 1980.

The following table summarizes the previous APFs assigned to full facepiece air-purifying respirators, beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

Full 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 max. (with QNFT)	10 (with DFM filter) 50 (with HEPA filter).	100

OSHA's proposed APFs for full facepiece air-purifying respirators. Although the 1992 ANSI standard assigned an APF of 100 to full facepiece air-purifying respirators, OSHA believes that studies completed after 1992 indicate that an APF of 100 is too high. Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) assessed the protection afforded to 13 employees over a four day period by the 3M 7800 full facepiece air-purifying respirator equipped with a HEPA filter. In this WPF study, the employees performed their regular tasks in the blast furnace, reverberatory furnace, and casting and warehouse areas of a lead smelter while the authors sampled lead dust and fumes inside and outside the respirator. The authors found a fifth percentile protection factor of 95 for the combined samples, but concluded that the respirator provided reliable protection at protection factors in excess of 50.

Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) completed the only SWPF study on a full facepiece air-purifying respirator at LANL; this study measured the protection afforded by the MSA Ultra Twin with a HEPA filter. Ten members of the respirator test panel used the respirator under varying temperature and humidity conditions in a test chamber while performing simulated work tasks. The authors reported fit factors with geometric means ranging from 1,000 to 5,300 for this respirator. However, 23 of the 60 measurements reported were less than 1,000, 7 were less than 100, and 3 of these measurements were less than 50.

After carefully reviewing these studies, OSHA is proposing an APF of 50 for full facepiece air-purifying respirators. The proposed APF agrees with the conclusion of Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) that this class of respirators provides reliable protection at an APF of 50. Additionally, the geometric mean simulated work fit factors reported by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) were low for a SWPF study, and a few of the individual measurements were below an APF of 50; in the workplace, the fifth percentile APF for this respirator may fall well below 100. Therefore, in view of the paucity of data reported for this class of respirators, and the constraints imposed by the available studies, the Agency is proposing a conservative APF that it believes would afford employees an adequate and consistent level of respirator protection in the workplace.

Importantly, an APF of 50 corresponds with the APF assigned to full facepiece air-purifying respirators by OSHA in its substance specific standards, and by NIOSH in its 1987 RDL. In determining that an APF of 50 was appropriate for protecting employees against the contaminants identified in its substance specific standards, the Agency reviewed the existing scientific and technical information, and carefully considered comments in the records. OSHA believes that the information now available does not justify revising the previous APF determined for its substance specific standards. To ensure that the final APF for this class of respirators provides employees with appropriate protection, the Agency requests that commenters submit to the record any additional WPF and SWPF studies that may be available on full facepiece air-purifying respirators.

4. Powered Air-Purifying Respirators (PAPRs)

Historical development of APFs for PAPRs. In 1976, Ed Hyatt of LANL gave PAPRs equipped with high efficiency filters, regardless of facepiece type, a protection factor of 1,000. In doing so, Hyatt assumed, based on quantitative fit tests, that both tight-fitting and loose-fitting facepiece PAPRs would always maintain a positive pressure inside the facepiece.

The committee responsible for drafting the 1980 ANSI standard assigned an APF of 3,000 to PAPRs equipped with high efficiency filters. When the respirators used DFM filters, they received an APF of 100. The ANSI committee did not require fit testing for PAPRs because it assumed, as did Hyatt, that these respirators would maintain positive pressure during use.

The 1987 NIOSH RDL assigned an APF of 25 to half-mask PAPRs after NIOSH reviewed the results of two WPF studies that it conducted on these respirators (Ex. 1–64–42 and 1–64–46). The RDL also gave loose-fitting PAPRs with hoods or helmet an APF of 25 based on data from two studies performed by Myers, Peach, Cutright, and Iskander (Exs. 1–64–47 and 1–64–48). However, the RDL recommended an APF of 50 for other PAPRs equipped with a tight-fitting facepiece or a hood or helmet, as well as high efficiency filters or gas-vapor cartridges used in combination with high efficiency filters.

The committee developing the 1992 ANSI standard updated the APFs specified in the 1980 ANSI standard. Accordingly, the committee recommended an APF of 50 for tight-fitting half-mask PAPRs based on the same WPF studies used by NIOSH in developing the 1987 RDL. Tight-fitting full facepiece PAPRs received an APF of 100 when equipped with dust filters (based on performance limitations of the filters), and an APF of 1,000 when used with HEPA filters. While the ANSI committee retained an APF of 25 for loose-fitting facepiece PAPRs, including loose-fitting hoods and helmets, it treated tight-fitting PAPRs with hoods or helmets much as it did tight-fitting full facepiece PAPRs (*i.e.,* by assigning them an APF of 100 when used with a dust filter, and an APF of 1,000 when equipped with a HEPA filter).

The following table summarizes the previous APFs assigned to PAPRs, beginning with Hyatt's studies at LANL in 1976 through the 1992 ANSI standard.

Powered air-purifying respirators (PAPRs)	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Half-mask	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	50.
Full facepiece	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	100 (with dust filter), 1,000 (with HEPA filter).
Hoods or helmets	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	100 (with dust filter), 1,000 (with HEPA filter).
Loose-fitting facepiece	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	25 (with any filter)	25.

OSHA's proposed APFs for half-mask PAPRs. In 1983, Meyers and Peach performed a WPF study on tight-fitting half-mask and full facepiece PAPRs in a silica-bagging operation (Ex. 1–64–46). The geometric mean protection factors for each of the seven employees who used the half-mask PAPRs ranged from 19 to 193, with a geometric mean protection factor of 54 for the entire sample. The authors attributed the poor performance of the half-mask PAPRs to leakage around the filter assembly connection where it attached to the PAPR blower housing, as well as to inadequate facepiece fit.

Lenhart and Campbell of NIOSH in 1984 conducted another WPF study of tight-fitting half-mask PAPRs used by employees in the sinter plant and furnace areas of a primary lead smelter

(Ex. 1–64–42). For the entire sample, the authors reported a geometric mean protection factor of 380 and a fifth-percentile protection factor of 58.

Two SWPF studies also evaluated tight-fitting half-mask PAPRs. Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) used fit testing to assess the performance of the respirators in a test chamber under variable temperature and humidity conditions. They found that the geometric mean protection factor for the entire sample ranged from 14,200 to 20,000. In the second SWPF study, da Roza, Cadena-Fix, and Kramer tested a panel of respirator users who exercised on a treadmill at different work rates (Ex. 1–64–94). The geometric mean protection factor for the entire sample (*i.e.,* combining respirator performance at all work rates) was 5,000.

The following table provides a summary of the WPF and SWPF studies for tight-fitting half-mask PAPRs.

WPF studies for half-mask PAPRs (by name of authors and type/model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Lenhart and Campbell (Ex. 1–64–42), MSA	25	380	2.6	58
Myers and Peach (Ex. 1–64–46), PAPR (manufacturer and model not specified)	10	54	2.44	

SWPF studies for half-mask PAPRs (by name of authors and type/model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile SWPF
Skaggs *et al.* (Ex. 1–38–3), MSA with Comfo II facepiece	60	14,200–20,000		
da Roza *et al.* (Ex. 1–64–94), MSA with Comfo facepiece	[1] 6	[2] 5,000		

[1] The six respirator users of the test panel exercised on a treadmill.
[2] The geometric mean is for all exercise rates combined.

In arriving at a proposed APF of 50 for tight-fitting half-mask PAPRs, OSHA relied to a large extent on the WPF study conducted by Lenhart and Campbell. This 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 Meyers 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. In addition, the proposed APF duplicates the APFs assigned to tight-fitting half-mask respirators by the 1987 NIOSH RDL and the 1992 ANSI standard, both of which based their APF determinations on data reported in the existing scientific literature, as well as the opinions of well known experts on respiratory protection.

OSHA's proposed APFs for full facepiece PAPRs and PAPRs with hoods or helmets. Two WPF studies determined protection factors for tight-fitting full facepiece PAPRs. Myers and Peach conducted the first of these studies in 1983 (Ex. 1–64–46); OSHA described this study in its earlier discussion of tight-fitting half-mask PAPRs. As noted in this discussion, the Agency did not use the results of this study because of problems involving filter assembly leakage and poor facepiece fit reported by the authors. The second WPF study, by Colton and Mullins, reported a geometric mean protection factor of 4,226, and a fifth percentile protection factor of 728 for employees in a secondary lead smelter (Ex. 1–64–12). Thirty-four samples in this study had no detectable lead inside the respirators; therefore, the authors used the limit of detection for lead as a proxy for the concentration of lead inside the facepiece. When the authors corrected their data analysis by including these samples, the geometric mean protection factor increased to 8,843, and the fifth percentile protection factor rose to 1,335. No SWPF studies on full facepiece PAPRs were available.

One WPF study and one SWPF study are available for tight-fitting PAPRs with hoods or helmets. In the WPF study, Keys, Guy, and Axon, determined the protection afforded to employees in a pharmaceutical manufacturing plant by three different respirators in this class (Ex. 1–64–40). The fifth percentile protection factors for these respirators were 997, 1,197, and 1,470. Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of the Organization Resources Counselors (ORC) performed the single SWPF study (referred to here as ''the ORC-LLNL SWPF Study'') in which they collected 576 test samples from four different PAPRs with hoods or helmets, and equipped with bibs (Ex. 3–4–2). The lowest protection factor among the 576 test samples was 11,000; overall, the 576 test samples had a fifth percentile protection factor greater than 250,000.

The following tables summarize the WPF studies for tight-fitting full facepiece PAPRs, and the WPF and SWPF studies involving PAPRs with hoods or helmets.

WPF studies for full facepiece PAPRs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Colton and Mullins (Ex. 1–64–12) 3M W–3205 Whitecap (with 3M 7800 full facepiece and HEPA filter):				
Study 1[1]	20	4,226	2.9	728

WPF studies for full facepiece PAPRs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Study 2	55	8,843	3.2	1,335
Myers and Peach (Ex. 1–64–46) Full facepiece PAPR (manufacturer and model not specified)	10	54	2.44	....

[1] Study 1 consisted of 20 samples with C_i values over the detection limit, while Study 2 consisted of 34 samples that had C_i values below the detection limit; for analytic purposes, the investigators assigned these 34 samples a C_i value equal to the detection limit.

WPF studies for PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Keys *et al.* (Ex. 1–64–40):				
Racal Breathe Easy 10 (hood, double bib, HEPA filter)	29	11,137	3.9	1,197
Bullard Quantum (hood, double bib, HEPA filter)	9	9,574	3.1	1,470
3M Whitecap II (helmet, double bib, HEPA filter)	22	42,260	9.8	997

SWPF studies for PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Range of SWPFs	Geometric median SWPF	5th percentile SWPF
ORC–LLNL SWPF Study (Ex. 3–4):			
3M Whitecap (helmet with bib and HEPA filter)	140,000–>250,000	>250,000	>250,000
3M Snapcap (Tyvek hood with bib and HEPA filter)	11,000–>250,000	>250,000	>170,000–210,000
Racal BE–5 Clear PVC (hood with bib and HEPA filter)	11,000–>250,000	>250,000	>250,000
Racal BE–10 (Tyvek hood with bib and HEPA filter)	94,000–>250,000	>250,000	246,000–>250,000

OSHA is proposing an APF of 1,000 for full facepiece PAPRs and PAPRs with hoods or helmets. With regard to full facepiece PAPRs, the corrected fifth percentile protection factor of 1,335 reported by Colton and Mullins in their WPF study fully supports the proposed APF. The WPF study of PAPRs with hoods or helmets by Keys, Guy, and Axon justifies the proposed APF of 1,000 for this respirator class. These authors reported that the average fifth percentile protection factor for the three respirators tested in their study was well over 1,000. Moreover, the ORC–LLNL SWPF Study (Ex. 3–4), in which this class of respirators received extremely high fifth percentile protection factors, lends substantial validation to OSHA's proposed APF. In addition, the proposed APFs for full facepiece PAPRs and PAPRs with hoods or helmets corresponds with the APFs assigned to these respirator classes in the 1992 ANSI standard; ANSI made these APF determinations only after a careful review and discussion of the available research by a panel of respirator experts. While the proposed APF for these respirators is much higher than the APF recommended in the 1987 NIOSH RDL, the Agency believes that the WPF and SWPF studies conducted on these respirators since publication of the RDL justify the proposed increase.

Footnote 4 of the proposed APF table states 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 1000 or greater, receive an APF of 1,000.'' The footnote continues, ''All other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.'' OSHA is proposing that respirators from this class be able to demonstrate that they maintain a positive pressure inside the facepiece during use and achieve a level of protection of 1000 or greater. Available WPF and SWPF studies have found that some of these respirators were shown to only achieve protection factors well below 1,000 (Exs. 3–4, 3–5). In all likelihood, the burden of conducting any testing would fall on respirator manufacturers, but the employer would be responsible for selecting a properly tested respirator, thereby assuring employees that they will receive adequate protection against toxic hazards.

OSHA's proposed APFs for loose-fitting PAPRs. A number of WPF and SWPF studies are available for loose-fitting facepiece PAPRs. An important purpose of these studies was to determine if APFs differed between loose-fitting facepiece PAPRs and PAPRs with tight-fitting hoods or helmets. The NIOSH WPF study by Myers, Peach, Cutright, and Iskander (Ex. 1–64–47) was the first to report that loose-fitting facepiece PAPRs did not perform at an APF of 1,000, the value determined by Ed Hyatt in 1976 after quantitatively fit testing a panel of respirator users. A follow-up study by Myers, Peach, Cutright, and Iskander (Ex. 1–64–48) reported a fifth percentile protection factor of 25 for this respirator class.

A WPF study conducted later by Albrecht, Gosselink, Wilmes, and Mullins (Ex. 1–64–23) reported a fifth percentile protection factor of 42 for the 3M Airhat, a loose-fitting facepiece PAPR with a helmet. Stokes, Johnston, and Mullins (Ex. 1–64–66) performed a WPF study in a roofing granule production plant using the 3M Airhat; they found a fifth percentile protection factor of 95. However, when employees used the respirator with a Tyvek shroud, the fifth percentile protection factor increased to 1,615. Gaboury and Burd (Ex. 1–64–24) reported a fifth percentile protection factor of 275 in a WPF study in which employees in an aluminum smelter wore a Racal Breathe Easy loose-fitting facepiece PAPR with a helmet. Collia, Colton, and Bidwell (Ex. 3–5) found a fifth percentile protection factor of 315 in a WPF study performed on the 3M Breathe Easy 12 PAPR with a loose-fitting head cover.

OSHA evaluated three SWPF studies addressing the performance of loose-fitting facepiece PAPRs with hoods or helmets. Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) reported geometric mean protection factors ranging from 1,900 to 5,600 for the 3M Airhat, and from 1,200 to 3,500 for the Racal AH3 PAPR with a loose-fitting helmet. A study by da Roza, Cadena-Fix, and Kramer (Ex. 1–64–94) found geometric mean protection factors ranging from 10 to 10,000, and from 100 to 20,000, for the two loose-fitting facepiece PAPRs with helmets they tested.

Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of ORC (Ex. 3–4) assessed the performance of one loose-fitting facepiece PAPR with a Tyvek head cover as part of the ORC–LLNL SWPF Study; the results of this study reported three APFs below 10,000, with the lowest value being 240. The fifth percentile protection factor for this respirator ranged from 150,000 to 230,000.

The following tables summarize the WPF and SWPF studies for loose-fitting facepiece PAPRs with hoods or helmets.

WPF studies for loose-fitting facepiece PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Myers *et al.*(Ex. 1–64–47):				
3M W–344 (helmet with HEPA filter)	23	165	3.57	26
Racal AH 3 (helmet with HEPA filter)	23	205	2.83	26
Albrecht *et al.* (Ex. 1-64–23) 3M Airhat (helmet with HEPA filter)	7	199	2.36	42
Myers *et al.* (Ex. 1–64-48):				
3M W–316 (helmet with DM filter)	22	135	1.89	25
Racal AH 5 (helmet with DM filter)	24	120	2.64	25
Gaboury and Burd (Ex. 1–64–24) Racal Breathe Easy I (helmet with HEPA or OV filter)	20	1,414	2.51	275
Collia *et al.* (Ex. 3–5) 3M Breathe Easy 12 (Tyvek head cover with HEPA filter)	41	2,523		315
Stokes *et al.* (Ex. 1-64–66):				
3M Airhat (helmet) with:				
HEPA filter (total)[1]	12	5,370	3.0	762
DM filter (without shroud)	27	877	5.2	53
DM filter (with shroud)	18	11,792	3.1	1,615
DM filter (total)	45	2,480	7.0	95

[1] The total consists of the shroud and no-shroud samples combined.

SWPF studies for loose-fitting facepiece PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric median	5th percentile SWPF
Skaggs *et al.* (Ex. 1–38–3):				
3M Airhat W–344 (helmet)	60	1,900–5,600		
Racal AH3 Airstream (helmet)	60	1,200–3,500		
da Roza *et al.* (Ex. 1–64–94):				
3M Airhat W–344 (helmet)	[1] 6	10–10,000		
Racal Breathe-Easy 1 (helmet)	6	100–20,000		
ORC–LLNL SWPF Study (Ex. 3–4):				
Racal BE–12 (Tyvek head cover)	144	240–250,000	250,000	150,000–230,000

[1] Used same panel of six respirator users for both respirators; panel exercised on treadmill at 80% cardiac capacity.

OSHA is proposing an APF of 25 for loose-fitting PAPRs with hoods or helmets, which is consistent with both WPF studies conducted by Myers, Peach, Outright, and Iskander (Ex. 1–64–47 and 1–64–48), as well as the APFs for this respirator class established by the 1987 NIOSH RDL and by the 1992 ANSI standard. The extreme variability of the fifth percentile protection factors in the WPF studies warrants a conservative approach in proposing an APF for this respirator class. In this regard, seven of the 11 WPF studies found fifth percentile protection factors of less than 100, and five of these APFs were below 50. The Agency believes that a proposed APF of 25 would provide employees who use these respirators with an adequate safety margin in view of the unreliability of the protection factors found for this respirator class.

The geometric means reported by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) were low for a SWPF study, as were a number of the geometric means determined by de Rosa, Cadena-Fix, and Kramer (Ex. 1–64–94) in their SWPF assessments. In the workplace, these low geometric mean SWPFs likely would translate into fifth percentile WPFs of less than 50. Therefore, the limited and highly variable data in the SWPF studies support OSHA's conclusion that a conservative APF of 25 would afford employees an adequate and consistent level of respirator protection in the workplace.

5. Supplied-Air Respirators (SARs)

Historical development of APFs for SARs. SARs operate in one of three modes—demand, continuous flow, or pressure demand. Demand or pressure demand respirators have either a tight-fitting half-mask or a tight-fitting full facepiece, while continuous flow respirators have either a tight-fitting, or a loose-fitting, hood or helmet, or a tight-fitting half-mask or full facepiece.

In 1976, Ed Hyatt of LANL published the initial protection factors for SARs (Ex. 2). In making these determinations, Hyatt gave an APF of 10 to half-mask SARs operated in the demand mode, while full facepiece SARs received an APF of 50 in the demand mode. These APFs are the same APFs that Hyatt assigned to negative pressure half-masks, and full facepiece, air-purifying respirators. Hyatt based the APF of 10 for half-mask SARs operating in the demand mode on LANL studies performed in 1971 and 1972 on a respirator test panel wearing eight half-mask air-purifying respirators equipped with HEPA filter. In determining an APF of 50 for full facepieces, Hyatt relied on LANL studies in which a respirator test panel consisting of 31 firemen wore full facepiece SCBAs operating in the demand mode.

Hyatt regarded SARs that operate in a positive pressure mode to be more protective than SARs used in a negative pressure mode; therefore, he assigned half-mask and full facepiece SARs that function in the continuous flow, pressure demand, or other positive pressure modes APFs of 1,000 and 2,000, respectively; the half-mask respirators received a lower APF than the full facepiece respirators because

Hyatt considered a half-mask to be less stable on the face than a full facepiece. SARs with hoods or helmets operated in continuous flow mode received an APF of 2,000, consistent with the APF Hyatt gave to full facepiece SARs operating in the continuous flow or pressure demand mode.

The 1980 ANSI standard differentiated APFs for some SARs depending on the type of fit testing performed. Accordingly, half-mask and full facepiece SARs used in the demand mode received APFs of 10 and 100, respectively, when qualitatively fit tested. When tested quantitatively, the APFs for these respirators were the protection factors achieved during fit testing, with the APF limited to the sub-IDLH value [10] of the hazardous substance in the workplace.

Half-mask or full facepiece SARs that functioned in continuous flow or pressure demand modes required no fit testing because of their positive pressure operation; consequently, these respirators received an APF limited only to the sub-IDLH value of the hazardous substance in the workplace when used without an auxiliary air supply or escape bottle (*i.e.*, the ''escape configuration''). When equipped in an escape configuration, these respirators had a maximum APF of 10,000. Continuous flow or pressure demand SARs with hoods or helmets also received a maximum APF of 10,000 when not used in an escape configuration; however, when operated in a escape configuration, the maximum APF for these respirators was of 10,000+ (*i.e.*, employees could use them to escape from IDLH atmospheres).

The 1987 NIOSH RDL recommended APFs of 10, 50, and 1,000, respectively, for half-mask SARs when operated in demand, continuous flow, and positive pressure (including pressure demand) modes. All SARs with hoods or helmets received an APF of 25 when used in the continuous-flow mode. The RDL assigned full facepiece SARs an APF of 50 when they functioned in the demand or continuous flow mode, an APF of 2,000 when operated in the pressure demand or other positive pressure mode, and a maximum APF of 10,000 when used in the pressure demand mode with an auxiliary SCBA.

The 1992 ANSI standard did not set different APFs for the same class of respirator based on the type of fit testing conducted because WPF studies performed after publication of the 1980 ANSI standard did not support this practice. After comparing the operational characteristics of half-mask and full facepiece SARs to half-mask and full facepiece air-purifying respirators, the 1992 ANSI standard gave APFs of 10 and 100, respectively, to half-mask and full facepiece SARs when operated in the demand mode. Pressure demand and continuous flow half-mask SARs received an APF of 50, consistent with their operational similarities with half-mask PAPRs. Full facepiece continuous flow SARs received an APF of 1,000, determined from their operational analogy to SARs having tight-fitting hoods or helmets. Based on their operational similarities to loose-fitting continuous flow PAPRs, the committee drafting the 1992 ANSI standard gave loose-fitting facepiece SARs operated in the continuous flow mode an APF of 25.

The following table summarizes the APFs given to the various classes of SARs (*i.e.*, half-mask, full facepiece, tight-fitting with hoods or helmets, and loose-fitting facepiece), beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

SARs	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Half-mask	10 (demand)	10 (demand; with QLFT).	10 (demand)	10 (demand).
	1,000 (continuous flow)	Same as QNFT factor (demand; sub-IDLH value max.).	50 (continuous flow)	50 (continuous flow).
	1,000 (pressure demand)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	1,000 (pressure demand)	50 (pressure demand).
Full facepiece	50 (demand)	100 (demand; with QLFT).	50 (demand)	100 (demand).
	2,000 (continuous flow)	Same as QNFT factor (demand; sub-IDLH value max.).	50 (continuous flow)	1,000 (continuous flow).
	2,000 (pressure demand)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	2,000 (pressure demand)	1,000 (pressure demand).
Hood or helmet	2,000 (continuous flow)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	25 (continuous flow)	1,000 (continuous flow).
Loose-fitting facepiece	....	....	25 (continuous flow)	25 (continuous flow).

[10] The concentration of the hazardous substance just below its IDLH value.

OSHA's proposed APFs for half-mask SARs. No WPF studies were available for half-mask SARs. Therefore, OSHA is proposing an APF of 10 for this respirator class when used in the demand mode based on their analogous operational performance with negative pressure half-mask air-purifying respirators tested during WPF and SWPF studies. In addition, the Agency proposes to give half-mask SARs that function in the continuous flow or pressure demand modes an APF of 50, consistent with the performance of half-mask PAPRs in WPF and SWPF studies (and operated at the same airflow rates). Additional support for the proposed APFs comes from the 1992 ANSI standard, which assigned an APF of 10 to half-mask airline SARs operated in the demand mode, and an APF of 50 when operated in the continuous flow or pressure demand mode. 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.

Regarding the recommended APF of 1,000, OSHA preliminarily finds that these respirators warrant the more conservative APF of 50 because of the possibility that negative pressure could develop inside the mask during tasks that stress the facepiece seal; moreover, in the absence of WPF and SWPF data for these respirators, the Agency believes that a conservative approach to setting this APF is appropriate.

OSHA's proposed APFs for full facepiece SARs. No WPF or SWPF studies were available involving tight-fitting full facepiece SARs operated in the demand mode. Therefore, in the absence any such data, the Agency is assigning this respirator class an APF of 50 based on the analogous operational characteristics between these respirators and negative pressure air-purifying respirators when operated in the demand mode under WPF conditions. The proposed APF is the same as the APF recommended for this respirator class by the 1987 NIOSH RDL, and similar to the APF (*i.e.*, 100) given to these respirators by the 1992 ANSI standard. In choosing an APF of 50 instead of 100 for this class of respirators, the Agency believes that the paucity of WPF and SWPF studies warrants taking a conservative approach in this determination.

While no WPF studies for full facepiece SARs operated in the pressure demand or other positive pressure modes were available, there was one SWPF study of this respirator class by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3). The study, performed at LANL, evaluated the respirators under different temperature and humidity conditions; the results of the study showed that these respirators had geometric mean protection factors ranging from 8,500 to 20,000. Therefore, the Agency is proposing an APF of 1,000 for full facepiece SARs used in the pressure demand or other positive pressure modes based on their performance in this study (*i.e.*, that the likelihood is high that the geometric mean SWPFs would translate to fifth percentile WPF of 1,000. Further justification for the proposed APF comes from the similarity in operational characteristics (including the same minimum airflow rates) between these respirators and tight-fitting full facepiece continuous flow PAPRs, which are receiving a proposed APF of 1,000 in this rulemaking. (See the discussion of these PAPRs above).

The proposed APF of 1,000 for full facepiece SARs operated in the pressure demand or other positive pressure modes also is consistent with the APFs of 1,000 assigned by the 1992 ANSI standard to these respirators when used in the continuous flow or pressure demand modes, and the APF of 2,000 recommended by the 1987 NIOSH RDL for pressure demand respirators in this class. Although the RDL gave an APF of 50 to these respirators in a continuous flow mode, the Agency believes that the SWPF study, as well as the WPF studies performed on analogous tight-fitting full facepiece continuous flow PAPRs, justify the proposed APF.

OSHA's proposed APF for SARs with hoods or helmets. The Agency found a number of WPF studies on these respirators, including one by Johnston, Stokes, Mullins, and Rhoe (Ex. 1–64–36).

These authors performed a WPF study on the 3M Whitecap continuous flow abrasive blasting helmet (equipped with an extended length shroud) used by four shipyard employees while sandblasting a barge. After performing several data analyses, the authors concluded that outside-the-respirator samples with filter loadings at least 1,000 times greater than the mean blank value were most representative of the respirator's performance. Therefore, OSHA is using only statistics based on these samples for its APF determinations; these statistics indicate that the estimated fifth percentile protection factor is 1,038 for these samples.

Johnston, Stokes, Mullins, and Rhoe (Ex. 1–64–37) conducted a second WPF study on the 3M Whitecap II general purpose SAR with a helmet. In this study, the authors sampled six employees while they performed grinding operations in a foundry. The authors stated that ''because of the relatively low sample loadings, the WPF numbers obtained significantly underestimate the performance capability of the respirator.'' Therefore, OSHA did not use the WPFs from this study in developing the proposed APF for this respirator class.

Colton, Mullins, and Bidwell (Ex. 1–64–17) published a WPF study on foundry employees who used the 3M Snapcap continuous flow SAR with an abrasive blasting hood while exposed to silica during tear-down operations. The authors reported a fifth percentile protection factor over 1,000, which they noted was consistent with the APF of 1,000 assigned to these respirators by the 1992 ANSI standard.

In another WPF study, Nelson, Wheeler, and Mustard (Ex. 3–6) sampled aircraft assembly employees involved in sanding and primer spraying operations while using the 3M H–422 continuous flow SAR hood with both an outer and inner shroud. The authors reported that 14 of the 31 samples taken during primer spraying operations showed measurable concentrations of strontium (Sr) outside the facepiece (C_o), but none of the samples showed any measurable concentration of Sr inside the facepiece (C_i). Based on these C_o data, and using the lowest detectable limit for C_i, the authors concluded that ''the WPFs were greater than 1,200 for all samples with a mass of Sr on the C_o samples 1,000 times the detection limit for the C_i samples.'' They stated further that their study supports the APF of 1,000 given to these respirators by the 1992 ANSI standard.

In a WPF study conducted at Avondale shipyard, Kiefer, Trout, and Wallace (Ex. 2–1) sampled the total particulate exposures (*i.e.*, small and large particle fractions combined) of employees involved in abrasive blasting operations while using the Bullard Type 88 CE (continuous flow) SAR abrasive blasting hood. The authors reported WPFs ranging from 2,817 to 10,000.

OSHA identified four SWPF studies of this respirator class, all performed by LLNL or LANL for manufacturers of continuous flow SARs with abrasive blasting hoods or helmets. The geometric mean protection factors found for these respirators were 40,000 for the Bullard Model 77 and 88 Type CE (continuous flow) SARs with an abrasive blasting hood (Ex. 1–157), and 100,000 for the Clemco Apollo 20 and 60 Type CE (continuous flow) SARs with an abrasive blasting hood (Ex. 3–7–3) and the 3M Whitecap Model W–8100 Type CE (continuous flow) SAR with abrasive blasting helmet (Ex. 3–9–2). Based on the results of these studies, OSHA granted these respirators an interim APF of 1,000 (Exs. 3–7–4, 3–8–4, 3–9–3).

In the latest SWPF study, Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of ORC (Ex. 3–4) tested six models of continuous flow SARs with hoods or helmets as part of the ORC–LLNL SWPF Study. Five of these respirators had fifth percentile SWPFs ranging from 86,000 to over 250,000. However, the fifth percentile SWPFs for the sixth respirator (the North Model 85302 T) ranged from 13 to 18. The authors attributed the poor performance of this respirator to the absence of a ''tuck-in'' bib. When the manufacturer corrected this design problem by adding a tuck-in bib, the resulting model (designated the North Model 85302 TB) performed as well as most of the other respirators tested in the study.

The following tables summarize the WPF and SWPF studies for tight-fitting SARs with hoods or helmets.

WPF studies for SARS with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Johnston *et al.* (Ex. 1–64–36) 3M W–8100 Whitecap II (abrasive blasting helmet with extended-length shroud)	15	4,076	2.3	1,038
Johnston *et al.* (Ex. 1–64–37):				
3M W–8000 Whitecap II (helmet)				
Study 1 (using >750 x field blank with iron dust samples)	8	1,012	2.6	199
Study 2 (using >30 x field blank with silicon dust samples)	8	1,417	3.0	224
Colton *et al.* (Ex. 1–64–17), 3M Snapcap W–3256 (abrasive blasting hood)	14	10,344	2.5	2,290
Nelson *et al.* (Ex. 3–6), 3M H–422 (hood)	31			>1,000
Kiefer *et al.* (Ex. 2–1), Bullard 88 Type Type CE (abrasive blasting hood)	11			>1,000

SWPF studies for SARs with hoods or helmets (by name of authors and model of respirator tested)	Range of SWPFs	Geometric mean/ median SWPF	5th percentile SWPF
Bullard-LLNL (Ex. 1–157) [1], Bullard 77 and 88 Type CE (abrasive blasting helmet)		>40,000 (mean)	
Clemco-LANL (Ex. 3–7–3) [2], Apollo 20 and 60 Type CE (abrasive blasting hood)		>100,000 (mean)	
3M–LANL (Ex. 3–9–2) [3], 3M Whitecap Model W–8100 Type CE (abrasive blasting helmet)		>100,000 (mean)	
ORC–LLNL SWPF Study (Ex. 3–4–2):			
3M Whitecap SAR (helmet with bib and chinstrap)	68,000–>250,000	>250,000 (median)	>250,000
3M Snapcap (Tyvek hood with bib and chinstrap)	13,000–>250,000	>250,000 (median)	170,000–250,000
MSA Versa-hood (Tyvek hood)	9,700–>250,000	>250,000 (median)	86,000–114,000
North Model 85302 TB (Tyvek hood with bib)	55,000–>250,000	>250,000 (median)	150,000–240,000
North Model 85302 T (Tyvek hood, no bib)	5–>250,000	1,217 (mean)	13–18
Bullard CC20TIC (Tyvek hood and bib and chinstrap)	160,000–>250,000	>250,000 (median)	>250,000

[1] Collected 288 samples (a panel of 4 respirator users × 12 exercises × 6 helmets).
[2] Collected 264 samples (a panel of 4 respirator users × 11 exercises × 6 helmets).
[3] Collected 132 samples (a panel of 4 respirator users × 11 exercises × 3 helmets).

The Agency is proposing an APF of 1,000 for continuous flow SARs with hoods or helmets based on their performance in the WPF and SWPF studies. In each of the WPF studies [except the second WPF study by Johnston, Colton, Stokes, Mullins and Rhoe (Ex. 1–64–37)], these respirators attained a fifth percentile protection factor over 1,000. In addition, the large geometric mean protection factors found for these respirators provide substantial evidence for this proposed APF.

The Agency qualified the proposed APF in footnote 4 of its proposed APF table. This footnote states 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 1000 or greater, receive an APF of 1000.'' and that ''[a]ll other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.'' Under this proposed requirement, an employer must select for employee use only continuous flow SARs with hoods or helmets that attained a protection factor of at least 1,000. While better performance has been associated with certain designs (*e.g.*, double bibs, neck seals or dams, blouses, higher airflows), the presence of such design considerations are no guarantee of superior performance. In order to receive an APF of 1,000, it is contingent upon the respirator manufacturer to be able to demonstrate that their particular respirator meets the criteria specified in Table I of the proposed standard. This level of performance can best be demonstrated by performing a WPF or SWPF study. OSHA is proposing this requirement because previous WPF and SWPF testing conducted on these respirators shows that they do not always result in the requisite protection factor (Exs. 3–4, 3–5).

Accordingly, researchers have recommended that such testing be performed to ensure that employees use only respirators from this class that provide them with the specified level of protection during exposure to hazardous substances. In this regard, while the respirator manufacturer most likely would perform the required testing, it would be incumbent on the employer to ensure that the respirators they selected for employee use received this testing.

While the 1987 NIOSH RDL recommended an APF of 25 for continuous flow SARs with hoods or helmets, this recommendation is the result of combining these respirators into a single class with loose-fitting facepiece SARs, and giving the entire class the low APF (*i.e.*, 25) assigned originally to loose-fitting facepiece respirators. However, the 1992 ANSI standard established a separate class for continuous flow SARs with hoods or helmets based on analogous operating characteristics between these respirators and airline respirators at the same flow rates, with the new class having an APF of 1,000 (loose-fitting facepiece SARs continued to receive an APF of 25). Accordingly, OSHA is proposing in this rulemaking to follow the procedure adopted by the 1992 ANSI standard and divide the two respirator types into separate classes, based principally on the WPF and SWPF performance of the continuous flow SARs with hoods or helmets.

OSHA's proposed APF for loose-fitting facepiece SARs. No WPF or SWPF studies involving this respirator class were available. Therefore, using analogous operational characteristics between these respirators and loose-fitting facepiece PAPRs, OSHA is proposing to assign loose-fitting facepiece SARs an APF of 25. In this regard, loose-fitting facepiece SARs, when evaluated under the NIOSH respirator-certification standards (42 CFR part 84), had the same minimum airflow rates found for loose-fitting facepiece PAPRs. Additional support for the proposed APF comes from the 1987 NIOSH RDL and the 1992 ANSI standard, both of which gave this respirator class an APF of 25.

6. Self-Contained Breathing Apparatuses (SCBAs)

Historical development of APFs for SCBAs. As he did with full facepiece SARs used in the demand mode, Hyatt in 1976 assigned a protection factor of 50 to a full facepiece SCBA operated 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 standard listed half-mask and full facepiece SCBAs operated in the demand mode as having APFs of 10 and 100, respectively, when qualitatively fit tested; when quantitatively fit tested, the APFs for half-mask or full facepiece SCBAs functioning in the demand mode were the protection factors obtained during 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 committee responsible for the 1992 ANSI standard could not reach a consensus on an APF for full facepiece pressure demand SCBAs. As noted in footnote 4 of the APF table in this ANSI standard, available WPF and SWPF studies reported that, in some individual cases, the respirators did not achieve an APF of 10,000 (Ex. 1–50). Nevertheless, the committee found that a maximum APF of 10,000 was appropriate when employers used the respirators for emergency planning purposes and could estimate levels of hazardous substances in the workplace.

Two newly developed 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 seal at the neck; an air cylinder supplies air to the facepiece. NIOSH reviewed this respirator in accordance with its certification requirements specified at 42 CFR part 84, and in January 2001 certified the respirator as a tight-fitting full facepiece demand SCBA, with the 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 Compliance Programs (Ex. 7–1), Mr. 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 reviewed the Survivair Puma respirator, which has a tight-fitting hood supplied by an air cylinder; and certified the respirator as a pressure demand SCBA with a tight-fitting facepiece. As part of the certification process, NIOSH specified that fit testing required of 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 instrumentation treats dander and other material shed by the hair as particulates from outside the respirator, causing the fit factor to be artificially low. However, 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 from Hyatt's 1976 studies at LLNL to the 1992 ANSI standard.

SCBAs	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
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 max. (emergency planning purposes only).

OSHA's proposed APFs for SCBAs. No WPF or SWPF studies for tight-fitting half-mask SCBAs and tight-fitting full facepiece SCBAs operated in the demand mode were available. 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 airflow requirements for respirators used by firefighters (Ex. 1–64–7). While the authors could not determine WPFs 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 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 (Ex. 1–64–86) determined the protection afforded to members of a respirator test panel consisting of 23 men wearing 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 airflow requirements; during testing, a panel of 27 respirator users 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 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
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	....

OSHA is proposing 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 WPF and SWPF studies on these respirators, the Agency derived the proposed APFs based on analogous operational characteristics between these respirators and half-mask facepiece and full facepiece air-purifying respirators for which WPF and SWPF studies (described previously) are available. In addition, the proposed APFs are consistent with the APFs recommended by the 1987 NIOSH RDL for these respirators. (Note that the 192 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 proposing an APF of 10,000, which is consistent with the 1987 NIOSH RDL and the 1992 ANSI standard. Empirical support for the proposed APF comes from the WPF study conducted by Campbell, Noonan, Merinar, and Stobbe (Ex. 1–64–7). This study showed that individual protection factors for these respirators, when operating at NFPA-compliant airflows, far exceed 10,000; however, four respirator users experienced momentary negative-pressure spikes inside the facepiece, indicating possible leakage of ambient contamination into the facepiece, and the breathing zone of the user, under some workplace conditions.

The two SWPF studies also provide support for the proposed APF, although several individual protection factors fell below 10,000 in the two studies, and the Johnson, da Roza, and McCormack study (Ex. 1–64–98) found negative-pressure incursions inside the facepiece during high exercise rates. Since the WPF and SWPF studies indicate that these respirators fail to provide the designated level of protection under some conditions, OSHA states in footnote 5 of its proposed APF table that ''[w]hen employers can estimate hazardous concentrations for emergency planning purposes, they must use a maximum assigned protection factor no higher than 10,000.'' Therefore, this proposed provision limits use of tight-fitting full facepiece positive pressure SCBAs to conditions for which an emergency-response plan exists and the employer can estimate the concentration of the hazardous substance in those conditions; in addition, the employer must restrict respirator use to conditions in which the required level of employee protection is at or below an APF of 10,000.

In proposing to limit use of tight-fitting full facepiece positive pressure SCBAs to planned emergency conditions only, OSHA acknowledges that while these respirators are among the most protective respirators available, the existing WPF and SWPF data demonstrate that they do not consistently provide employees with a protection level of 10,000 under some exposure conditions. Therefore, the Agency is proposing that employers not use these respirators routinely for protecting employees against workplace exposures requiring an APF above 1,000, but instead limit their use to non-routine (*i.e.*, emergency) conditions that require high levels of respirator protection. In this regard, the Agency believes that few, if any, routine exposure conditions in the workplace require protection above an APF of 1,000; consequently, the proposed restriction would have minimal effect on routine respirator use.[11]

[11] In preparing the risk analysis for the final Respiratory Protection Standard, OSHA reviewed data in its Integrated Management Information System for the years 1992 to 1996 to determine overexposure rates to the hazardous substances listed in Table Z (''Limits for air contaminants'') of

Continued

To use full facepiece positive pressure SCBAs under emergency exposure conditions, the proposal specifies that employers must develop an emergency plan (which several substance specific standards already require), and provide an estimate of the concentration levels likely to result under the emergency conditions. Emergency plans would limit employee exposure to the hazardous conditions by informing them in advance of the specific tasks they are to perform, while estimating concentration levels of the hazardous substance would increase the likelihood that their exposures to the substance will remain within the APF assigned to the respirator. In addition, OSHA's proposal to limit use of these respirators to emergency conditions is similar to the restriction placed on them in footnote 4 of the APF table published in the 1992 ANSI standard; this restriction reads, in part:

> [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. (Ex. 1–50)

For the class of respirators designated as pressure demand SCBAs with tight-fitting hoods or helmets, including the Survivair Puma, OSHA is proposing an APF of 10,000 maximum. The basis for this proposed APF are the analogous operational characteristics between these respirators and tight-fitting full facepiece pressure demand SCBAs. Accordingly, the Agency proposes to limit use of demand SCBAs with tight-fitting hoods or helmets to emergency planning purposes, similar to the restriction it is placing on tight-fitting full facepiece pressure demand SCBAs.

Paragraph (d)(3)(i)(B)—MUC Provisions

These proposed requirements consist of four separate paragraphs [(d)(3)(i)(B)(*1*) through (d)(3)(i)(B)(*4*)]. Paragraph (d)(3)(i)(B)(*1*), which proposes requirements on 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 proposed paragraph 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 conditions specified by the MUC, which is the exposure limit specified for the hazardous substance multiplied by the respirator's APF. Accordingly, the proposed requirement ensures that employers maintain employees' direct exposure to hazardous substances (*i.e.*, inside the respirator) within levels specified by OSHA's Z tables and substance-specific standards, and where OSHA has no standards, within consensus standards levels. Therefore, this provision would not only provide employee protection consistent with prevailing industrial-hygiene practice, but with existing regulatory and statutory requirements as well.

The single note in the proposed MUC provisions follows paragraph (d)(3)(i)(B)(*1*). This note reads that ''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.'' This provision implies that MUCs are dependent on the APFs of the respirators selected by employers to protect employees against airborne contaminants. In this regard, the Agency determined the APF for a respirator or class of respirators based on studies that assessed the respirator under conditions that met or exceeded the program requirements of its Respiratory Protection Standard at 29 CFR 1910.134. These studies ensured that the study participants who used the respirators received thorough respirator training and fit testing, and used the respirators correctly; also, employers (or research staff in the case of SWPF studies) maintained the respirators in proper operating condition. Consequently, the APF used in calculating a MUC is valid for this purpose only if employers implement a continuing, effective, and comprehensive respiratory-protection program as required by OSHA's Respiratory Protection Standard. When employers do not meet the conditions specified in this note, they may not use the respirator's APF in determining the MUC.

The next MUC provision, proposed paragraph (d)(3)(i)(B)(*2*), states that ''[e]mployers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.'' While OSHA believes that a MUC calculated according to the proposed MUC definition normally would provide adequate employee protection, it defers to respirator manufacturers when they recommend a lower MUC for their respirators under specific hazardous-substance conditions. Respirator manufacturers warrant such deference because they are most familiar with the functional limitations of their respirators when exposed to airborne concentrations of hazardous substances. Also, manufacturer's may base their recommended MUCs on unpublished WPF or SWPF studies; such studies, when conducted properly, would increase the validity of their recommendations. As with a MUC determined using OSHA's proposed calculation method, the Agency believes that the protection afforded to employees by a respirator manufacturer's MUC depends on the employer's full compliance with the comprehensive respiratory-protection program specified by OSHA's Respiratory Protection Standard.

The Agency would not defer to respirator manufacturers who recommend higher MUCs than an employer would obtain using the proposed calculation method because such results would not be consistent with the maximum ambient level of a hazardous substance in which employees can use the respirators, *i.e.*, the maximum ambient level of a hazardous substance would exceed the level determined from the known exposure limit for the hazardous substance and the protection of the APFs determined by this proposed rulemaking. Under these conditions, the respirator manufacturer would be basing the recommendation on an invalid application of the known exposure limit or the APF (or both); therefore, such an invalid application would cause employers to select respirators that are incapable of protecting employees from the ambient level of a hazardous substance, resulting in serious health impairments to their employees.

Paragraph (d)(3)(i)(B)(*3*) of the proposed MUC provisions states, ''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.'' Accordingly, employers could not use the proposed MUC calculation method (or a respirator manufacturer's MUC) to select a respirator for employees who are entering an IDLH atmosphere. OSHA found support for these proposed requirements in comments cited in the preamble to the final Respiratory Protection Standard. These comments noted that employers should not use MUCs to select respirators for employees exposed to IDLH

29 CFR 1910.1000. The Agency found that less than 0.01% of the exposures to these substances exceeded an APF of 1,000.

atmospheres (Ex. 1–54–381), or stated that employees should not use air-purifying respirators, including powered air-purifying respirators, while exposed to IDLH or oxygen-deficient atmospheres (Ex. 1–54–38); these commenters believed that the MUCs (and the APFs on which they are based) would not protect employees under these extremely hazardous exposure conditions.

For employees exposed to IDLH conditions, employers must select a respirator according to the requirements specified by paragraph (d)(2) of OSHA's Respiratory Protection Standard. Paragraph (d)(2) requires employers to select 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, for IDLH exposures. 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 and respirator authorities, including NIOSH, ANSI, and both labor and management, agree that, for IDLH atmospheres, the most highly protective respirators, with escape capability, should be required (63 FR 1201).

The last proposed MUC provision, paragraph (d)(3)(i)(B)(*4*), requires 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.'' As with manufacturers' MUCs, these limiting factors would take precedence over the calculated MUC when they result in lower employee exposures to the hazardous substances than the calculated MUC; consequently, employees would receive increased protection against these hazardous substances.

This proposed paragraph cites several performance limits (*i.e.*, the IDLH or LEL for a hazardous substance, or the service life of a cartridge or canister) as examples of limiting factors. In this regard, OSHA is including these limiting factors as examples only; other limiting factors specified in a variety of OSHA standards, or used by employers to meet their obligation to provide a safe and healthful workplace, also would be applicable to this proposed requirement. In addition, commenters cited in the preamble to the final Respiratory Protection Standard believed that employers should not rely on MUCs determined using the proposed calculation method to estimate the service life of cartridges and canisters (Exs. 1–54–153, 1–54–165A, 1–54–222, 1–54–381).

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

1. Introduction

The substance-specific standards in 29 CFR parts 1910, 1915, and 1926 specify numerous requirements for regulating employee exposure to toxic substances, including APFs for respirator selection. Under this proposed rulemaking, OSHA would revise the provisions in its substance-specific standards that regulate APFs (except the APF requirements for the 1,3-Butadiene Standard at 29 CFR 1910.1051). These proposed revisions would remove the APF tables from these standards, as well as any references to these tables, and would replace them with a reference to the APF and MUC provisions specified in proposed paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of the Respiratory Protection Standard at 29 CFR 1910.134. The Agency believes that the proposed revisions would simplify compliance for employers by removing many inconsistencies in APF requirements across its substance-specific standards; therefore, the proposed revisions would enhance consolidation and uniformity of these requirements. Accordingly, the purpose of revising the APF provisions of OSHA's substance-specific standards is to conform these standards, to the extent possible, to each other and to general APF and MUC requirements specified by 29 CFR 1910.134.

The proposed revisions would improve the substance-specific standards because the Agency developed these proposed APF requirements after careful review and analysis of the available scientific data and the most recent consensus standards (*i.e.*, the APF provisions in the NIOSH RDL and the ANSI Z88.2–1992 respiratory protection standard). In this regard, the Agency preliminarily finds that the proposed APFs are a significant improvement over the existing NIOSH and ANSI APFs because it developed them based on the latest WPF and SWPF studies, and used advanced statistical methods to identify common and unique variance among respirator classes. Therefore, the proposed APFs represent the best data and analytic techniques available, thereby lending a high degree of reliability and validity to the results. Accordingly, the proposed APFs will provide employers with confidence that their employees will receive the level of protection from airborne contaminants signified by these APFs. In addition, applying the proposed APFs to the substance-specific standards is consistent with OSHA's goal of bringing uniformity to its respiratory-protection requirements. Moreover, protection for workers is increased since the proposed APFs will provide equivalent or increased protection compared to the ANSI Z88.2–1992 standard, and incorporates the use of APFs into the employer's respiratory protection program. The Agency believes that superseding the APF requirements of its existing substance-specific standards would result in regulatory consistency, which would improve employer compliance with these provisions, reduce the compliance burden on the regulated community, and, consequently, further enhance the protection afforded to employees who use respirators.

In the final rulemaking for 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.) In this regard, the Agency believes that, to the extent possible, future substance-specific standards should refer to provisions of the final Respiratory Protection Standard instead of containing their own respirator requirements, including the generic APF and MUC provisions specified in this proposed rulemaking. However, on occasion a substance-specific standard may have respirator-selection requirements that supplement or supplant the generic APF and MUC provisions (*e.g.*, organic-vapor cartridge and canister procedures, prohibiting use of filtering facepieces or half-mask respirators) that are necessary for ensuring adequate employee protection against the toxic substance regulated by the standard. Accordingly, the Agency is retaining a number of existing respirator-selection provisions that are unique to the substance-specific standards; the following paragraphs describe these provisions, and provide OSHA's rationale for retaining them.

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

As noted earlier in this section, OSHA is not proposing to revise the respirator-selection provisions of the 1,3-Butadiene Standard (''BD Standard''). Therefore, the APFs located in Table 1 (''Minimum Requirements for Respiratory Protection for Airborne BD'') of the BD Standard would remain as currently published in paragraph (h)(3) (''Respirator selection'') of 29 CFR 1910.1051.

The BD Standard requires that employers use respirators during work operations when engineering and work-practice controls ''are not yet sufficient to reduce employee [BD] exposures to or below the [permissible exposure limits]'' [*see* 29 CFR 1910.1051(h)(1)(iii)]. Employers must select these respirators based on the APFs listed in Table 1 of the BD Standard; in addition, they must equip air-purifying respirators with organic-vapor cartridges or canisters.

OSHA adopted the APFs in Table 1 from the Respirator Decision Logic developed by the National Institute for Occupational Safety and Health (NIOSH), even though a negotiated agreement between manufacturers who use BD and the unions representing their employees recommended the more permissive ANSI Z88–1992 APFs.

In the preamble to the final BD Standard, the Agency 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.) While developing the final BD Standard, OSHA reviewed the breakthrough test data that were available for organic-vapor cartridges and canisters challenged against BD (and summarized in Table X–1 of the preamble to the final BD Standard; see 61 FR 56817). Based on this review, 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.

In summary, test data cited by the Agency in the final BD Standard demonstrate short breakthrough times for BD concentrations above 50 ppm. Accordingly, these short breakthrough times justified limiting to 50 ppm the upper limit at which employees can use air-purifying respirators for protection against BD exposures. From the Agency's analysis of these data, OSHA also developed change schedules for cartridges and canisters that are unique for BD exposures (*see* Table 1 of the BD Standard). Additionally, these conclusions still are likely to be valid because OSHA reviewed the test data only six years ago (*i.e.*, 1996). Therefore, the Agency is proposing to retain the conservative NIOSH APFs as necessary to protect employees from BD exposures. Nevertheless, OSHA is asking employers and employees who are subject to the provisions of the existing BD Standard to provide additional information that supports retaining the existing APFs or adopting the generic APFs specified under this proposed rulemaking (See Section VII , Issues, of this preamble).

3. Retaining the Respirator-Selection Provisions in Other Substance-Specific Standards

While OSHA is proposing to retain the existing BD Standard in its entirety, it also is proposing to retain a number of respirator-selection provisions in other substance-specific standards as well. The respirator-selection requirements proposed for retention often provide protection against a hazardous characteristic or condition that is unique to the regulated substance. Additionally, OSHA believes that retaining these requirements in their present form (except for plain-language revisions, as appropriate) would not increase existing employer burden because they already must comply with these requirements; consequently, retaining these provisions will maintain the level of respirator protection currently afforded to employees. The following sections describe the most important provisions that the Agency is proposing to retain.[12]

[12] Most of the provisions described in these sections are in, or are footnotes to, the respirator-selection tables proposed for removal from the substance-specific standards. These sections also describe several other respirator-selection provisions that are not part of these tables, but which OSHA is retaining and which may be of interest to the regulated community. If this proposal does not specifically identify or describe a respirator-selection provision for removal or revision, then OSHA is retaining that provision in its existing form. The Agency believes that retaining these provisions does not increase the regulatory burden of employers because they must currently comply with them.

• Lines 13–17 [13] and 21–21 under ''Required apparatus'' in the undesignated table of 29 CFR 1910.1017 (Vinyl Chloride (VC) Standard); and footnote 1 to Table 1 of 29 CFR 1910.1028 (Benzene Standard). These provisions specify a minimum service life for cartridges and canisters used to protect employees during exposure to these substances. In the VC Standard, employers must provide organic-vapor cartridges or canisters with a service life of at least one hour at VC concentrations up to 10 ppm when using chemical-cartridge respirators. These cartridges and canisters must have a service life of at least four hours at VC concentrations up to 25 ppm when using a canister with a powered air-purifying respirator that has a hood, helmet, half-mask, or full facepiece; the four-hour service-life requirement also applies when an employee uses a gas mask, but in this case, the employee must use a front-or back-mounted canister. According to the Benzene Standard, employers must 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%; testing for canisters used with tight-fitting and loose-fitting powered air-purifying respirators must be at flow rates of 115 Lpm and 170 Lpm, respectively.

The Agency believes that these minimum service-life specifications ensure that employers use the designated respirators at appropriate concentration levels of the regulated substances. Accordingly, OSHA is proposing to retain these specifications to provide employees with a minimum level of cartridge and canister endurance when they use the designated respirators at these concentrations. While retaining these specifications may limit employers' flexibility in adopting change schedules, the Agency considers this limitation warranted in view of the properties of the substance that require greater protection or a higher level of protection for employees. Moreover, retaining these specifications adds no regulatory burden on employers because they must use the specifications under the existing standards.

• Paragraphs (h)(3)(ii), and lines 6, 7, 10, and 11 under ''Required respirator'' in Table II of 29 CFR 1910.1018 (Inorganic Arsenic Standard); lines 1–4

[13] Only lines with written text were counted in determining the number of lines; blank lines that occurred before a written line were ignored for counting purposes.

under ''Respirator type'' in Table 1 of 29 CFR 1910.1028 (Benzene Standard); line 1 under ''Minimum required respirator'' in Table 1 of 29 CFR 1910.1047 (Ethylene Oxide Standard); lines 1–4 under ''Minimum respirator required'' in Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard); and lines 1–3 and 8, and footnote 2, under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline (MDA) Standards).

These paragraphs identify the types of cartridges and canisters employers must select under specific respirator-use conditions. The Inorganic Arsenic Standard requires employers to provide employees with: Air-purifying respirators that have a combination high-efficiency particulate air (HEPA) filter with an appropriate gas-sorbent cartridge or canister when their exposure exceeds the permissible exposure level for inorganic arsenic, and their exposure also exceeds the relevant limit for other gases; 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 $\mu g/m^3$; and half-mask air-purifying respirators equipped with HEPA filters and acid-gas cartridges when the inorganic arsenic concentration is at or below 100 $\mu g/m^3$. The Benzene Standard specifies that employers must use an organic-vapor cartridge or canister with air-purifying respirators, and a chin-style canister with full facepiece gas masks. The Ethylene Oxide Standard states that employers are to equip air-purifying, full facepiece respirators with front- or back-mounted canisters approved for protection against ethylene oxide, while the same respirators under the Formaldehyde Standard must use a cartridge or canister approved for protection against formaldehyde. The MDA Standard requires that employers provide air-purifying respirators with a combination HEPA filter and organic-vapor cartridge or canister when MDA is in liquid form or is part of a heated process.

• Line 1 under ''Required respirator'' in Table 1 of 29 CFR 1910.1001, 1915.1001, and 1926.1101(Asbestos Standards); line 6 under ''Required respirator'' in Table I of 29 CFR 1910.1029 (Coke Oven Emissions Standard); and line 2 under ''Required respirator'' in Table I of 29 CFR 1910.1043 (Cotton Dust Standard).

These provisions prohibit the use of disposable respirators (single-use respirators in the Coke Oven Emissions Standard) to protect employees against these toxic substances; the Cotton Dust Standard prohibits their use at exposures greater than five times the permissible exposure level (PEL). However, the Agency does not define the terms ''disposable respirator'' or ''single-use respirator'' in any of its standards, including its Respiratory Protection Standard at 29 CFR 1910.134; therefore, to update these requirements, the Agency is proposing to replace these terms with ''filtering facepiece,'' which it defines in paragraph (b) of 29 CFR 1910.134. OSHA believes this revision will not only make these provisions consistent with its new Respiratory Protection Standard, but will prevent employers from using respirators not designed with the high-efficiency particulate filters necessary to capture respirable asbestos fibers (*see* 51 FR 22718) and coke oven emissions (*see* 41 FR 46773–46774), and, in the case of cotton dust, to provide protection at exposure levels higher than five times the PEL (*see* 50 FR 51153–51154).

• Paragraphs (h)(2)(iv) of 29 CFR 1915.1001 and (h)(3)(iii) of 29 CFR 1926.1101 (Asbestos Standards) also prohibit employers from selecting disposable respirators for employees who conduct specific types of Class II and III asbestos work. Consistent with the explanation and rationale provided in the previous section, OSHA is proposing to revise the term ''disposable respirator'' to ''filtering facepiece'' in these standards. The Agency also is proposing to revise these paragraphs, as well as paragraph (h)(2)(v) of 29 CFR 1915.1001 and (h)(3)(iv) of 29 CFR 1926.1101 (which address respirator selection for conducting Class I asbestos work in regulated areas), into plain language to clarify the multifaceted requirements specified by these paragraphs. By improving employer understanding of the respirator-selection requirements, OSHA believes that the revisions proposed for these paragraphs would enhance employee protection without increasing employers' regulatory burden.

• Lines 2, 3, and 4 under ''Required respirator'' in Table 1 of 29 CFR 1910.1001, 1915.1001, and 1926.1101(Asbestos Standards); lines 5–6, 8, and 11 under ''Required respirator'' in Table I , and lines 6 and 10 under ''Required respirator'' in Table II, of 29 CFR 1910.1018 (Inorganic Arsenic Standard); lines 1, 2, and 3 under ''Required respirator'' in Table II of 29 CFR 1910.1025 (Lead Standard); lines 1, 3, 5, 6, and 10 under ''Required respirator type'' in Table 2 of 29 CFR 1910.1027 (Cadmium Standard); lines 1, 3, 4, and 5 under ''Required respirator'' in Table I of 29 CFR 1910.1043 (Cotton Dust Standard); lines 1, 2, 3, and 8 under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline Standard); lines 1, 3–4, 7, and 8 under ''Required respirator'' in Table 1 of 29 CFR 1926.62 (Lead Standard); and lines 1, 3, 6, 8, and 11 under ''Required respirator type'' in Table 1 of 29 CFR 1926.1127 (Cadmium Standard).

Under these provisions, employers must equip air-purifying (including powered air-purifying) respirators with high-efficiency particulate air (HEPA) filters, high-efficiency and high-efficiency particulate filters (defined as a filter that is at least 99.97% efficient against mono-dispersed particles of 0.3 micrometers in diameter or larger), and particulate filters (for the Cotton Dust Standard only). While OSHA is proposing to retain these provisions, it is also proposing to replace the terms ''high-efficiency filters'' and ''high-efficiency particulate filters'' with the term ''HEPA filters.'' These three terms have the same meaning, so use of the term ''HEPA'' would impose no additional burden on employers, nor would it diminish employee protection. The Agency believes that the usual and customary practice among employers in the cotton-dust industry is to use HEPA filters with air-purifying respirators; therefore, employers should experience no additional burden, and employee protection should remain at current levels, as a result of this revision. In addition, the proposed revision would make the filter requirements of the Cotton Dust Standard consistent with other OSHA substance-specific standards and with its Respiratory Protection Standard, thereby reducing any confusion that may exist among the regulated community regarding the appropriate filter to use with air-purifying respirators.

• Footnote 2 to Table II of 29 CFR 1910.1018 (Inorganic Arsenic Standard). This provision prohibits the use of half-mask respirators for protection against arsenic trichloride because it is rapidly absorbed through the skin. OSHA is retaining this provision to protect employees from the cumulative toxic effects that result from skin absorption.

• Footnote 2 to Table II of 29 CFR 1910.1025, and footnote 2 to Table 1 of 29 CFR 1926.62 (Lead Standard). These footnotes specify that employers must provide employees with full facepiece respirators when employees experience eye or skin irritation that results from exposure to lead aerosols at use concentrations. These provisions prevent serious eye and skin injuries among employees.

• Footnote b to Table 2 of 29 CFR 1910.1027 and footnote b to Table 1 of

29 CFR 1926.1127 (Cadmium Standard). These provisions require a full facepiece respirator when an employee experiences eye irritation, thereby reducing the risk of eye injury among employees.

• Table 1 of 29 CFR 1910.1047 (Ethylene Oxide (EtO) Standard). This table lists only full facepiece respirators, or respirators with hoods or helmets, implying that employers must not select half-mask respirators for protection against EtO. The preamble to the final EtO Standard states:

> The record reflects that high exposures to EtO have been shown to cause eye irritation and that such effects may occur at exposures that may be reached for short periods. Therefore, OSHA has chosen to retain the requirement for full-facepiece respirators in the final rule. (49 FR 25781)

Accordingly, in this proposal the Agency is making explicit the prohibition against the use of half-mask respirators to ensure that employers select only those respirators (*i.e.*, full facepiece respirators, and respirators with hoods or helmets) that OSHA found, in the earlier rulemaking, will provide the requisite level of protection to their employees.

• Footnote 2 to Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard). This provision requires that employers who select half-mask respirators instead of full facepiece respirators for formaldehyde exposures up to 7.5 ppm provide effective gas-proof goggles for employees to use in combination with the half-mask respirators.

• Table 2 of 29 CFR 1910.1052 (Methylene Chloride (MC) Standard). This table lists only full facepiece respirators, or respirators with hoods or helmets, thereby indicating that employers are not to select half-mask respirators for protection against MC. In the preamble to the final MC Standard, the Agency states:

> OSHA has determined that this standard is necessary because exposure to MC places employees at significant risk of developing exposure-related adverse health effects. These effects include * * * skin and eye irritation. (62 FR 1572)

Later in the preamble, the Agency states that ''employers are required to provide employees who are at risk of skin and/ or eye contact with MC with appropriate protective clothing and eye protection.'' (*See* 62 FR 1589.)

The risk of MC-related skin and eye irritation and the need for proper skin and eye protection convinced OSHA to limit respirator selection to full facepiece respirators and respirators with hoods and helmets in the final MC Standard to ensure that employees' facial skin and eyes are protected during MC exposure. Here the Agency is directly prohibiting the selection of half-masks, and explicitly limiting respirator selection to respirators (*i.e.*, full facepiece respirators, and respirators with hoods or helmets) that would provide the appropriate level of protection to employees.

• Lines 10 and 11 under ''Respirator type'' in Table 1 of 29 CFR 1910.1028 (Benzene Standard); lines 6–11 under ''Respirator type'' in Table 1 of 29 CFR 1910.1044 (1,2-dibromo-3-chloropropane Standard); lines 16 and 17 under ''Respirator type'' in Table I of 29 CFR 1910.1045 (Acrylonitrile Standard); line12 under ''Minimum required respirator'' in Table 1 of 29 CFR 1910.1047 (Ethylene Oxide Standard); lines 11–13 under ''Minimum respirator required'' in Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard); lines 8–10 under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline Standards); lines 13 and 14 under ''Minimum respirator required'' in Table 2 of 29 CFR 1910.1052 (Methylene Chloride Standard).

These provisions specify which respirators employers are to use under emergency-escape conditions. With regard to respirators used for escape, OSHA adopts the same position it did in the final rulemaking for the Respiratory Protection Standard. In the final rulemaking for this standard, the Agency noted the variety of escape respirators permitted under its substance-specific standards, and found that these standards addressed hazards associated with many different substances and escape situations. In support of this conclusion, the Agency cited the following examples:

> [U]nder current 29 CFR 1910.1050, the standard covering exposure to methylenedianiline (MDA), escape respirators may be any full facepiece air-purifying respirator equipped with HEPA cartridges, or any positive pressure or continuous flow self-contained breathing apparatus with full facepiece or hood; for formaldehyde exposure, escape respirators may be a full facepiece with chin style, front, or back-mounted industrial canister approved against formaldehyde (29 CFR 1910.1048).

(63 FR 1202.) As noted earlier in this section, the adverse physical effects of specific substances (*e.g.*, skin and eye irritation) often limit respirator selection; these limitations would apply as well to the selection of escape respirators. Accordingly, OSHA is retaining the requirements for escape respirators identified in the existing substance-specific standards because previous rulemakings identified these respirators based on the unique characteristics of the regulated substances, as well as the conditions under which employees must use escape respirators.

As is required currently, respirators covered by these emergency-escape provisions must meet the requirements of paragraph (d)(2)(ii) of OSHA's Respiratory Protection Standard, which specifies that these respirators must be NIOSH-certified for escape from the atmosphere in which employees will use them. In addition, employees are to use these respirators only for escaping from, not entering, IDLH atmospheres. For entering such atmospheres, paragraph (d)(2)(i) of the Respiratory Protection Standard requires that employees use only full facepiece, pressure demand SCBAs certified by NIOSH for a minimum service life of 30 minutes, or full facepiece, pressure demand SARs with an auxiliary self-contained air supply.

• Paragraphs (g)(2)(ii) of 29 CFR 1910.1001, (h)(2)(iii)(A) of 29 CFR 1915.1001, and (h)(3)(ii) of 29 CFR 1926.1101 (Asbestos Standards); (f)(3)(ii) of 29 CFR 1910.1025 (Lead Standard); (f)(3)(ii) of 29 CFR 1910.1043 (Cotton Dust Standard); and (g)(3)(iii) of 29 CFR 1910.1048 (Formaldehyde Standard).

These paragraphs require employers to upgrade a negative pressure respirator, or a non-powered air-purifying respirator in the case of the Cotton Dust Standard, to a tight-fitting powered air-purifying respirator (PAPR) when the employee chooses to use a tight-fitting PAPR; for the Formaldehyde Standard, this requirement applies when the employee has difficulty using a negative pressure respirator and the tight-fitting PAPR provides the employee with adequate protection against the airborne contaminant. OSHA is proposing to retain these requirements because tight-fitting PAPRs increase the protection provided to employees when the respirator-selection provisions identify a low-end respirator (*i.e.*, a negative pressure respirator or a non-powered air-purifying respirator) for use.

• Paragraph (h)(2)(iii)(B) of 29 CFR 1915.1001 (Asbestos Standard). The Agency also is proposing to retain this paragraph in the Asbestos Standard for Shipyards, which specifies that employers must inform employees that they (the employees) may require employers to provide them with a tight-fitting PAPR instead of a negative pressure respirator. This requirement provides an extra margin of protection to employees by ensuring that employers take positive action to inform them of their option to upgrade to a more protective respirator than the one that they would normally receive for use when exposed to asbestos.

• While the paragraphs described in the previous section require employers to upgrade employee respirators, every substance-specific standard has a provision, usually as a footnote to its APF table, that gives employers discretion to select respirators that provide employees with more protection from atmospheric contaminants than the required respirator. Under this proposal, the Agency would consolidate this discretionary alternative into a generic provision in proposed paragraph (d)(3)(i)(A) of the Respiratory Protection Standard (*i.e.*, ''[employees must * * * select a respirator that meets or *exceeds* the required level of employee protection'' [emphasis added]). The Agency concludes that relocating this provision in proposed paragraph (d)(3)(i)(A) of the Respiratory Protection Standard will highlight this alternative to employers, and will encourage more of them to select more protective respirators for their employees than is now the case.

4. Substantive Revisions to the Respirator-Selection Requirements in Substance-Specific Standards

OSHA is proposing to revise respirator-selection requirements in several substance-specific standards that regulate employee exposure to organic-vapor substances. The following sections describe these proposed revisions.

• Paragraphs (g)(2) of 29 CFR 1910.1017 (Vinyl Chloride Standard), (g)(2)(i) of 29 CFR 1910.1028 (Benzene Standard), (h)(2)(i) of 29 CFR 1910.1045 (Acrylonitrile Standard), and (g)(2)(i) of 29 CFR 1910.1048 (Formaldehyde Standard). These paragraphs exempt employers from paragraphs (d)(3)(iii)(B)(1) and (B)(2) of OSHA's Respiratory Protection Standard; the exempted paragraphs consist of respirator-selection provisions that protect employees against gases and vapors. Because OSHA would be removing the existing change schedules from these substance-specific standards under this proposed rulemaking, it becomes necessary to identify requirements that it believes would provide employees with at least the same level of protection as the existing provisions. These requirements are paragraphs (d)(3)(iii)(B)(1) and (B)(2) of its Respiratory Protection Standard; by removing the current exemptions, employers would apply paragraphs (d)(3)(iii)(B)(1) and (B)(2) of the Respiratory Protection Standard to select respirators that protect employees against the gases and vapors regulated by these substance-specific standards. In addition, this revision would provide employers with increased flexibility in selecting respirators without adding to their compliance burden (*i.e.*, their existing respirator-selection procedures would be acceptable under this revision). (Note that the exemption would still remain for the 1,3-Butadiene Standard because, as noted above, the Agency is retaining the existing respirator-selection provisions of that standard.)

• Paragraph (g)(2)(ii) of 29 CFR 1910.1048 (Formaldehyde Standard). This paragraph specifies a change schedule for chemical cartridges and canisters used for formaldehyde exposures that do not have an end-of-service life indicator (ESLI) approved by NIOSH. OSHA is proposing that employers select respirators according to paragraphs (d)(3)(iii)(B)(1) and (B)(2) of its Respiratory Protection Standard instead of these requirements.

The paragraphs proposed for removal require employers who use a change schedule to select a cartridge or canister that has a NIOSH-approved ESLI, or to use a change schedule for which they must provide ''objective information or data that will ensure that canisters and cartridges are changed before the end of their service life'' (*see* paragraph (d)(3) of OSHA's Respiratory Protection Standard). When they choose the latter option, this revision would limit the change schedule to one work shift because of possible vapor migration in the cartridges and canisters during storage. The Agency believes that this revision would: Provide employers with flexibility to use other change schedules when a NIOSH-approved ESLI is not available; not increase the regulatory burden of employers because the existing change schedule would remain valid; and ensure that employees receive at least the same level of protection as they receive with the existing change schedule, because employers must use a change schedule that they can demonstrate is safe for this purpose.

5. Use of Plain Language for Proposed Revisions

Whenever possible, OSHA is using plain language in revising the regulatory text of the substance-specific standards identified in this proposal. The Agency believes that this approach improves the comprehensibility and uniformity of the proposed revisions. OSHA believes that these improvements would enhance employer compliance with the provisions, thereby increasing the level of protection afforded to employees.

6. Summary of Superseding Actions

The following table summarizes OSHA's proposed revisions to existing substance-specific standards. This table lists only those provisions for which the Agency is proposing substantive revisions (*e.g.*, proposing to replace existing requirements with new requirements); it does not list provisions that OSHA is proposing to retain in their present form (although the Agency is rewriting them in plain language).

SUMMARY OF SUPERSEDING ACTIONS FOR SPECIFIC STANDARDS

Existing section (29 CFR 1910)	Proposed 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)	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 I and revise.
1045(h)(2)(i)	Revise.
1045(h)(3)	Remove Table I and revise.
1047(g)(3)	Remove Table I 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.

Existing section (29 CFR 1915)	Proposed action (29 CFR 1915)
1001(h)(2)(i) through (h)(2)(v).	Remove Table 1 and revise.

Existing section (29 CFR 1926)	Proposed action (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.

Section XII (''Proposed Amendments to Standards'') of this notice provides the full regulatory text of the proposed revisions to OSHA's existing substance-specific standards dealing with respirator selection. This section describes both substantive revisions proposed for the existing respirator-selection requirements, as well as respirator-selection requirements retained in their current form but rewritten in plain language.

VIII. Issues

OSHA requests the public to comment on, and to provide additional information regarding, any of the issues listed below. Please provide a detailed explanation of each response you make.

Developing and Updating APFs

1. Is the method used by OSHA in developing the proposed APFs appropriate? OSHA used a multi-faceted approach incorporating both analyses of data collected in WPF and SWPF studies, as well as OSHA's review of all relevant materials. OSHA requests comment on the usefulness of this approach to data collection.

2. Are there any additional studies that may be useful in determining APFs, that have not already been identified by OSHA in Section IV of this proposal? Please provide these to the Agency.

3. Are statistical analyses, treatments, or approaches, other than those described in Section IV of the proposal, available for differentiating between or comparing the highly variable respirator-performance data?

4. OSHA is aware of discussions within the respirator community indicating some sentiment for setting APFs for filtering facepiece respirators at 5, and for setting an APF of 10 for other half-mask air-purifying respirators. Based upon OSHA's reviews, OSHA cannot differentiate between the performance of the two types of respirator, and OSHA finds compelling evidence from the large number of observed data points (N = 917 Co/Ci pairs) to support proposing an APF of 10 for both of these classes of respirators. Is there evidence that a different APF should be provided for these respirator classes?

5. While there are no WPF or SWPF studies for quarter-mask respirators, the 1976 LANL Respiratory Protection Factor by Hyatt found protection factors ranging from 5 to 10. Should OSHA continue to include quarter-masks in the half-mask class, or separate them into a class of their own with and APF of 5?

6. OSHA is proposing a method by which to separate loose-fitting facepiece supplied-air and PAPR hood/helmet respirators from the better-performing hood/helmet respirators. Respirator performance studies have shown that some PAPR and continuous-flow supplied-air respirators provide greater protection than others of the same class. The 1987 NIOSH Respirator Decision Logic gives an APF of 25 for all of these respirators while ANSI's 1992 respirator standard gives an APF of 25 to loose-fitting facepiece models and an APF of 1000 to hood/helmet models. OSHA is proposing an APF of 25 except for those models that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with a protection factor of 1000 or greater, in which case those models would receive an APF of 1000. Is this the appropriate method by which to distinguish high-performing hood/helmet respirators from others?

7. The assigned protection factor for a full facepiece respirator in Table 1 of the proposed standard does not currently take into account the type of particulate filter that is used. An N95 particulate filter could potentially, under a worst case scenario, have up to 5% leakage through the filter. This would decrease the APF for a full facepiece respirator to a maximum of 20 when N95 filters are used. Should OSHA take into account the limitations of the filter and assign an APF of 20 for full facepiece respirators when N95 filters are used?

8. Other Federal Agencies, such as the Nuclear Regulatory Commission (NRC), have set no APF for filtering facepiece air-purifying respirators (APRs) for use in their particular work environments. In some cases, such APRs are not allowed to be used at all. In other settings, *e.g.*, the healthcare industry, some employers rely very heavily upon such APRs to protect their employees who work with patients who have infectious airborne illnesses. How should OSHA incorporate such information, if at all, into an APF requirement for all industries under OSHA's jurisdiction?

9. Proper facepiece fit is important in achieving the proposed APF for tight-fitting respirators. Accordingly, the Agency would appreciate receiving information on current testing and procedures used by respirator manufacturers to ensure that the facepieces they make will fit respirator users properly.

10. When a limiting factor such as IDLH, LEL, or the performance limit specified for a cartridge and canister by the manufacturers are less than the calculated MUC, proposed paragraph (d)(3)(i)(B)(*4*) requires employers to set the MUC at the lower limit. Accordingly, OSHA is seeking comment on the following questions:

a. What other limiting factors should OSHA include as examples in this proposed paragraph?

b. Should the Agency specify the LEL or 10% of the LEL as the limiting factor?

11. Some hazardous substances found in the workplace do not have an OSHA PEL. However, a number these substances may have an exposure limit designated by sources other than OSHA (*e.g.*, recommended by the chemical manufacturer, ACGIH, NIOSH, EPA). Accordingly, the Agency is asking for comment on the following issues involving MUCs:

a. Should OSHA expand the definition and application of MUC to hazardous substances that it does not regulate?

b. Should the Agency require employers to determine MUCs for substances that have no OSHA PEL (*i.e.*, substances not regulated specifically by OSHA), and to base respirator selection on such a determination?

c. For hazardous substances that OSHA does regulate, should it require employers to comply with the MUC values developed by NIOSH when these values are lower than the calculated MUC values (*i.e.*, MUC = APF $\times$ PEL)?

12. A prevailing view is that exposure to multiple contaminants in the workplace affect the performance of respirator filters and cartridges differently than exposure to single contaminants. To assist it in developing MUCs for single and multiple contaminants, OSHA is asking the public to address the following issues:

a. What information and data are available that either support or do not support this view?

b. Should MUCs for contaminant mixtures differ from MUCs for single mixtures?

13. Section VII proposes to revise most of the respirator-selection requirements in OSHA's substance-specific standards. Accordingly, the Agency is asking for comment on the following questions:

a. This proposal excludes the respirator-selection provisions of the 1,3-Butadiene Standard from any revision. Is this exclusion warranted?

b. Special or unique respirator-selection requirements in the substance-specific standards (*e.g.*, requirements for emergency-escape, HEPA filters, upgrading respirators at the employee's request, eye protection) remain largely intact. Should the Agency standardize these provisions across all of its substance-specific standards, and, if so, what requirements should it standardize.

14. The Agency has developed its Preliminary Economic Analysis (PEA) based on survey data indicating what types of respirators employees are using currently. The Agency does not, however, have data on the exposure levels as a multiple of the PEL that respirator users are currently exposed to. For the purposes of this analysis, the Agency has used its internal Integrated Management and Information System (IMIS) data to estimate the distribution of exposures as a multiple of the PEL. The Agency also assumes that employers are currently using the respirator with the lowest possible costs that can still satisfy existing guidance on APFs, allowing employees to be exposed up to the full limit of a currently assigned APF for that class of respirator. OSHA seeks comment on whether other data sources or methodologies for making this projection exist.

a. Is it common for employers to put employees in respirators at the highest exposure levels permitted by the APF range?

b. Are there particular types of respirators that frequently do not fit this pattern (*i.e.*, are selected for reasons other than having a high APF or due to a medical reason for a particular employee)?

c. How do employers approach the issue of uncertainty in possible exposure levels when integrating APFs into their respirator selection?

d. To what extent will having a single OSHA APF table result in less confusion than the existing multiplicity of APF tables?

e. Do OSHA's cost estimates of using different types of respirators adequately represent all of the costs associated with each type of respirator use?

f. Are their any alternative approaches consistent with the OSH Act that could reduce the burden of this standard on small entities?

IX. Public Participation—Comments and Hearings

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal, and by providing oral testimony and documentary evidence at the informal public hearing that the Agency will convene after the comment period ends. In this regard, the Agency invites interested parties having knowledge of, or experience with, APFs and MUCs to participate in this process, and welcomes any pertinent data and cost information that will provide it with the best available evidence on which to develop the final regulatory requirements.

This section describes the procedures the public must use to submit their comments to the docket in a timely manner, and to schedule an opportunity to deliver oral testimony and provide documentary evidence at the informal public hearings. Comments, notices of intention to appear, hearing testimony, and documentary evidence will be available for inspection and copying at the OSHA Docket Office. You also should read the sections above titled **DATES** and **ADDRESSES** for additional information on submitting comments, documents, and requests to the Agency for consideration in this rulemaking.

Written Comments. OSHA invites interested parties to submit written data, views, and arguments concerning this proposal. In particular, OSHA would encourage interested parties to comment on the issues raised in section VIII (''Issues'') of the preamble. When submitting comments, parties must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES.** The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the proceedings record, and will be available for public inspection and copying at the OSHA Docket Office.

Informal Public Hearings. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity at an informal public hearing to provide oral testimony concerning the issues raised in this proposal. The hearings will commence at 9:30 a.m. on the first day. At that time, the presiding administrative law judge (ALJ) will resolve any procedural matters relating to the proceeding. The hearings will reconvene on subsequent days at 8:30 a.m.

The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of such hearings is an ALJ, and questioning by interested parties is allowed on crucial issues, the proceeding is informal and legislative in purpose. Therefore, the hearing provides interested parties with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. In addition, the hearing is an informal administrative proceeding, rather than adjudicative one in which the technical rules of evidence would apply, because its primary purpose is to gather and clarify information. The regulations that govern public hearings, and the pre-hearing guidelines issued for this hearing, will ensure participants fairness and due process, and also will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will favor development of the record.

Conduct of the hearing will conform to the provisions of 29 CFR part 1911, ''Rules of Procedure for Promulgating, Modifying, or Revoking Occupational Safety and Health Standards.'' The regulation at 29 CFR 1911.4 ''Additional or Alternative Procedural Requirements,'' specifies that the Assistant Secretary may, on reasonable notice, issue alternative procedures to expedite proceedings or for other good cause. Although the ALJs who preside over these hearings make no decision or recommendation on the merits of OSHA's proposal, they do have the responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner.

To ensure that interested parties receive a full and fair informal hearing as specified by 29 CFR part 1911, the ALJ has the authority and power to: Regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine the presentations to matters pertinent to the issues raised; use appropriate means to regulate the conduct of the parties who are present at the hearing; question witnesses, and permit others to question witnesses; and limit the time for such questioning. At the close of the hearing, the ALJ will establish a post-hearing comment period for parties who participated in the hearing. During the first part of this period, the participants may submit additional data and information to OSHA, while during the second part of this period, they may submit briefs, arguments, and summations.

Notice of Intention To Appear To Provide Testimony at the Informal

Public Hearings. Interested parties who intend to provide oral testimony at the informal public hearings must file a notice of intention to appear by using the procedures specified above in the sections titled DATES and ADDRESSES. This notice must provide the: Name, address, and telephone number of each individual who will provide testimony, and their preferred hearing location; capacity (*e.g.*, name of the establishment/organization the individual is representing; the individual's occupational title and position) in which each individual will testify; approximate amount of time required for each individual's testimony; specific issues each individual will address, including a brief statement of the position that the individual will take with respect to each of these issues; and any documentary evidence the individual will present, including a brief summary of the evidence.

OSHA emphasizes that the hearings are open to the public, and that interested parties are welcome to attend. However, only a party who files a proper notice of intention to appear may ask questions and participate fully in the proceedings. While a party who did not file a notice of intention to appear may be allowed to testify at the hearing if time permits, this determination is at the discretion of the presiding ALJ.

Hearing Testimony and Documentary Evidence. Any party requesting more than 10 minutes to testify at the informal public hearing, or who intends to submit documentary evidence at the hearing, must provide the complete text of the testimony and the documentary evidence as specified above in the sections titled DATES and ADDRESSES. The Agency will review each submission and determine if the information it contains warrants the amount of time requested. If OSHA believes the requested time is excessive, it will allocate an appropriate amount of time to the presentation, and will notify the participant of this action, and the reasons for the action, prior to the hearing. The Agency may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements; in such instances, OSHA may request the participant to return for questioning at a later time.

Certification of the Record and Final Determination After the Informal Public Hearing. Following the close of the hearing and post-hearing comment period, the presiding ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health; the record will consist of all of the written comments, oral testimony, and documentary evidence received during the proceeding. However, the ALJ does not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review the proposed APF provisions in light of all the evidence received as part of the record, and then will issue the final APF provisions based on the entire record.

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

Assigned protection factors, Hazardous substances, Health, Occupational safety and health, Respirators, Respirator selection.

Authority and Signature

John L. Henshaw, 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 the proposed 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 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); 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 May 28, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

X. Proposed Amendments to Standards

OSHA proposes to amend 29 CFR parts 1910, 1915, and 1926 as follows:

PART 1910—[AMENDED]

Subpart I—[Amended]

1. The authority citation for subpart I of part 1910 is revised 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), or 3–2000 (62 FR 50017).

Sections 1910.132, 1910.134, and 1910.138 or 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. Section 1910.134 is amended as follows:

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

b. The text of paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) is added; and

c. Paragraph (n) is revised.

The added and revised text read 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 29 CFR 1910.134.

* * * * *

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.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) *Assigned Protection Factors (APFs).* Employers must use the assigned protection factors listed in Table I 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.

Note to paragraph (d)(3)(i)(A): The assigned protection factors listed in Table I 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.

TABLE I.—ASSIGNED PROTECTION FACTORS

Type of respirator [1] [2]	Half mask	Full facepiece	Helmet/hood	Loose-fitting facepiece
1. Air-Purifying Respirator	[3] 10	50		
2. Powered Air-Purifying Respirator (PAPR)	50	1000	[4] 1000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator:				
• Demand mode	10	50		
• Continuous-flow mode	50	1,000	[4] 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 [5] (maximum)	10,000 [5] (maximum)	

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 I only apply when the employer implements a continuing, effective respirator program as specified by OSHA's Respiratory Protection Standard at 29 CFR 1910.134, including training, fit testing, maintenance and use requirements.

[3] This APF category includes quarter masks, filtering facepieces, and half-masks.

[4] Previous studies involving Workplace Protection Factor (WPF) and Simulated Workplace Protection Factor (SWPF) testing on helmet/hood respirators show that some of these respirators do not provide a level of protection consistent with an APF of 1000. Therefore, 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 1000 or greater, receive an APF of 1000. All other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.

[5] Although positive pressure SCBAs appear to provide the highest level of respiratory protection, a SWPF study of SCBA users concluded that all users may not achieve protection factors of 10,000 at high work rates. When employers can estimate hazardous concentrations for planning purposes, they must use a maximum assigned protection factor no higher than 10,000.

(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.

Note to paragraph (d)(3)(i)(B)(1): 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.

(*2*) Employers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.

(*3*) 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.

(*4*) When 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.

* * * * *

(n) *Effective date.* Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective September 4, 2003.

* * * * *

Subpart Z—[Amended]

3. The general authority citation for subpart Z of part 1910 is revised 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. Section 1910.1001 is amended 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 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 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 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 µg/m³; and half-mask air-purifying respirators equipped with HEPA filters and acid-gas cartridges when the inorganic arsenic concentration is at or below 100 µg/m³.

* * * * *

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 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 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 air-purifying respirators, and a chin-style canister with full-facepiece gas masks.

(D) Ensure that canisters used with nonpowered 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 must not select or use filtering facepieces for protection against coke oven emissions.

* * * * *

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 X) the PEL.

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

(ii) Employers must provide an employee with a powered air-purifying respirator (PAPR) instead of a nonpowered 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 paragraph (g)(3)(i) 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 programs.* (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) If 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 if 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 provide adequate protection against their 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 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 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; or a gas mask with an organic-vapor canister.

* * * * *

PART 1915—[AMENDED]

18. The authority citation for part 1915 is revised 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), or 3–2000 (62 FR 50017).

Sections 1915.120 and 1915.152 also issued under 29 CFR 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 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.

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PART 1926—[AMENDED]

Subpart D—[Amended]

20. The authority citation for subpart D of part 1926 is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); 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 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 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 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 part of a process requiring heat.

* * * * *

22. In § 1926.62, remove Table 1 in paragraph (f)(3) 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 cause eye or skin irritation at the use concentrations.

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

* * * * *

Subpart Z—[Amended]

23. The authority citation for subpart Z of part 1926 is revised 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, 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 11.

Section 1926.1102 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 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 air-purifying respirators.

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