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Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926
Respiratory Protection; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket No. H–049]

RIN 1218–AA05

Respiratory Protection

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

ACTION: Final rule; Request for comment on paperwork requirements.

SUMMARY: This final standard, which replaces the respiratory protection standards adopted by OSHA in 1971 (29 CFR 1910.134 and 29 CFR 1926.103), applies to general industry, construction, shipyard, longshoring, and marine terminal workplaces. The standard requires employers to establish or maintain a respiratory protection program to protect their respirator-wearing employees. The standard contains requirements for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions. The final standard also simplifies respirator requirements for employers by deleting respiratory provisions in other OSHA health standards that duplicate those in the final standard and revising other respirator-related provisions to make them consistent. In addition, the standard addresses the use of respirators in Immediately Dangerous to Life or Health (IDLH) atmospheres, including interior structural firefighting. During interior structural firefighting (an IDLH atmosphere by definition), self-contained breathing apparatus is required, and two firefighters must be on standby to provide assistance or perform rescue when two firefighters are inside the burning building.

Based on the record in this rulemaking and the Agency's own experience in enforcing its prior respiratory protection standards, OSHA has concluded that compliance with the final rule will assist employers in protecting the health of employees exposed in the course of their work to airborne contaminants, physical hazards, and biological agents, and that the standard is therefore necessary and appropriate. The final respiratory protection standard covers an estimated 5 million respirator wearers working in an estimated 1.3 million workplaces in the covered sectors. OSHA's benefits analysis predicts that the standard will prevent many deaths and illnesses among respirator-wearing employees every year by protecting them from exposure to acute and chronic health hazards. OSHA estimates that compliance with this standard will avert hundreds of deaths and thousands of illnesses annually. The annual costs of the standard are estimated to be $111 million, or an average of $22 per covered employee per year.

DATES: The final rule becomes effective April 8, 1998.

Compliance: Start-up dates for specific provisions are set forth in § 1910.134(n) of the regulatory text. However, until the Department of Labor publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB), affected parties are not required to comply with the new or revised information collection requirements contained in the following paragraphs: § 1910.134(c) written procedures for selecting respirators, medical evaluations, fit testing, use of respirators, maintaining respirators, training, and periodically evaluating the effectiveness of the program; (e)(3)–(6) medical questionnaire, examination, and information for the physician or other licensed health care professional (PLHCP); (f)(1) fit testing; (i)(4) tagging sorbent beds and filters; and (m)(1)–(2) and (4) recordkeeping. Publication of the control numbers notifies the public that the OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995. Although affected parties will not have to comply with the revised standard's information collection requirements until these have been approved by OMB, they must comply with those requirements of 29 CFR 1910.134 (OSHA's existing respirator protection standard) that have already been approved by the OMB under the Paperwork Reduction Act. Approved requirements include the written program, emergency-use respirator certification records, and emergency-use respirator compartment marking.

Comments: Interested parties may submit comments on the information collection requirements for this standard until March 9, 1998.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, as the recipient of petitions for review of the standard.

Comments on the information collection requirements of this final rule (see **SUPPLEMENTARY INFORMATION**) are to be submitted to the Docket Office, Docket No. ICR 97–5, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, N.W., Washington, D.C. 20210, telephone (202) 219–7894. Written comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 219–5046.

Copies of the referenced information collection request are available for inspection and copying in the Docket Office and will be mailed immediately to persons who request copies by telephoning Adrian Corsey at (202) 219–7075. For electronic copies of the Respiratory Protection Final Standard and the Information Collection Request, contact OSHA's WebPage on the Internet at http://www.osha.gov/.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, OSHA Office of Public Affairs, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Telephone (202) 219–8148. For additional copies of this regulation contact: OSHA, Office of Publications, U.S. Department of Labor, Room N–3101, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Telephone (202) 219–4667.

SUPPLEMENTARY INFORMATION:

1. Collection of Information: Request for Comment

This final Respiratory Protection standard contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA95), 44 U.S.C. 3501 *et seq.* (see also 5 CFR 1320). PRA95 defines collection of information to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.'' [44 U.S.C. § 3502(3)(A)]

The title, the need for and proposed use of the information, a summary of the collections of information, description of the respondents, and frequency of response required to implement the required information collection are described below with an estimate of the annual cost and reporting burden (as required by 5 CFR 1320.5 (a)(1)(iv) and § 1320.8 (d)(2)). Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OSHA invites comments on whether the proposed collection of information:

- Ensures that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Estimates the projected burden accurately, including whether the methodology and assumptions used are valid;
- Enhances the quality, utility, and clarity of the information to be collected; and
- Minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Title: Respiratory Protection, 29 CFR 1910.134.

Description: The final Respiratory Protection standard is an occupational health standard that will minimize occupational exposure to toxic substances. The standard's information collection requirements are essential components that will protect employees from occupational exposure to these toxins. The information will be used by employers and employees to implement the protection required by the standard. OSHA will use some of the information to determine compliance with the standard.

Respondents: The total number of respondents for the first year is 1,300,000, and for the second year 1,430,000 (1,300,000 (1st year) plus 10% (130,000)).

Average Time Per Response: 2.21 hours (this is the result of dividing the total number of responses (19,767,461) by the total number of burden hours (8,926,558)).

Average Time Per Firm: 6.87 hours (this represents the average time a firm would need to comply with all of the information collection provisions, including the written respiratory protection program. This is a result of dividing the total number of burden hours (8,926,558) by the total number of firms (1,300,000)).

SUMMARY OF THE COLLECTIONS OF INFORMATION

Information collection requirement	No. of responses (Yr 1)	No. of responses (Yr 2)	Frequency of response	Time per response	Total 1st year burden	Estimated cost (1st year)
Respiratory Protection Program 1910.134(c).	1,274,000	26,000	All Existing Firms to Update Existing Program.	2 Hours for Small Firms; 4 Hours for Large Firms.	2,652,000	$60,916,440
	127,400	2,600	Initially for New Employers.	8 Hours to Develop.		
			Updates (Every 5 Years).	30 Minutes for Small Firms; 1 Hour for Large Firms.		
Questionnaire Administration 1910.134(e)(3).	5,000,000	575,000	All Employees Will Receive in the First Year.	15 Minutes for Employees to Complete.	740,000	$13,593,800
			50% of those Receiving Exams Will Receive Follow-up Questionnaires.			
Medical Examinations 1910.134(e)(4)	1,150,000	287,500	23% of the Existing Employees.	All Medical Exams will Take 1.5 Hours to Complete which includes travel time.	1,021,200	$18,759,444
			2nd & Recurring Yrs—25% of the 23% would receive Follow-up Exams.			
Information Provided to PLHCP 1910.134(e)(5).	1,150,000	287,500	Dependent on the Number of Exams.	15 Minutes for Each Employee.	170,200	$2,358,972
Fit Testing 1910.134(f)(1)	4,335,000	4,335,000	346,800 Employees to Receive Quantitative Fit Tests.	30 Minutes for Employees to be Fitted (Quantitative and Qualitative Fit Testing).	3,780,140	$76,813,315
			799,640 Employees to Receive Qualitative Fit Tests.	30 Additional Minutes for Employers to Conduct (Only for In-House Fit Testing).		
			3,188,560 Employees to Receive In-House Fit Tests.			
			4,335,000 Total Employees.			
Emergency-Use Respirator Marking 1910.134(h)(2)(ii)(B).	0	260,000	Only New Employers E.	5 Minutes per Emergency-Use Respirator.	0	$0
			xisting Employers Have Already Complied (Old Requirement).			

SUMMARY OF THE COLLECTIONS OF INFORMATION—Continued

Information collection requirement	No. of responses (Yr 1)	No. of responses (Yr 2)	Frequency of response	Time per response	Total 1st year burden	Estimated cost (1st year)
Emergency-Use Respirator Certification 1910.134(h)(3)(iv)(A)&(B).	671,880	67,200	Currently, 27,995 Employers Using Emergency-Use Respirators (1st Year). 2nd Year = 1st Year Employers plus 10%.	Assuming 2 Per Employer: 10 Minutes (Total Time Per Month).	114,220	$2,098,221
Certificate of Analysis of Cylinders 1910.134(i)(4)(i)(B).	0	0	All Existing and New Employers.	Provided by Supplier, therefore no burden incurred.	0	$0
Sorbent Beds and Filters 1910.134(i)(4)(iii)(B).	74,181	74,181	Currently, 24,727 Compressors in Use.	3 Changes Per Year, assuming 5 minutes per change.	5,934	$109,008
Medical Records 1910.134(m)(1)	1,150,000	287,500	Dependent on the Number of Exams.	5 Minutes Per Employee Examined.	54,464	$754,871
Fit Testing Records 1910.134(m)(2)	4,335,000	4,335,000	Dependent on the Number of Fit Tests.	5 Minutes Per Fit Test.	348,400	$4,828,824
Employee Access 1910.134(m)(4)	500,000	500,000	10% of the Total Number of Employees.	5 Minutes per Request.	40,000	$554,400
Totals	19,767,461	11,037,481	.....	.....	8,926,558	$180,787,295

MARGINAL DIFFERENCES IN BURDEN HOURS AND COSTS (I.E., BETWEEN THE EXISTING AND REVISED STANDARDS)

Information collection requirement	Current OMB inventory existing 1910.134	Adjustment (to 1st year only)	1st yr. burden revised 1910.134	Estimated cost	2nd & recurring yr. burden revised 1910.134	Estimated cost
Respiratory Protection Program	395,489	2,256,511	2,652,000	$60,916,440	1,570,400	$36,072,088
Questionnaire Administration	–	740,000	740,000	$13,593,800	85,100	$1,563,287
Medical Examinations	–	1,021,200	1,021,200	$18,759,444	255,300	$4,689,861
Information Provided to PLHCP	–	170,200	170,200	$2,358,972	42,550	$589,743
Fit Testing	–	3,780,140	3,780,140	$76,813,315	3,780,140	$76,813,315
Emergency-Use Respirator Marking	433	–433	0	$0	448	$8,230
Emergency-Use Respirator Certification ..	785,842	–671,622	114,220	$2,098,221	11,424	$209,859
Certificate of Analysis of Cylinders	–	0	0	$0	0	$0
Sorbent Beds and Filters	–	5,934	5,934	$109,008	5,934	$109,008
Medical Records	–	54,464	54,464	$754,871	13,616	$188,718
Fit Testing Records	–	348,400	348,400	$4,828,824	348,400	$4,828,824
Employee Access	–	40,000	40,000	$554,400	40,000	$554,400
Hour Kept in Inventory for Revised 1910.134	1	–1	0	$0	0	$0
Totals	1,181,765	7,744,793	8,926,558	$180,787,295	6,153,312	$125,627,333

Under the column for ''Current OMB Inventory,'' dashes denote burdens that were not taken for the Existing Respiratory Protection Standard, but are counted in the Revised Respiratory Protection Standard. Both Medical Examinations and Fit Testing are required by the existing standard; however, because these requirements are not accompanied by a recordkeeping requirement, no burden was taken. In the revised standard, recordkeeping is required for these provisions, and thus burden is counted for these provisions.

Interested parties are requested to send comments regarding this information collection to the OSHA Docket Office, Docket No. ICR 97–5 , U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Written comments limited to 10 pages or fewer may also be transmitted by facsimile to (202) 219–5046.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the final information collection request; they will also become a matter of public record.

Copies of the referenced information collection request are available for inspection and copying in the OSHA Docket Office and will be mailed to persons who request copies by telephoning Adrian Corsey at (202) 219–7075. Electronic copies of the Respiratory Protection Final information collection request are available on the OSHA WebPage on the internet at http://www.osha.gov/ under Standards.

2. Federalism

This final standard has been reviewed in accordance with Executive Order 12612 (52 FR 41685, October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions which would restrict state policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of state law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act) expresses Congress' clear intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Where such standards are applicable to products distributed or used in interstate commerce, they may not unduly burden commerce and must be justified by compelling local conditions (see OSH Act, Section 18(c)).

The final Federal standard on respiratory protection addresses hazards which are not unique to any one state or region of the country. Nonetheless, states with occupational safety and health plans approved under Section 18 of the OSH Act will be able to develop their own state standards to deal with any special problems which might be encountered in a particular state. Moreover, because this standard is written in general, performance-oriented terms, there is considerable flexibility for state plans to require, and for affected employers to use, methods of compliance which are appropriate to the working conditions covered by the standard.

In brief, this final standard addresses a clear national problem related to occupational safety and health in general industry, construction, and maritime employment. Those states which have elected to participate under Section 18 of the OSH Act are not preempted by this standard, and will be able to address any special conditions within the framework of the Federal Act while ensuring that the state standards are at least as effective as that standard.

3. State Plans

The 25 states and territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of a final standard. These 25 states are: Alaska, Arizona, California, Connecticut, New York (for state and local government employees only), 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. Until such time as a state standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these states.

4. Unfunded Mandates

The final respiratory protection rule has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed below in the Summary of the Final Economic Analysis (FEA) (Section VI of this document), OSHA estimates that compliance with the revised respiratory protection standard will require the expenditure of more than $100 million each year by employers in the private sector. Therefore, the final rule establishes a Federal private sector mandate and is a significant regulatory action, within the meaning of section 202 of UMRA (2 U.S.C. 1532). OSHA has included this statement to address the anticipated effects of the final respiratory protection rule pursuant to section 202.

OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt an OSHA State Plan. Consequently, the respiratory protection standard does not meet the definition of a ''Federal intergovernmental mandate'' (Section 421(5) of UMRA (2 U.S.C. 658(5)). Thus, the final respiratory protection standard does not impose unfunded mandates on state or local governments.

The anticipated benefits and costs of this final standard, and other issues raised in section 202 of the UMRA, are addressed in the Summary of the FEA (Section VI of this preamble), below, and in the FEA (Ex. 196). In addition, pursuant to section 205 of the UMRA (2 U.S.C. 1535), having considered a reasonable number of alternatives as outlined in the preambles to the proposal and the final rule and in the FEA (Ex. 196), the Agency has concluded that the final rule is the most cost-effective alternative for implementation of OSHA's statutory objective of reducing significant risk to the extent feasible. This is discussed in the FEA (Ex. 196) and in the Summary and Explanation (Section VII of this preamble) for the various provisions of the final standard.

5. Executive Order 13045—Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, signed by the President on April 21, 1997, requires that for certain Federal agency ''regulatory actions submitted to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866, the issuing agency shall provide to OIRA the following information developed as part of the Agency's decisionmaking process, unless prohibited by law:

(a) An evaluation of the environmental health or safety effects of the planned regulation on children; and

(b) An explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.''

''Covered Regulatory Actions'' under this Order are rules that may:

(a) Be ''economically significant'' under Executive Order 12866 (a rulemaking that has an annual effect 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

(b) Concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

''Environmental health risks and safety risks' mean risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breathe, the food we eat, the water we drink or use for recreation, the soil we live on, and the products we use or are exposed to).

The final standard on respiratory protection does not concern ''Environmental health risks and safety risks'' to children as defined under the Executive order. The respirator standard is only concerned with means of limiting employee exposures to toxic substances. The Agency believes, therefore, that the requirement noted above to provide OIRA with certain information does not apply since the respiratory protection standard is not a

''covered regulatory action'' under Executive Order 13045.

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.'' In compliance with the requirement, the Agency has reviewed the standards proposed through this rulemaking with reference to the ANSI Z88.2–1992 standard for Respiratory Protection. OSHA has discussed the relationship between individual regulatory provisions and the corresponding consensus standards in the Summary and Explanation of the final rule.

6. Reasons Why the Revised Rule Will Better Effectuate the Purposes of the Act Than the Existing Consensus Standard

This process was facilitated by the fact that the previous OSHA standards on respiratory protection were start-up standards adopted directly from the ANSI Z88.2–1969 standard, ''Practices for Respiratory Protection'' under section 6(a) of the OSH Act, 29 U.S.C. 655(a). Therefore, even with subsequent revisions to the ANSI standards and the Agency's consideration of a widely varied and substantial body of information in the rulemaking record, the requirements of the OSHA final rule would tend to resemble the corresponding provisions of the current ANSI standards. In a number of instances, OSHA has utilized language identical to that in the current ANSI standard. These instances are noted in the Summary and Explanation. Where the Agency has determined that the pertinent ANSI language is not appropriate for this OSHA standard, the Summary and Explanation provides the basis for that decision.

I. General

The preamble accompanying this final standard discusses events leading to the final rule, the types of respiratory hazards experienced by employees, the degree and significance of the risk presented by failure to comply with this revised standard, the Final Economic Analysis, and the rationale behind the specific provisions set forth in the final standard. The discussion follows this outline:

II. Pertinent Legal Authority

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

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) if it substantially reduces or eliminates significant risk or prevents it from developing, and is economically feasible, technologically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency actions, supported by substantial evidence, and is better able to effectuate the Act's purposes than any national consensus standard it supersedes. See 58 FR 16612–16616 (March 30, 1993).

A standard is technologically feasible if 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. *American Textile Mfrs. Institute* v. *OSHA*, 452 U.S. 490, 513 (1981) (''ATMI''), *American Iron and Steel Institute* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991)(''AISI'').

A standard is economically feasible if industry can absorb or pass on the cost of compliance without threatening its long term profitability or competitive structure. See *ATMI*, 452 U.S. at 530 n. 55; *AISI*, 939 F. 2d at 980.

A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. *ATMI*, 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994)(''LOTO III'').

All standards must be highly protective. See 58 FR 16614–16615; LOTO III, 37 F.3d at 668. However, standards regulating exposure to toxic substances or hazardous physical agents must also meet the ''feasibility mandate'' of Section 6(b)(5) of the Act, 29 U.S.C. 655(b)(5). Section 6(b)(5) requires OSHA to select ''the most protective standard consistent with feasibility'' that is needed to reduce significant risk when regulating these hazards. *ATMI*, 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, 29 U.S.C. 655(b)(5). OSHA shall 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.

Section 6(b)(7) of the Act authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. 655(b)(7).

Finally, whenever practical, standards shall ''be expressed in terms of objective criteria and of the performance desired.'' Id.

Respiratory protection is a backup method which is used to protect employees from toxic materials in the workplace in those situations where feasible engineering controls and work practices are not available, have not yet been implemented, are not in themselves sufficient to protect

employee health, or in emergencies. The revisions to the respirator standard made in this rulemaking are intended to ensure that, when employers require employees to wear respirators to be protected from significant risk, protective respirators will be selected and those respirators will be used effectively to meet their design capabilities. Otherwise respirators will not reduce significant risk. The standard's provisions are designed to be feasible and cost effective, and are expressed in terms of objective criteria and the performance desired.

Further authority is provided by section 8(c)of the Act, which authorizes OSHA to require employers to maintain certain records. Section 8(g)(2) authorizes OSHA ''to prescribe such rules and regulations as (it) may deem necessary to carry out its responsibilities under the Act.''

III. Events Leading to the Final 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 Congress in the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et seq.*), OSHA 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,'' is the basis of the first six sections of OSHA's previous standard, 29 CFR 1910.134, ''Respiratory Protection.'' The seventh section was a direct, complete incorporation of ANSI Standard K13.1–1969, ''Identification of Gas Mask Canisters.'' OSHA's previous construction industry standard for respiratory protection, 29 CFR 1926.103, was promulgated in April 1971. On February 9, 1979, 29 CFR 1910.134 was formally recognized as also being applicable to the construction industry (44 FR 8577). Until the adoption of these standards by OSHA, most guidance on respiratory protective device use in hazardous environments was advisory rather than mandatory.

OSHA's maritime standards were originally promulgated in the 1960s by agencies that preceded OSHA. The original OSHA code designations of these standards and their 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). Section 1910.134 was incorporated by reference into OSHA's Marine Terminals standard (part 1917) on July 5, 1983 (48 FR 30909). OSHA has recently updated and strengthened its Longshoring and Marine Terminal standards, and both standards incorporate 29 CFR 1910.134 by reference.

OSHA did not propose to expand coverage of 29 CFR 1910.134 to agricultural workplaces covered by 29 CFR part 1928, and this final Respiratory Protection standard, like the proposal, does not apply to agricultural operations. The prior standard likewise did not apply to agricultural operations. (See 29 CFR 1928.21.) OSHA received no public comment requesting a change in coverage. Accordingly, the issue of respirator use during agricultural operations was not a part of this rulemaking. OSHA notes, however, that respirator use during pesticide operations and handling is covered by EPA's Worker Protection Standard, 40 U.S.C. part 170, adopted under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

Under OSHA's previous standard, employers needed to follow the guidance of the Z88.2–1969 ANSI standard to ensure proper selection of respirators (see discussion 59 FR 58887). OSHA published an Advance Notice of Proposed Rulemaking (ANPR) to revise the respirator standard on May 14, 1982 (47 FR 20803). Part of the impetus for this notice was OSHA's inclusion of new respirator requirements in comprehensive substance-specific standards promulgated under section 6(b) of the Act, e.g., fit tests; use of powered air-purifying respirators (PAPRs) upon request; change of the filter elements of a respirator whenever an increase in breathing resistance is detected; employee permission to wash faces and respirator facepieces; and referral to a physician trained in pulmonary medicine for an employee who exhibits difficulty breathing, either at fit testing or during routine respirator use (see, e.g, 29 CFR 1910.1025 (lead standard)). The respirator provisions in these substance-specific standards took account of advances in respirator technology and changes in related guidance documents, particularly the recognition that standardized fit testing protocols greatly increase the effectiveness of respirators.

OSHA's 1982 ANPR sought information on the effectiveness of the current respiratory protection provisions, the need for revision of those provisions, and the substance of the revisions. Responses were received from 81 interested parties. The commenters generally supported revising OSHA's respiratory protection provisions and provided suggestions for approaches the Agency might take (Ex. 15).

On September 17, 1985, OSHA announced the availability of a preliminary draft of the proposed Respiratory Protection standard. The preproposal draft standard reflected the public comments received on the May 1982 ANPR, and OSHA's own analysis of changes needed in the standard to take into account the current state-of-the-art for respiratory protection. Responses were received from 56 interested parties (Ex. 36), and their comments were reviewed in preparing the proposal.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and announced its intention to convene an informal public hearing on the proposal (59 FR 58884). The informal public hearing was convened on June 6, 1995, pursuant to notice and in accordance with Section 6(b) of the OSH Act, 29 U.S.C. 655(b)(3). Post-hearing submissions of data from parties at the hearing were received through September 20, 1995.

On November 7, 1995, OSHA reopened the record (60 FR 56127) and requested additional comment on a study performed for OSHA by Dr. Mark Nicas titled ''The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors.'' That study, which was placed in the rulemaking docket on September 20, 1995, addressed the use of statistical modeling for determining respirator APFs. Comments on the Nicas study were received through the end of January 1996. The Nicas report, and comments received in response to the November 1995 notice, have convinced OSHA to deliberate further on the complex issues surrounding the establishment of APFs.

The entire record including 200 exhibits, more than 3,000 individual items, and approximately 2,300 transcript pages, was certified by the presiding administrative law judge on June 30, 1997, in accordance with 29 CFR 1911.17. Copies of materials contained in the record may be obtained from the OSHA Docket Office, Room N–2439, U.S. Department of Labor, 200 Constitution Avenue, N.W.,

Washington, D.C. 20210; (202) 219–7894.

The final revisions to 29 CFR 1910.134 are based on consideration of the entire record of this proceeding, including materials discussed or relied upon in the proposal, the record of the informal hearing, and all written comments and exhibits received.

B. Justification for Revising the Previous Standard

1. Purpose of the Revision

The intent of this revision is to enhance the protection of worker health, promote more effective use of respirators, provide greater compliance flexibility, and clarify the policies and procedures employers must follow when implementing a respiratory protection program. Evidence in the record, including case reports and studies of respirator use among workers, indicates that selecting or using respirators improperly can result in employee illness and even death. (See discussion below.) The revised standard is therefore expected to reduce the number of occupational illnesses and deaths among workers who wear respirators. OSHA is also consolidating many of its respirator-related provisions in other substance-specific health standards into one standard to make these provisions easier for employers to administer. Through consolidation, repetitive and duplicative respirator requirements have been deleted from many existing OSHA health standards, and future health standards will reference the revised final rule for many respirator requirements.

Advances in technology also made the previous standard out-of-date in many areas. Nearly all rulemaking participants, including representatives of private industry, other Federal agencies, respirator manufacturers, and unions, agreed that revision is necessary to address these advances (e.g., NIOSH, Ex. 28; Eastman Chemical Co., Ex. 54–245; 3M, Ex. 54–218A; AFL–CIO, Ex. 54–315; Building and Construction Trades Department/AFL–CIO, Ex. 29; American Petroleum Institute, Ex. 37; ISEA, Ex. 54–363). (See also 59 FR 58889.) Other agencies and committees have already updated their guidance on respirator use. For example, the ANSI standard has been revised twice (Exs. 10, 50), and NIOSH has revised its certification standard (42 CFR part 84; 60 FR 30336; 6/8/95), as well as developed a Respiratory Decision Logic (1987) to provide guidance to employers on the selection of respirators.

OSHA's experience in enforcing the previous standard also indicated that some of that standard's requirements were not understood clearly by the regulated community, and so were not adequately effective in protecting workers. The clarifications in this new standard will contribute to enhanced compliance by reducing misinterpretations and inconsistencies. A review of OSHA enforcement data for 1994 and 1995 revealed that failure to comply with the previous standard was a critical factor in at least 47 fatalities and 126 catastrophic injuries. The most frequently cited deficiencies included failure to provide respirators at all or to have standard operating procedures governing respirator use, and failure to train or fit test respirator users adequately [Source: OSHA's Federal Inspection Compliance Data (IMIS; 10/92 to 12/95)].

In addition, considerable research has been performed to determine the extent to which respirators used in workplaces actually reduce the quantity of contaminant breathed by the respirator user. Researchers have compared the in-mask concentrations of contaminants to the concentration levels outside the masks. This work was begun by NIOSH during the mid-seventies to assess respirator effectiveness in coal mines and abrasive blasting operations (Ex. 64–5) and spray paint operations (Ex. 64–68). The studies assessed the effectiveness of respirators under various conditions, and measured employee exposure in situations when respirators were not worn. The effectiveness ratings obtained in these studies are usually termed ''Effective Protection Factors'' (EPF).

More recent studies by NIOSH and private researchers have monitored respirator use even more closely to isolate variables that may affect the levels of respirator performance. Many of these studies concerned the performance of powered air-purifying respirators (PAPRs), which were not achieving in workplaces the levels of performance that had been predicted based on laboratory tests (see, e.g., Exs. 64–46, 64–42, and 64–47).

A third group of studies, ''workplace protection factor studies,'' conducted mostly by manufacturers and other private interests, was designed to determine the optimum performance of respirators by eliminating the impact of program defects under very tightly supervised workplace conditions. The results of these studies may overstate the degree of respirator effectiveness most employers can expect under conditions of workplace use because study conditions are rarely replicated in the field; nevertheless, these studies show the potential for respirators to reduce employee exposure to workplace contaminants (see, e.g., Exs. 64–25, 64–42, 64–47, 64–513).

This revised standard is intended to take account of up-to-date knowledge and technology and to make the requirements in the standard easier to understand. The standard now reflects current technology and research, as well as the findings and guidance of other expert bodies. OSHA has also included a new definitions section to enhance clarity. The revised standard includes detailed protocols for performing fit tests and lists the topics in which respirator users must be trained. It also contains provisions addressing skin and eye irritation, both of which must be considered in respirator selection. Wherever possible, OSHA has used performance-oriented language to allow for flexibility in accommodating future changes in respirator technology and to address the needs of small businesses and unusual operations. Through these improvements, OSHA expects to reduce the number of respirator-related illnesses, fatalities, and catastrophic injuries occurring among respirator wearers in U.S. workplaces.

2. Respirator Use and Hazards

The purpose of a respirator is to prevent the inhalation of harmful airborne substances or oxygen-deficient air. Basically, a respirator is an enclosure that covers the nose and mouth or the entire face or head. Respirators are of two general ''fit'' types: (1) Tight-fitting (quarter masks, which cover the mouth and nose; half masks, which fit over the nose and under the chin; and full facepiece, which cover the face from the hairline to below the chin); and (2) loose-fitting (hoods, helmets, blouses, or full suits which cover the head completely). There are also two major classes of respirators: air-purifying respirators (which remove contaminants from the air), and atmosphere-supplying respirators (which provide clean breathing air from an uncontaminated source). In general, atmosphere-supplying respirators are used for more hazardous exposures.

Effective respirator use can protect employees from exposure to a wide variety of toxic chemicals. In 1994, approximately 215 deaths, or five percent of all workplace fatalities, occurred as a result of exposure to harmful substances and environments [CFOI, BLS, 6/11/96; CFOI/FAX]. There are a number of workplace situations that involve toxic substances and for which engineering controls may be inadequate to control exposures, and respirators are used in these situations

as a back-up method of protection. Substances that have been associated with death or serious incidents include carbon monoxide, trichloroethylene, carbon dioxide, chromic acid, coal tar, several toxic metal fumes and dusts, sulphur dioxide, wood dust, and welding fumes; these substances cause adverse health effects ranging from transient, reversible effects such as irritation or narcosis, through disabling diseases such as silicosis and asbestosis, to death caused either by acute exposure or by a cancer resulting from chronic exposures (Rom, W., *Environmental and Occupational Medicine*, 2nd ed., Little, Brown & Co., Boston; 1992, p. 598.) Respirators are available that can provide protection against inhalation of these toxic substances.

Airborne contaminants may also be radioactive (''Radiologic Health in Occupational Medicine Practice,'' George L. Voelz, pg. 500 in *Occupational Medicine,* Carl Zenz, ed., Year Book Medical Publishers, Inc., Chicago, 1975; Jacob Shapiro, *Radiation Protection,* 3rd ed., Harvard University Press, Cambridge, MA, 1990, pg. 273). (See also 29 CFR 1910.1096.) Exposure to ionizing radiation can cause acute effects such as nausea and vomiting, malaise and fatigue, increased temperature, and blood changes. More severe delayed effects include leukemia, bone and lung cancer, sterility, chromosomal and teratogenic damage, shortened life span, cataracts, and radiodermatitis, a dry, hairless, red, atrophic skin condition which can include skin cracking and depigmentation (George L. Voelz, M.D., ''Radiologic Health in Occupational Medicine Practice'', in Zenz, *Occupational Medicine,* pp. 513–519; Herman Cember, *Introduction to Health Physics,* 2nd edition, Pergamon Press, New York, 1983, pg. 181–194). Respirators to provide protection against the inhalation of radioactive particles are commonly used by workers exposed to these hazards.

''Bioaerosols'' are airborne contaminants that are alive or were released from a living organism (OSHA Docket No. H–122; ACGIH Guidelines; Ex. 3–61C, page 1; 1994). Pulmonary effects associated with exposure to certain bioaerosols include rhinitis, asthma, allergies, hypersensitivity diseases, humidifier fever, and epidemics of infections including colds, viruses, tuberculosis, and Legionnaires Disease. Cardiovascular effects manifested as chest pain, and nervous system effects manifested as headache, blurred vision, and impaired judgment, have occurred in susceptible people following exposure to bioaerosols. Viral infections caused by the inhalation of bioaerosols can result in health effects that range in intensity from undetected or mild to more severe and even death. Bacterial infections resulting from inhalation of bacteria and their products cause a range of diseases, including tuberculosis, Legionnaires Disease, and hypersensitivity pneumonitis. Among workers in sewage treatment plants, health-related problems can be associated with occupational exposures to protozoa [Burge, H., 1990, ''Bioaerosols: Prevalence and health effects in the indoor environment,'' *J. Allergy and Clinical Immunology;* 86 (5); see also Exs. 3–61B and 3–61C in Docket No. H–122.] Allergic asthma and allergic rhinitis can be induced by chronic exposure to low levels of antigens. Hypersensitivity pneumonitis can occur when a worker inhales concentrated aerosols of particles released by bacteria, fungi, and protozoa (Exs. 3–61B and 3–61C in Docket No. H–122). In 1994, the Centers for Disease Control reported 41 deaths of workers for which there was evidence of work-related hypersensitivity pneumonitis (*Work-Related Lung Disease Surveillance Report,* 1994; USDHHS, CDC, DHHS (NIOSH) Number 94–120). Respirators to protect against the inhalation of biological agents are widely used in healthcare and other workplace settings where exposure to such agents presents a hazard to workers.

Respirators can also provide protection from oxygen-deficient atmospheres. Human beings must breathe oxygen in order to survive, and begin to suffer adverse health effects when the oxygen level of their breathing air drops below the normal atmospheric level. Below 19.5 percent oxygen by volume, air is considered oxygen-deficient. At concentrations of 16 to 19.5 percent, workers engaged in any form of exertion can rapidly become symptomatic as their tissues fail to obtain the oxygen necessary to function properly (Rom, W., *Env. Occup. Med.,* 2nd ed; Little, Brown; Boston, 1992). Increased breathing rates, accelerated heartbeat, and impaired thinking or coordination occur more quickly in an oxygen-deficient environment. Even a momentary loss of coordination may be devastating to a worker if it occurs while the worker is performing a potentially dangerous activity, such as climbing a ladder. Concentrations of 12 to 16 percent oxygen cause tachypnea (increased breathing rates), tachycardia (accelerated heartbeat), and impaired attention, thinking, and coordination (e.g., Ex. 25–4), even in people who are resting.

At oxygen levels of 10 to 14 percent, faulty judgment, intermittent respiration, and exhaustion can be expected even with minimal exertion (Exs. 25–4 and 150). Breathing air containing 6 to 10 percent oxygen results in nausea, vomiting, lethargic movements, and perhaps unconsciousness. Breathing air containing less than 6 percent oxygen produces convulsions, then apnea (cessation of breathing), followed by cardiac standstill. These symptoms occur immediately. Even if a worker survives the hypoxic insult, organs may show evidence of hypoxic damage, which may be irreversible (Exs. 25–4 and 150; also reported in: Rom, W., *Environmental and Occupational Medicine,* 2nd ed; Little, Brown; Boston, 1992).

A number of workplace conditions can lead to oxygen deficiency. Simple asphyxiants, or gases that are physiologically inert, can cause asphyxiation when present in high enough concentrations to lower the oxygen content in the air. Other toxic or chemical asphyxiants poison hemoglobin, cytochromes, or other enzyme systems (Rom, W., *Environmental and Occupational Medicine,* 2nd ed., Little, Brown, and Co., Boston, 1992). A number of asphyxiants are gases that can evolve from explosions, combustion, chemical reactions, or heating. A high-temperature electrical fire or arc welding accident causing a complete flashover in an enclosed area can temporarily eliminate oxygen from that area. Asphyxiation and the severe lung damage it can cause are major concerns for firefighters; of 30 firefighter deaths investigated by OSHA recently, five resulted from either asphyxiation, smoke inhalation, or flashovers (IMIS; 8 State plan states; 10/91–3/97). (See also mortality study of causes of death among firefighters, Guidotti, 37 *JOEM* 1348, 1995.)

In 1994, 110 employees died from oxygen deficiency [National Census of Fatal Occupational Injuries (CFOI); BLS; CFOI/FAX; 6/11/96)], i.e., about two percent of the total number of employees who died of occupational injuries. OSHA believes that many of these deaths could have been prevented if the victims' employers had realized that respirators were needed (BLS; CFOI/FAX, 6/96).

In some cases, respirator use itself can cause illness and injury to employees. There are a number of physiological burdens that are associated with the use of certain types of respirators. The

weight of the respirator, breathing resistances during both normal operation and if the air-purifying element is overloaded, and rebreathing exhaled air from respirator ''dead space'' can all increase the physiologic burden of respirator use (Exs. 113, 22–1, 64–427). Job and workplace conditions, such as the length of time a respirator must be worn, the level of physical exertion required of a respirator user, and environmental conditions, can also affect the physiological burden (Exs. 113, 64–363). In addition, workers who wear glasses or hearing aids may have problems achieving appropriate fit with some respirator facepieces.

Evidence of Adverse Health Effects From Respiratory Hazards. There is ample evidence that the previous standard was not doing an adequate job of protecting workers from these respiratory hazards, and that exposure to these hazards has continued to cause adverse health effects among exposed workers. An analysis of OSHA inspection data from 1976 through 1982, when the previous standard had been in effect for between five and eleven years (Ex. 33–5), found that in most cases (55.6%) where respirators were used to protect employees from excessive levels of air contaminants, respiratory protection programs were deficient in one or more elements, thus increasing the potential for employee exposure. Even more significant was the fact that in 72.1% of inspections in which an overexposure to a substance listed under 29 CFR 1910.1000 was cited, respirator use did not comply with the respiratory protection standard. OSHA performed a similar analysis of enforcement data for 1990–1996, and found similar levels of noncompliance. [See also *Work-Related Lung Disease Surveillance Report,* 1994; USDHHS, CDC, DHHS (NIOSH) Number 94–120.] The provisions of the new respirator standard are designed to regulate how an employer selects, maintains, fit tests, and trains employees in the proper use of respiratory equipment, and to provide employers with the tools needed to implement an effective respiratory protection program. OSHA has concluded that the new standard will eliminate many of the unnecessary illnesses and deaths described in this section.

C. Responses to Advisory Committee on Construction Safety and Health

The revised respirator standard replaces the previous respiratory protection standard in the construction industry (29 CFR 1926.103). Since this revision affects the construction industry, the September 1985 preproposal draft standard was presented to the Advisory Committee for Construction Safety and Health (ACCSH) for its comments. The ACCSH comments, combined with the other comments received, were considered in preparing a revision of the September 1985 draft proposal.

As part of the Notice of Proposed Rulemaking (NPRM) approval process, the revised NPRM was presented at the March 1987 ACCSH meeting and the Committee's comments were presented to OSHA at the August 1987 meeting (Ex. 39). OSHA responded to the Committee's comments in the NPRM, published in November, 1994. As noted in that response, OSHA modified the draft proposal to respond to the concerns of the Committee (59 FR 58931–58935).

The final standard replaces the previous construction industry standard for respiratory protection, 29 CFR 1926.103, with an amended 29 CFR 1926.103. The provisions of the previous respiratory protection standard (29 CFR 1926.103) are deleted by this action. The title, Respiratory Protection, will remain in the Code of Federal Regulations but will now be followed by the statement ''Respiratory protection for construction employment is covered by 29 CFR 1910.134.'' The full text of this new standard will be printed in the general industry standards, and the construction standard will reference the revised 29 CFR 1910.134.

The Agency's responses to the Committee's specific concerns follow:

Paragraph (a)—Permissible Practice

The Construction Advisory Committee recommended that paragraph (a)(1) of the standard be changed to require that all feasible engineering controls be used by employers and that the employer demonstrate that engineering controls are not feasible before respirators may be used. The recommended change also would have eliminated the requirement that appropriate respirators be used while engineering controls are being installed. OSHA has stated elsewhere in the summary and explanation section of this preamble that paragraph (a)(1) of the previous standard remains unchanged in the new final standard because this paragraph was not proposed for revision and was therefore not a subject of rulemaking in this proceeding. The purpose of the Respiratory Protection standard is to improve the level of protection provided to employees who use respirators to protect them from respiratory hazards, regardless of whether that use occurs in an environment where engineering controls are in place.

The Committee proposed that paragraph (a)(2) be modified to require that employers provide respirators to employees exposed to contaminant concentrations when the concentration reaches one-half the PEL or TLV, and that employees be required to wear them before the PEL is exceeded. To accompany this revision the Committee proposed a new definition establishing an ''action level'' of one-half the PEL for all regulated substances. OSHA has not adopted this ACCSH recommendation because the recommended changes are beyond the scope of this rulemaking.

Paragraph (b)—Definitions

ACCSH suggested that OSHA add a definition for ''Grade D breathing air'' to the standard. The properties of Grade D breathing air are listed in paragraph (i) of the final standard, Supplied Air Quality and Use. OSHA believes that repeating these elements in the definition section is redundant and unnecessary.

The Committee also recommended that the rule include a definition for ''competent person,'' as defined in 29 CFR 1926.32(f). The competent person would review the respiratory protection program and perform the function of the respiratory program administrator required in paragraph (c)(2) of the proposal. OSHA has not included a definition of competent person in the standard because 29 CFR 1926.32(f) already has such a definition. OSHA recognizes, however, that, in construction settings, the competent person is often also the administrator of the respirator program.

The Committee also recommended that the NIOSH Recommended Exposure Limits (RELs) be used along with the TLVs, to define a hazardous exposure level in the absence of a PEL. This point is no longer relevant because the concept of ''hazardous exposure level'' is not included in the final respiratory protection standard.

The proposal would have limited the use of air-purifying respirators for hazardous chemicals with poor or inadequate warning properties. ACCSH recommended a change to the definitions of ''inadequate warning properties'' and that OSHA add a new definition for ''odor threshold.'' Because the final standard takes a different approach to determining when air-purifying respirators are appropriate, OSHA has not adopted the changes recommended by ACCSH.

ACCSH also suggested that OSHA revise the proposed definition of maximum use concentration (MUC). In

the final standard the definition of MUC has been reserved, pending completion of a subsequent stage of this rulemaking that will concentrate on establishing OSHA Assigned Protection Factors (APFs).

The Construction Advisory Committee also recommended replacing the proposal's definition of ''respirator;'' because the final standard contains no definition of ''respirator,'' this suggestion has not been adopted. The Committee also recommened revising the proposed definition of ''service life.'' However, since OSHA's definition of this term has been broadened in the final rule and the rule contains detailed requirements for change schedules for cartridges and canisters, ACCSH's concerns have largely been addressed.

Paragraph (c)—Respirator Program

Paragraph (c)(1) of the proposal contained a requirement that the employer establish a respirator program that ''covers'' certain elements, as applicable. OSHA has followed the Commitee's recommendation that OSHA change the word ''cover'' to ''include'' but not removed the phrase ''as applicable,'' as recommended by the Committee, because not all elements of the program apply in all situations, and thus the ''as applicable'' language is appropriate.

The Committee also recommended that OSHA add an element to the written respirator program on procedures for monitoring the work environment, using monitoring results when selecting respirators, and selecting the most protective respirators in situations where monitoring cannot be performed (as is often the case in construction). OSHA considered this comment in drafting the final standard, which permits the employer to make reasonable estimates of exposure as part of the respirator selection process. In most cases, as discussed in the summary and explanation of paragraph (d), monitoring results will form the basis of a reasonable estimate. Where the employer cannot estimate exposure, the atmosphere must be considered immediately dangerous to life or health (IDLH). For IDLH atmospheres, the most protective respirators are required.

One of the elements in the written respirator program, paragraph (c)(1)(vi), states that the program shall include procedures to ensure proper air quality for atmosphere-supplying respirators. ACCSH asked OSHA to add the words ''quantity and flow'' to provide more direction for employers on what the procedures should cover. OSHA agrees and has revised the wording of this element accordingly.

ACCSH recommended that OSHA substitute the term ''competent person'' in paragraph (c)(2) for the language ''person qualified by appropriate training and/or experience.'' This recommendation has already been discussed above, in connection with ACCSH's comments on paragraph (b).

The written respiratory protection program, in paragraph (c)(3), is required to reflect current workplace conditions and respirator use. The Committee urged OSHA to add the term ''training'' to this element. OSHA has not done so because training is addressed in another program element. The Committee also recommended that OSHA add to paragraph (c) a provision allowing employees and designated representatives access to exposure and medical records maintained by the employer. Because this requirement is already included in 29 CFR 1910.1020, the medical and exposure records access standard, and referenced in this final respiratory protection standard, the Agency has not done so.

Proposed paragraph (c)(5) required employers to make the written program available to affected employees, designated representatives, and OSHA. The Committee requested that employers be required to send a copy of the program to the OSHA Special Assistant for Construction. However, the proposed requirement has been moved to paragraph (m) of the final standard, which requires that all written materials maintained under the standard be made available upon request to affected employees and the Assistant Secretary. This requirement should meet any need that may arise for copies of the written program.

The Committee further recommended that the written respirator program be maintained and made available to employees at the job site, and that the medical and monitoring results pertaining to respirator use be available at the work site as well. The final standard in paragraph (m) now requires employers to allow employees to examine and copy written programs upon request. Access to medical and monitoring records for employees exposed to toxic substances or harmful physical agents is regulated by OSHA in a separate standard, 29 CFR 1910.1020. That standard applies to construction workplaces as well as general industry workplaces and requires the employer to ensure that access to medical and monitoring records is provided in a reasonable time, place, and manner (1910.1020(e)(1)(i)). Nothing in the final respiratory protection standard is intended to alter this requirement.

Paragraph (d)—Selection of Respirators

In its review of paragraph (d) of the proposal on selection of respirators, the Committee requested OSHA to add a new provision that would require monitoring for contaminants when air-purifying respirators are used. This request is related to the recommendation for mandatory monitoring, discussed above. The final standard requires that employers make reasonable estimates of employee exposure levels when selecting all respirators, not just air-purifying ones. Even if current monitoring results are unavailable, employers must base their exposure estimates on reliable data, which might include, for example, the results of past monitoring for similar construction jobs. Extensive discussion of this issue is contained in the summary and explanation section of this preamble for paragraph (d). OSHA believes that allowing exposure estimates that may be based on past monitoring and other representative data makes sense for the construction industry, where jobs are often short-lived and current monitoring data relating to specific employees/operations may not be available when respirators must be selected. Because the final standard allows employers to rely on reasonable estimates of exposure as well as monitoring results, OSHA has not added a requirement to the standard mandating that employers ''obtain'' needed information, as recommended by the Committee.

The Committee also recommended removal of the proposed phrase ''when they exist'' to modify the requirement that employers select only NIOSH-approved respirators. Instead, the Committee recommended use of the most protective respirator available, an SCBA or supplied air respirator, in cases where no approved air-purifying respirator exists. OSHA has removed the phrase ''when they exist'' from the final standard, for reasons explained in the summary and explanation discussion relating to paragraph (d).

The Committee urged OSHA to include poor odor warning properties as a reason for prohibiting the use of air-purifying respirators, and to remove proposed paragraph (d)(6)(ii), which, under limited circumstances, would have allowed their use with substances with poor odor warning properties. Final paragraph (d)(3) modifies the proposal, and places many limitations on air-purifying respirator use with gases and vapors, regardless of the existence of warning properties.

The Committee objected to the use of air-purifying respirators in an

atmosphere with an oxygen content of 19.5 percent at altitudes of 14,000 feet or below; in the Committee's view, supplied air respirators should be required in this situation. OSHA continues to treat atmospheres at altitudes of 14,000 feet or below that have oxygen concentrations of at least 19.5% as non-oxygen-deficient, and to require atmosphere-supplying respirators in these atmospheres. OSHA's reasons for this determination are detailed in the summary and explanation section for paragraph (d).

Paragraph (e)—Medical Evaluations

The Committee recommended that a mandatory medical examination be required in accordance with ANSI Z88.2, and that the standard include a list of diseases and conditions that should be considered in determining an individual's ability to wear a respirator. The final standard allows employers to rely on a screening questionnaire to identify employees with specified conditions that will require follow-up medical examinations. The questionnaire specifies medical conditions that OSHA has determined often relate to an employee's ability to use a respirator. OSHA believes that this provision responds to the Committee's concern.

Based on the comments of ACCSH and others, OSHA has decided to eliminate the proposed exemption for employees wearing respirators for no more than 5 hours per week, for the reasons explained below in the Summary and Explanation. The final rule also reflects the Committee's recommendation that the medical opinion provided to the employer include only limitations on the employee's ability to use a respirator.

The Committee recommended that OSHA add a provision to this paragraph requiring the employer to inform the person performing the medical examination of the atmospheric contaminants to which the employee would be exposed. The final standard meets this concern by requiring that the physician or other licensed health care professional (PLHCP) receive a copy of the employer's written respirator program, and information about other environmental conditions an employee may encounter; this information will allow the medical professional to judge whether the employee is medically capable of wearing the respirator.

The final rule allows an employer who has, within the preceding 12 months, provided his or her employees with a medical evaluation that fulfills the requirements of the revised standard to rely on the results of that evaluation. OSHA believes that this provision is responsive to the Committee's concern that limitations be placed on the ''portability'' of medical evaluations.

The Committee recommended that OSHA add a new provision to paragraph (e) to require that the employer provide a powered air-purifying respirator or atmosphere-supplying respirator to any employee found medically unable to wear a negative pressure respirator but otherwise able to perform the task to be done. The final standard requires the employer to provide a PAPR to an employee when the PLHCP informs the employer that the employee has a medical condition that may place the employee's health at increased risk of material impairment if the employee uses a negative pressure respirator (paragraph (e)(6)(ii)) and is thus responsive to the Committee's concern.

Paragraph (f)—Fit Testing

With respect to fit testing procedures, the Committee recommended that proposed paragraph (f)(1) be rewritten to state that respirators must fit the employee so as to ensure that no exposure above the TLV or ceiling level occurs. OSHA agrees with the Committee's emphasis on fit testing and believes that the final rule's fit testing requirements and the fit test protocols in an appendix to the standard will ensure that employees are protected from the overexposures of concern to the Committee.

The Committee also suggested clarifying that a fit test is required whenever a different make or size respirator is used or when the facial characteristics of the employee change. The final rule addresses both of these points.

The Committee recommended limiting the fit testing requirements to tight-fitting negative pressure respirators. This issue, and OSHA's reasons for requiring fit testing of all tight-fitting respirators, is discussed in the fit testing section of the Summary and Explanation. OSHA has also deleted the proposed provision, objected to by the Committee, that would have allowed the employer to use a qualitative fit test for selecting respirators for employees who require fit factors greater than 10 in situations where outside contractors who do the quantitative fit testing are not available.

Paragraph (g)—Respirator Use

Paragraph (g)(1) of the final standard adopts the proposed provision prohibiting the use of respirators that rely on a tight facepiece fit when facial conditions such as a beard or scarring would prevent such fits. The Committee urged OSHA to extend this provision to cover loose-fitting respirators as well as tight-fitting ones. OSHA explains in the Summary and Explanation for this paragraph that conditions such as a beard or facial scarring would have no effect on the performance of loose-fitting hoods or helmets, and OSHA therefore does not regard it as appropriate to make this change.

Employees who wear glasses were required in proposed paragraph (g)(4) to wear them in a manner that does not interfere with the facepiece seal of the respirator. The final standard continues this requirement (paragraph (g)(l)(ii)). The Committee suggested an additional requirement stating that, where the employee must wear corrective lenses and the respirator requires that these be of special design, the employer provide the lenses at no cost to the employee. OSHA believes, however, that such a requirement is not necessary because, in most cases where negative pressure respirators may be worn, half-masks are acceptable, and half-masks eliminate the concern about corrective glasses interfering with facepiece seal. Because the final standard allows contact lenses to be worn, full facepiece respirators can be worn by persons needing corrective lenses; contact lenses obviously do not interfere with facepiece seal. Thus, the final rule gives employers several options for addressing this concern of the Committee's.

Paragraph (h)—Maintenance and Care of Respirators

The Committee urged OSHA to add the phrase ''on paid time'' to this paragraph to ensure that employers not require employees to clean their respirators on their own time. OSHA has decided in the final rule simply to require employers to ensure that respirators are cleaned according to mandatory procedures or their equivalents. OSHA believes that this approach is appropriate because the record demonstrates that on-site, employer-supervised cleaning is the prevalent cleaning procedure and the standard's rigorous requirements for cleaning respirators will limit off-site cleaning of respirators by employees.

Paragraph (k)—Training

The training section of the proposal would have required that employers provide a training program for employees who are required to wear respirators. The Committee urged OSHA to add language to paragraph (k)(1) to require employers to provide, conduct and document the effectiveness of the training program. The final standard takes a more integrated approach in that

it requires employers to evaluate the entire respiratory protection program rather than the training program specifically.

Paragraph (m)—Recordkeeping

OSHA has adopted the Committee's recommendation to add the phrase ''and make available'' to proposed paragraph (m)(1)(iii), which required employers to maintain records of medical evaluations in accordance with 29 CFR 1910.1020, the Access to Employee Exposure and Medical Records standard (see paragraph (n)(1) of the final rule).

Appendix B—Recommended Practices

Appendix B–1 of the standard contains practices for performing positive and negative pressure faceseal checks. Respirator wearers are required by paragraph (g)(iii) to perform a faceseal check before entering the work area either by following the mandatory faceseal check methods in Appendix B–1 or by following the respirator manufacturer's recommended method, if the employer shows that the manufacturer's method is as effective as the required methods. The Committee urged OSHA to add new fit check methods to Appendix B–1, and OSHA has responded to this recommendation by allowing the methods suggested by the Committee if they are as effective as the methods in the Appendix.

ACCSH also recommended that OSHA issue a separate respirator standard for the construction industry. OSHA has reviewed the Committee's comments to identify which construction-specific concerns call for provisions that differ from those applicable to general industry. First, many of the final standard's provisions are stated in performance language, which is flexible enough to accommodate differences in particular workplaces or industries. For example, approved fit test systems, both quantitative and qualitative, are portable and can be used on construction work sites as well as in fixed industrial facilities. Another example is the final rule's requirement for medical surveillance; the frequency of medical reevaluation is now event driven, which will greatly simplify evaluations for employees who frequently change employment, as is the case with many construction workers. Thus, OSHA believes that the final rule is responsive to the Committee's concerns about the uniqueness of the construction industry and is sufficiently flexible to be used on worksites in this sector.

D. Assigned Protection Factors

OSHA is reserving the sections of this standard addressing assigned protection factors (APFs) pending further rulemaking. OSHA is working diligently to complete the reserved portions of the standard. In the interim, OSHA expects employers to take the best available information into account in selecting respirators. As it did under the previous standard, OSHA itself will continue to refer to the NIOSH APFs in cases where it has not made a different determination in a substance-specific standard.

E. Small Business Considerations

Pursuant to 5 U.S.C. 605(b) of the Regulatory Flexibility Act, OSHA certified to the Small Business Administration that the proposed respiratory protection standard would not have a significant impact on a substantial number of small entities.

For the purposes of fulfilling the requirements of the Regulatory Flexibility Act, the Agency in its Preliminary Regulatory Impact Analysis (PRIA) [Ex. 57] examined the impact of the standard on a number of different small establishment-size classes (1–7 employees, 8–19 employees, etc). Although some economies of scale associated with the proposed standard were noted, the Agency found that, given the modest costs per establishment and the limited impact of the proposed regulatory revisions as a whole, the standard would not impose a significant economic impact on a substantial number of small entities. These findings were summarized in the NPRM (59 FR 58894). At the time that OSHA published the NPRM for this rulemaking (Nov. 15, 1994), the Agency transmitted the certification setting forth this conclusion, along with the full PRIA, to the Small Business Administration.

In developing the final standard, the Agency has conducted a screening analysis to identify any significant impacts on a substantial number of small entities. The details of the screening analysis are presented in the Final Economic Analysis, which is available in the docket; a summary of the analysis appears in section VI. Based on this screening OSHA has again determined that the final rule will not impose a significant impact on a substantial number of small entities. The costs of the standard will equal no more than 0.02 percent of revenues for small firms in any affected industry, and will therefore pose no threat of business disruption, whether these costs are absorbed by affected firms or passed on to consumers. OSHA therefore certifies that the final rule will not have a significant impact on a substantial number of small entities.

Nevertheless, the Agency has designed the standard to minimize impacts on all affected establishments, and particularly on small entities. OSHA's special consideration of small businesses is in accord with the Agency's continuing policy to remain sensitive to the needs of small entities affected by Agency regulations.

Provisions that recognize the special needs of small businesses are discussed in more detail under specific sections of the Summary and Explanation of the standard, Section VIII. Examples of provisions where consideration was given to small businesses in making regulatory decisions include:

—Reduction in the number of repeat fit tests required for quantitative fit testing;

—Allowing employers to use a questionnaire (Appendix C is an example) as a minimal medical evaluation tool to ascertain an employee's ability to use respirators, rather than requiring a hands-on physical examination;

—Allowing medical evaluations to be conducted either by a physician or by another licensed health care professional (PLHCP), which will reduce medical surveillance costs without compromising employee protection;

—Making the frequency of medical evaluations, after the initial assessment, event-related instead of time-related, e.g., only requiring such evaluations when specific conditions indicate a need for a reevaluation;

—Reducing the amount of paperwork required in connection with medical evaluations. OSHA's previous standard required a physician to determine pertinent health and physical conditions, and further required that the respirator user's medical status be reviewed periodically (for instance, annually). Historically, employers have had physicians evaluate their employees' physical conditions, and have maintained records documenting those evaluations;

—Revising the requirements for disinfecting respirators from ''after each use'' to ''as necessary to be maintained in a sanitary condition'' to allow flexibility for small businesses;

—Requiring only that tags be used to document respirator inspections, rather than requiring written records; and

—Allowing the employer to obtain a certificate of analysis of breathing gas

from the supplier rather than requiring employers to conduct gas analyses themselves.

In the Small Business Administration's *Annual Report to Congress,* a summary of SBA's comments to the respirator docket (Ex. 54–318) was provided. (Note that these comments pertain to the proposed rather than final rule.) SBA's comments have been examined alongside others with regard both to the proposal and its supporting economic analysis. As indicated, many of SBA's suggestions have been adopted; the SBA's comments on the Preliminary Regulatory Impact Analysis are discussed in detail in the economic impact chapter of the Final Economic Analysis.

Revised 29 CFR 1910.134 is intended to serve as a ''building block'' standard with respect to future standards that may contain respiratory protection requirements; that is, future standards that regulate respirator use in controlling employee exposure to hazardous conditions will refer to provisions in the final respiratory protection standard. Further, OSHA has found that the respirator provisions of existing substance-specific standards (Asbestos, Cadmium, Lead, etc.) were especially in need of revision in view of newly revised § 1910.134. Except for a limited number of respirator provisions unique to each substance-specific standard, the remaining regulatory text on respirators now reads virtually the same for each of these standards. For example, all provisions addressing respirator use, selection, and fit testing were deleted from the substance-specific standards, making these standards consistent with the final respiratory protection standard with respect to these requirements. The Agency believes that the revisions being made to 29 CFR 1910.134 are sufficiently comprehensive to allow deletion of those provisions in the substance-specific standards that duplicated provisions in the revised final rule. A provision was retained only when it addressed conditions (for example, medical evaluation) that were unique and/or integral to the substance-specific standard.

The Agency concludes that deletion of duplicative provisions from the substance-specific standards will enhance compliance, especially for small businesses, and will thus will improve the protection afforded to employees who use respirators.

IV. Certification/Approval Procedures

Section 1910.134(b)(8) of the previous standard required that only those respirators approved jointly by NIOSH and MSHA be used by the employer. The current respirator testing and approval regulation, 30 CFR 11, which authorized the Bureau of Mines and NIOSH to jointly approve respiratory protection devices, was promulgated on March 25, 1972 at 37 FR 6244. On November 5, 1974 the Mine Enforcement Safety Administration (MESA) succeeded the Bureau of Mines and joined NIOSH in jointly approving respirators. Following the transfer of MESA to the Department of Labor, where it became the Mine Safety and Health Administration (MSHA), authority was transferred on March 24, 1978 to MSHA for joint approval with NIOSH of respirators. Most of the Bureau's respiratory testing methods, developed in the 1950s or earlier, were changed in the 1970s to reflect changes in testing technology.

NIOSH initiated revision of 30 CFR 11 in 1980. A public meeting was held in July 1980 to address the certification program. On August 27, 1987, NIOSH published a notice of proposed rulemaking (52 FR 32402) that would have allowed NIOSH to certify respirators under the new 42 CFR part 84 regulations, replacing the current joint NIOSH/MSHA 30 CFR 11 certification regulations. The proposed NIOSH certification regulations contained new and revised requirements for testing and certification of respirators, and included a set of assigned protection factors for various classes of respirators. Public hearings on the first draft of the NIOSH proposal were held in January 1988. On the basis of the comments received, NIOSH prepared a revised proposal for further public comment. On June 8, 1995 NIOSH published revised respirator certification procedures for particulate respirators (60 FR 30336) and recodified the previous certification standards for the other respirator classes as 42 CFR Part 84. These certification procedures address N, P and R class particulate respirators at 95%, 99%, and 99.7% levels of effectiveness. Additional public comment was sought at public meetings convened in June 1996 to assist NIOSH in preparation of future rulemakings that will continue the revision of the certification procedures for other classes of respirators. In October 1997, NIOSH announced the intended priority order for these future rulemakings. Relevant aspects of these proceedings are discussed in the Summary and Explanation.

V. Significance of Risk

Respirators are used by American workers as a means of protection against a multitude of respiratory hazards that include chemical, biological, and radiological agents. Situations in which respirators are relied upon to provide protection from these hazards include those that involve immediately life-threatening situations as well as routine operations where engineering controls and work practices are not able to provide sufficient protection from these hazards. In these situations, respirators must ''seal off'' and isolate the worker's respiratory system from the contaminated environment. The risk that a worker will experience an adverse health outcome when relying on respiratory protection is a function of the toxicity or hazardous nature of the air contaminants present, the concentrations of the contaminants in the air, the duration of exposure, and the degree of isolation provided by the respirator. When respirators fail or do not provide the degree of protection expected by the user, the user is placed at an increased risk of any adverse health effects that are associated with exposure to the respiratory hazards present. Therefore, it is critical that respirators perform as they are designed to do to ensure that users are not at an increased risk of experiencing adverse effects caused by exposure to respiratory hazards.

OSHA has discussed the nature of adverse health effects caused by exposure to airborne chemical hazards many times in previous rulemaking efforts (see, for example, Appendix A of the Hazard Communication standard, 29 CFR 1910.1200 and the preambles to any of OSHA's single substance standards codified in 29 CFR 1910.1001 to 1910.1052). In all instances where OSHA has promulgated new or revised PELs for chemical air contaminants, OSHA has determined that the health effects associated with exposure to the contaminants represent material impairment of health because the effects are life-threatening, cause permanent damage, or significantly impair the worker's ability to perform his or her job in a safe manner. As discussed in Section VI of this preamble, OSHA expects that thousands of illnesses and hundreds of fatalities that are presently being caused by exposure to hazardous substances will be avoided annually among respirator wearers as a result of improvements and clarifications made to the earlier standard by this final rule.

Evidence on current workplace exposure levels confirms that respirators are needed in many work situations to protect workers against serious work-related illness. To illustrate, OSHA identified several substances that represent a range of adverse effects and

for which OSHA's Integrated Management Information System (IMIS) database has documented workplace exposures that exceed the current PELs for these substances. The effects represented by this subset of the IMIS and the associated substances for which there are documented overexposures include:

—Sudden death/asphyxiation—carbon monoxide, carbon dioxide;
—Loss of lung function—wood dust, welding fume, manganese fume, copper fume, cobalt metal fume, silica;
—Central nervous system disturbances—carbon monoxide, trichloroethylene;
—Cancer—chromic acid, wood dust, silica; and
—Cardiovascular effects—carbon monoxide.

When respirators are used during operations where exposures exceed OSHA's PEL, OSHA believes that there is little or no margin that would protect the worker in the event that the respirator does not perform as well as designed or expected. For all of the substances for which OSHA has promulgated a comprehensive health standard (i.e., 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), OSHA has determined that exposure above the PEL is associated with a significant risk of material impairment of health, and believes as a matter of policy that exposures below the PEL may be associated with risk levels that are significant. That is, there is no exposure level near or somewhat above the PEL that can be considered to be at a low or insignificant risk level. Therefore, where workers perform jobs that result in exposures above the PEL for any of these substances, use of properly functioning respirators is essential to ensure that workers are not placed at significant risk of material impairment of health.

Throughout this preamble, OSHA has demonstrated that adequate fit testing, proper respirator selection, worker training, and thorough inspection and maintenance are essential elements of a respirator program. Without these requirements, OSHA believes that there is a greater chance that a respirator user will inhale potentially dangerous air contaminants, either by improper selection of equipment, excessive respirator leakage, improper use of the respirator, or any combination of these. This section presents an analysis conducted by OSHA to evaluate the improved protection to workers who use respiratory protection equipment by the type of effective respirator program required by the final rule.

In the context of a respiratory protection program, the health risk presented to workers can be represented as the risk that a respirator will fail to provide some minimum expected level of protection, which increases the possibility that the user of the respirator will be overexposed to a harmful air contaminant. This presumes that respirators will be selected and used in work settings where exposure to ambient concentrations of air contaminants poses an unacceptable health risk, and, if the respirator performs as expected, the wearer will be protected from that risk. For example, an employer who provides a half-mask, chemical cartridge respirator for employee use might typically assume that the respirator will filter out 90 percent of the contaminant and base his or her choice of respirator on that assumption. If the respirator performs less effectively than expected, the employer's expectation that the respirator will provide effective protection will not be fulfilled.

This concept of risk differs from that used by OSHA in its substance-specific health standards, in which the Agency typically defines risk as the probability that a worker will acquire a specific work-related illness. Quantifying that kind of risk requires the analysis of data that relates the magnitude or intensity of exposure to the incidence or prevalence of adverse effects seen among exposed populations or experimental animals. In contrast, the kinds of hazardous situations covered by the final respiratory protection standard are varied in terms of the nature of the hazard present (i.e., acute, chronic, or both), the frequency and magnitude of exposure, and the types of illnesses associated with exposure to those hazards. As a consequence, the health risks addressed by the final rule cannot be described in terms of an illness-specific risk, but instead relate to the more general probability that a respirator will provide insufficient protection causing the wearer to be exposed to a dangerous level of one or more air contaminants.

Certain studies, referred to as ''workplace protection factor'' (WPF) studies, have attempted to measure the effectiveness of respirators under actual conditions of use in the workplace. The WPF is a measure of the reduction in exposure achieved by using respiratory protection and is represented by an estimate of the ratio of the concentration of a contaminant found in the workplace air to the concentration found inside the respirator facepiece while the respirator is being worn. As the degree of protection afforded by the respirator increases, the WPF increases. Alternatively, the degree of protection provided by a respirator can be expressed as a penetration value, which is the reciprocal of the WPF and reflects the ratio of the concentration of contaminant inside the facepiece to the concentration outside. For example, a WPF of 50 equates to a penetration value of 0.02 and means that the concentration inside the respirator facepiece is one-fiftieth of the ambient level.

Because WPF studies are designed to evaluate the field effectiveness of respiratory protection equipment, study protocols usually have been designed to minimize factors that can reduce respirator performance. Such factors include selecting the wrong type of respirator for the working conditions under which the study is being conducted, use of poorly fitting respirator facepieces (i.e., testing of respirator fit is routinely done in well-conducted WPF studies), inadequate training of wearers in proper respirator adjustment and use, or excessive leakage caused by malfunctioning or dirty respirator parts. Typically, WPF study protocols include procedures for properly selecting respirators and ensuring that they are in good working order, assigning respirators to workers on the basis of valid qualitative or quantitative fit tests, training wearers on how to adjust strap tension properly and use the respirator, and ensuring that neither facial hair nor other personal protective equipment is likely to interfere with respirator fit. In addition, workers included in WPF studies are usually monitored throughout the period that respirators are worn to verify that the equipment is being properly used. All of these conditions reflect the principal elements of a strong respirator program in which respirator performance is optimized; therefore, the results from a good WPF study can mirror the results obtained by an employer who implements a well-run respiratory protection program.

To quantitatively evaluate the impact of implementing a good respirator program on respirator performance, OSHA identified several WPF studies that were conducted using methods that reflect a comprehensive program, and compared these results to other workplace studies that did not employ all of the elements of a good program. Quantitative approaches are used to develop (1) aggregate estimates of respirator effectiveness in both the presence and absence of a good

respiratory protection program, and (2) estimates of the frequency with which workers are likely to achieve inadequate protection while using a respirator, given the presence or absence of a good underlying program. All of the studies used in this analysis pertain to the effectiveness of half-mask, negative-pressure respirators, and all are contained in OSHA's rulemaking docket (H–049).

Many of the well monitored WPF studies conducted were reviewed by Nelson et al. in 1995 (Ex. 64–514); these authors selected data from seven such studies to evaluate the overall field effectiveness of half-mask, negative-pressure respirators. Each of the studies described by Nelson et al. ensured selection of properly fitted respirators either by an accepted qualitative fit test (QLFT) (i.e., isoamyl acetate or saccharin) or by a quantitative fit test (QNFT) where only respirators that provided a minimum protection factor to the wearer of at least 100 were selected. Each of these studies provided for worker instruction in proper respirator use, and workers were monitored during each study to ensure proper use. An additional six studies were reviewed by Nelson et al. but were rejected either because they allegedly used biased sampling methods to determine ambient and in-facepiece contaminant concentrations or because the authors believed that improper or invalidated fit test procedures were employed.

In the studies selected by Nelson *et al.* for analysis, workers used elastomeric or disposable respirators equipped with dust-mist, dust-mist-fume, or high-efficiency particulate (HEPA) filters, and the collection of studies represented a range of workplace exposure situations, including pigment production, metals refining, asbestos exposure during brake-repair work, welding, and spray painting. Geometric Mean (GM) WPF values from these studies ranged from 47 to 3,360, with an overall GM WPF of 290. The 5th percentile WPF from the data set was estimated to be 13, with a 95% confidence interval of 10–18. Nelson et al. concluded from the analysis of the overall data set that the assigned protection factor of 10 for half-mask, negative-pressure respirators was reasonable given that a WPF of less than 10 would not likely occur more than 5 percent of the time. In addition, Nelson et al. found no significant difference in the field performance of disposable respirators compared to elastomeric models. OSHA has not conducted a detailed comparative evaluation of WPF values obtained from disposable vs. elastomeric respirators; if, in fact, disposable respirators provide less protection than elastomeric respirators, the WPFs that can be achieved under a good respirator program will be overstated in this analysis since Nelson et al.'s compiled data reflect the use of both types of respirators.

Each of the studies reviewed by Nelson involved worker exposures to dusts. OSHA could identify only one WPF study, by Galvin et al. in 1990 (Ex. 64–22), that examined respirator effectiveness against exposure to a vapor-phase contaminant rather than a particulate. In this study, WPF measurements were taken on a group of 13 styrene workers who used half-mask, air-purifying respirators equipped with chemical cartridge filters. All employees were assigned respirators based on passing an irritant smoke fit test, and all were trained on how to properly don the respirator and conduct fit checks. In-mask and ambient styrene concentrations were measured over one-hour periods, during which employees were instructed not to readjust the facepiece. Chemical cartridges were changed with each new sampling period to ensure that there was no breakthrough. In-mask styrene concentrations were adjusted upwards by 40 percent to account for pulmonary retention, which avoided potentially overestimating the WPF. The GM WPF for the overall cohort was reported to be 79, with a geometric standard deviation (GSD) of 3.51. There was no significant difference in WPF values between those workers engaged in relatively physical operations, such as spraying, compared to those performing less physical work tasks. The GM WPF found by Galvin et al. for styrene-exposed workers lies within the range of GM WPF values reported in the studies reviewed by Nelson for worker cohorts exposed to particulate-contaminated environments.

Nelson in his 1995 report (Ex. 64–514) excluded the Galvin *et al.* study from his analysis because fit tests were performed using the irritant smoke protocol. As discussed in the Summary and Explanation section of this preamble, OSHA has determined that the irritant smoke qualitative fit test provides a valid, effective test of respirator facepiece fit. The procedures used by Galvin et al. to ensure adequate worker training and respirator use are consistent with the elements of a permissible respirator program, and OSHA, therefore, finds it appropriate to include this study in the set of WPF studies that are representative of effective respiratory program practices.

In contrast, OSHA has identified three studies where investigators also determined WPF values for half-mask, negative-pressure respirators, but where few steps were taken to ensure maximum respirator performance. OSHA believes that these studies illustrate the relative lack of protection afforded by respirators when certain critical elements of the respiratory protection program are missing or inadequate. The studies identified by OSHA are those by Toney and Barnhart in 1972 (Ex. 64–68), Moore and Smith in 1976 (Ex. 64–49), and Harris *et al.* in 1974 (Ex. 27–11).

Toney and Barnhart (Ex. 64–68) conducted a WPF study to evaluate the effectiveness of half-mask, chemical-cartridge respirators on reducing exposures of spray painters to solvent vapors and aerosols. Data were obtained from painters working at 39 different sites and included both in-mask and ambient concentrations. WPFs were found to be low; from the raw data presented in the study, OSHA calculated a GM WPF of 3.8 for solvent exposure (GSD=2.28, N=39) and a GM WPF of 11.4 for aerosol exposure (GSD=4.12, N=40). Penetration tests performed on unused respirator cartridges of the same types used in the field indicated that the poor WPFs achieved in the field tests were caused by poor respirator fit and a lack of respirator maintenance, and were not due to any inherent defect in the cartridges. The authors concluded that respirators being used by painters were not effective and cited several reasons, all pointing to the lack of a respiratory protection program at the facilities tested. For example, 28 percent of respirators used by the painters were poorly maintained. Some of the conditions found by the investigators included deteriorating rubber on the facepieces, the presence of stuck or warped valves, missing head straps, and evidence of leakage around the cartridge seal. In addition, it was apparent that some of the cartridges had not been changed for extended periods of time. Many of the facilities studied supplied non-approved respiratory protective devices (respirators were approved by the Bureau of Mines at the time of the study), and most had no formal training or maintenance program in place. The authors found that ''* * * management and workers are extremely uninformed on the subject of selection, use, and care of respiratory protective devices.'' (Ex. 64–68, p. 93).

The second study, conducted by Moore and Smith in 1976 (Ex. 64–49), measured WPF values obtained by workers exposed to sulfur dioxide (SO_2) during a furnace charging operation at a copper smelter. Three models of half-mask, chemical cartridge respirators

were tested on each of nine workers; in-mask and ambient SO_2 concentrations were measured during the furnace charging operation while the respirators were worn. There is no indication in the study that qualitative or quantitative fit testing was performed to verify adequate facepiece fit. A total of 81 samples were collected, 5 of which were excluded from the analysis because the subjects removed or lifted the respirator facepiece during the sampling period. Average ambient SO_2 concentrations varied in the range of 53 to 61 mg/m^3 (20.4 to 23.5 ppm) during the sampling period. Geometric mean WPF values reported for each of the three models of respirator were 22.1 (SD=22.6), 18.4 (SD=14.2), and 12.9 (SD = 11.0). Moore and Smith concluded that the overall protection afforded by the respirators was poor, and that between one-third and one-half of the protection factors achieved would be below 10, the accepted minimum protection factor for that type of respirator. Reasons given by the authors for the poor fits observed among the subject workers included the possibility that strap tension was not properly adjusted (the authors did not control or monitor strap tension), variation in facial hair (despite the lack of beards or wide sideburns), and normal work activities that caused head motion and deep breathing associated with heavy work.

The third study is that of Harris *et al.* in 1974 (Ex. 27–11), who evaluated the performance of five half-mask dust respirators among 37 miners working in 4 coal mines. In-mask and ambient dust measurements were made throughout the workshifts, during which miners intermittently used respiratory protection. Thus, this study differs from the others described above in that the ratio of in-mask to outside concentrations included periods of time where the respirator was not worn, in contrast to the typical WPF study. The ratio of in-mask to outside concentration determined during periods of intermittent respirator use, termed the ''effective protection factor'' (EPF), is not directly comparable to WPF values because, to the extent that workers spend time in contaminated atmospheres without respiratory protection, the WPF will tend to understate the actual protection obtained while the respirator is being worn. However, according to Poppendorf in 1995 (Ex. 54–512), it is possible to use EPF data to estimate the WPF that was likely to have been achieved during periods of respirator use if both of the following are known or can be estimated: (1) The fraction of time during which the respirator was not worn by the subject, and (2) the ratio of contaminant concentration in areas where the respirator was worn to that in areas where the respirator was not worn. Poppendorf (Ex. 54–512) described the mathematical relationship between the EPF and WPF and suggested that the likely range of average WPF values achieved by the miners during periods of respirator use was 3.6 to 5.7. This estimate of WPF is based on an observation by Harris et al. that miners wore their respirators about half of the time during the sampling periods, and an assumption by Poppendorf (Ex. 54–512) that the dust levels in the air while respirators were worn were at least 5 times higher than airborne dust levels during periods of respirator non-use. OSHA believes that the latter assumption is reasonable given that Harris et al. reported that, for the most part, miners wore their respirators only when visible airborne dust was present. Harris et al. noted that the hard hats worn by the miners interfered with proper respirator strap positioning and adjustment; OSHA believes that this factor, as well as the apparent lack of fit testing, is likely to have contributed to the low protection factors experienced by the miners.

OSHA believes that the studies described above demonstrate that improved respirator performance can be achieved under actual workplace conditions if fit testing is used to select respirators, if respirators are clean and in good working order, and if employees are properly trained and supervised in their use. This is evident when the summary statistics from aggregate protection factor data obtained from field studies on groups of employees using respirators in the absence of a strong respirator program (i.e., Moore and Smith, Toney and Barnhart, Harris *et al.*) are compared with those obtained from cohorts using respirators under the condition of a strong program (i.e., the studies reviewed by Nelson and the study by Galvin *et al.*). Summary protection factor data from these studies are presented in Table V–1 as geometric mean and mean WPF values, and the geometric standard deviation (GSD) of the distribution of WPF values. From these summary statistics, OSHA computed a weighted geometric mean WPF across cohorts exposed to particulate contaminants to compare the central tendency in protection factors achieved both with and without an adequate underlying respirator program (see footnote on Table V–1).

In general, groups of employees using respirators against particulate exposures under a strong program achieved an overall GM protection factor about 25-fold higher than groups using respirators without the elements of a strong respiratory protection program. In studies that did not implement all of these elements, mean WPF values among the particulate-exposed worker cohorts tested ranged from about 6 to 22. Mean WPF values for particulate-exposed worker cohorts included in the WPF studies where elements of a good program were implemented ranged from 72 to 2,400, with the mean WPF from one study estimated to be 11,500. The results from studies that examined respirator effectiveness against gas or vapor, also included in Table V–1, show an 8-fold difference in overall GM WPF values. With only one exception, the 95 percent confidence intervals around the GM WPF values computed from the studies reflecting inadequate program practices do not overlap with those computed from the studies reflecting strong program elements (see Table V–1); thus, the hypothesis that there are no differences in the GM WPF values between the two groups of studies is rejected. This analysis suggests that implementation of a good respiratory protection program containing the elements described by the final rule can contribute to a substantial increase in the overall performance of respirators used in actual workplace settings, as measured by the mean WPF across groups of workers.

TABLE V–1.—SUMMARY RESULTS FROM WORKPLACE PROTECTION FACTOR (WPF) STUDIES AND ESTIMATED FREQUENCIES OF RESPIRATOR FAILURE, BASED ON A ONE-FACTOR ANOVA ANALYSIS OF DATA FROM WORKPLACE PROTECTION FACTOR (WPF) STUDIES

Study	Geometric mean WPF (95% C.I.[1])	Geometric standard deviation	Mean WPF	Estimated percent of workers with:			
				Mean WPF ≤10[2]	Mean WPF ≤2[2]	WPF ≤10 at least 5% of the time[3]	WPF ≤2 at least 5% of the time[3]
Studies Reflecting Inadequate Program Elements							
Particulate Exposure							
Toney and Barnhart [1972] (Ex. 64–68)	[4]11.4 (3.2–39.6)	[4]4.12	31.1	76.8	9.0	100	60.4
Harris et al. [1974] (Ex. 27–11)							
Low Estimate	[5]3.6 (1–17.9)	[5]2–93	6.4	99.7	38.8	100	96.4
High Estimate	[5]5.7 (1.6–20.4)	[5]2.93	10.2	97.0	12.5	100	82.3
Weighted Geometric Mean	[6]5.6						
Gas/Vapor Exposure							
Moore and Smith [1976] (Ex. 64–69)							
Respirator A	15.29 (8.3–28.1)	[7]2.36	22.1	36.2	<0.01	98.9	1.9
Respirator B	13.72 (7.7–24.4)	[7]2.15	18.4	41.3	<0.01	99.7	0.5
Respirator C	9.59 (4.8–19.2)	[7]2.16	12.9	83.1	<0.01	100	9.0
Toney and Barnhart [1972] (Ex. 64–68)	[4]3.8 (1.2–11.9)	[4]2.28	5.3	100	14.7	100	95.7
Weighted Geometric Mean	[6]9.4						
Studies Reflecting Good Program Elements							
Particulate Exposure							
Dixon and Nelson [1984][8]	3360 (3101–3640)	4.8	11,498	<0.01	<0.01	<0.01	<0.01
Gaboury and Burd [1989][8]	47 (31–72)	2.5	72	0.2	<0.01	30.1	<0.01
Lenhart and Campbell [1984][8]	166 (120–228)	3.8	405	0.1	<0.01	9.0	0.02
Nelson and Dixon [1985][8]	258 (192–347)	5.2	1004	0.7	<0.01	14.5	0.3
Gosselink et al. [1986][8]	96 (75–123)	2.3	136	<0.01	<0.01	0.1	<0.01
Colton and Mullins [1992][8]	147 (117–185)	2.5	224	<0.01	<0.01	0.1	<0.01
Myers [1990][8]	346 (256–468)	7.2	2,428	2.8	0.1	22.2	1.7
Weighted Geometric Mean	[6]142						
Gas/Vapor Exposure							
Galvin et al. [1990] (Ex. 64–22)	79 (54–115)	3.5	173	1.1	<0.01	31.7	0.2

[1] 95% confidence interval of the geometric mean WPF calculated as follows for simultaneous confidence intervals: $\tilde{y} \pm SD \div \sqrt{n}\ t_{n-1,1-\alpha/2}$, $\alpha = 1-(1-0.05)^{1/N}$
where n is the number of WPF measurements in each study and N is the number of studies being compared (i.e., 10 for particulate studies and 5 for gas/vapor studies).
[2] Calculated from equation 9 as described in the text; $\delta = 0.1$ for WPF = 10, $\delta = 0.5$ for WPF = 2.
[3] Calculated from equation 10 as described in the text; $\kappa = 0.1$ for WPF = 10, $\kappa = 0.5$ for WPF = 2.
[4] Calculated by OSHA from raw data presented by the authors.
[5] Range of WPF values estimated by Popendorf [1995] (Ex. 54–512), from effective protection factor values (EPF) reported by Harris et al. GSDs calculated by OSHA from median and mean EPF values reported by Harris et al.
[6] Calculated as a weighted geometric mean as follows: $\exp[(\sum \ln GM/(\ln GSD)^2)/\sum(1/(\ln GSD)^2)]$.
[7] Calculated by OSHA from median and mean WPF values reported by Moore and Smith.
[8] Studies reviewed by Nelson [1995] (Ex. 64–514).

The three WPF studies representing deficient program practices were all conducted 10 to 20 years earlier than the WPF studies reflecting good program elements. Thus, differences between the two groups of studies in working conditions, processes and exposures, or respirator equipment and technology could confound the comparison of respirator effectiveness measures. OSHA is not aware of any recent studies that have been conducted that were designed to evaluate the impact of respirator program elements on respirator effectiveness, nor are recent studies available that have attempted to measure respirator effectiveness under conditions of a poor respiratory protection program. OSHA believes that this analysis of program impacts on respirator performance is based on the best available data. However, OSHA has considered whether confounding factors related to the elements of a good respirator program may also have contributed to the differences in respirator performance reported by the two groups of WPF studies. For example, respirator fit can be adversely affected by vigorous work activity requiring head motion and deep breathing. Heavy work loads also contribute to respirator discomfort, which may cause a worker to wear a respirator too loosely. The nature of the air contaminant affects respirator performance in that different types of respirator filters have different capabilities in purifying contaminated air and gas-phase contaminants and small-particulate aerosols pass more readily through leak points than do aerosols comprised mostly of larger particles.

OSHA does not believe that any systematic differences in working conditions or respirator technology contribute substantially to the differences in respirator effectiveness found between the two groups of studies included in the analysis. For example, both groups of studies represent a range of workplace situations that involve strenuous and non-strenuous work. In the studies that do not reflect good program practices, workers were engaged in active, strenuous work (smelter operations and coal mining) as well as less active work (spray painting). Similarly, studies that reflect good program practices have also been conducted on worker cohorts engaged in both active work (metals refining) and less active work (spray painting, brake repair). Both groups of studies also involve a range of contaminants, including both gas-phase and various kinds of particulate. Some of the studies reviewed by Nelson included information on the size distribution of

particulates to which workers were exposed, with the range across these studies including both respirable and non-respirable particles. Other studies included in the Nelson analysis reported that workers were exposed to both dust and fume. Therefore, the differences in WPFs found between the two groups of studies cannot be explained by differences in particulate sizes or characteristics. Both groups of studies also represent a variety of half-mask respirator designs and filters, including single-use respirators and respirators equipped with dust/mist (i.e., non-HEPA) filters. OSHA believes it unlikely that the 14-fold difference in overall WPFs between the two groups of studies can be primarily attributed to any fundamental differences in respirator equipment or technology. Therefore, OSHA finds that the differences in WPF values obtained from the two groups of studies are more likely to reflect differences in how well the respirators fit the subject workers, the condition of the respiratory equipment used, and the extent to which the equipment was used properly, rather than any confounding caused by systematic differences in work settings, the nature of the exposures, or the age of the WPF studies.

The kinds of summary statistics presented in Table V–1 have been used by several investigators to demonstrate how poorly or how well respirators can protect workers under actual conditions of use (see, for example, Moore and Smith (Ex. 64–69), Nelson et al. (Ex. 64–514)). However, such descriptive measures can only provide information on the aggregate frequency distribution of protection factor values in a group of workers. Although it is useful to rely on summary statistics from aggregate protection factor data to make general statements about the effectiveness of respirators, such measures do not adequately convey information on the number or proportion of workers who remain at risk of overexposure to air contaminants despite the use of respiratory protection, or how frequently an individual worker might experience poor fits.

Nicas (Ex. 156) and Nicas and Spear in 1992 (Ex. 64–425) have suggested that using statistics from aggregate protection factor data does not adequately describe the true risk of overexposure to workers using respirators because the approach fails to recognize that there are two different sources of variability that account for the overall variation in protection factor values measured from a given cohort of workers. One source of variability in protection factors is the variation typically experienced by a single worker from one day to the next; this is termed within-worker variability. The second source of variability reflects the observation that different workers within a group will achieve different average protection factors over a given period of time; this is termed between-worker variability. In a peer-reviewed article, Nicas and Spear (Ex. 64–425) have described a statistical model that accounts for both sources of variability. This model has been used by OSHA to estimate the following from the protection factor studies described above to better characterize risks to workers who use respirators both in the absence of and under a strong respiratory protection program:

(1) The proportion of workers who fail to achieve a long-term average protection factor at or above some specified target level, exposing the worker to an increased risk of a chronic health hazard (i.e., a health hazard that is typically associated with long-term cumulative exposure); and

(2) The proportion of workers who achieve a protection factor below some specified target level at least 5 percent of the time that the respirator is worn, thus increasing the frequency with which a worker may be exposed above an effect concentration associated with an acute health hazard.

The Nicas and Spear model (Exs. 64–425, 156) used by OSHA in this analysis is a one-factor analysis of variance and is described briefly as follows. Let P denote a penetration value experienced by the wearer of a respirator during a randomly selected wearing time (P is defined as the reciprocal of the protection factor PF measured in the workplace, or 1/PF). For example, a P value of 0.1 for a respirator wearer reflects that a protection factor of 10 was achieved in the workplace for that individual. If one were to measure the penetration values among members of a group of workers over time and aggregate the results, the total distribution of P values can be described by the following parameters:

$$P = \mu_p \times B \times W \quad (1)$$

$$GM[P] = \mu_p \times GM[B] \times GM[W] \quad (2)$$

$$GSD[P] = \exp\left(\sqrt{\ln^2 GSD[B] + \ln^2 GSD[W]}\right) \quad (3)$$

Where:

P = the penetration value for a worker for a particular wearing period,

μ_p = the arithmetic mean penetration value for the population,

B = a lognormally distributed factor that transforms μ_p to the arithmetic mean penetration value for the individual worker, and

W = a lognormally distributed factor that transforms $\mu_p \times B$ to the P value experienced by the individual worker for a particular wearing time.

The factors W and B describe within-worker variability and between-worker variability, respectively.

Since workplace protection factor studies typically report the geometric mean and geometric standard deviation of protection factor values obtained from a cohort of respirator wearers (i.e., GM[P] and GSD[P]), the parameters described above for within-worker and between worker variability can be estimated as follows if the relationship between GSD[B] and GSD[W] are known or assumed. Let R represent the ratio of GSD[W]/GSD[B]; then GSD[B] can be estimated from GSD[P] and R by the relationship

$$GSD[B] = \exp\left(\left[-\frac{1}{2}\ln R\right] + \frac{1}{2}\left[\sqrt{\ln^2 R + 2\left(\ln^2 GSD(P) - \ln^2 R\right)}\right]\right). \quad (4)$$

GSD[W], GM[B], and GM[W] are estimated by:

$$(5) \qquad GSD[W] = GSD[B] * R$$

$$(6) \qquad GM[W] = 1/\exp\left(0.5 * \ln^2\left(GSD[W]\right)\right), \text{and}$$

$$(7) \qquad GM[B] = 1/\exp\left(0.5 * \ln^2\left(GSD[B]\right)\right).$$

The arithmetic mean of the total distribution of penetration values across the whole cohort, μ_p, is estimated by:

$$(8) \qquad \mu_p = \frac{GM[P]}{(GM[B] * GM[W])}$$

Nicas (Ex. 156) defines two additional values, δ and κ, that are based on the parameters described above. The value δ represents the 95th percentile of the between-wearer distribution of average penetration values among a cohort of respirator wearers; thus, there is a 5 percent chance that a respirator wearer in the cohort could have an average penetration value of δ or higher. If δ is set to some penetration value reflecting some minimum acceptable value of protection, the probability that a respirator wearer would fail, on average, to achieve the minimum acceptable penetration value is Pr(Z>z), where

$$(9) \qquad z = \frac{\left(\ln \delta - \left(\ln \mu_p + \ln GM[B]\right)\right)}{\ln GSD[B]}$$

and Z is the standard normal deviate. By estimating the parameters μ_p, GM[B], and GSD[B] from WPF data, one can estimate the probability that a respirator wearer could have an average penetration value greater than some specified value δ.

The value κ is defined by Nicas (Ex. 154) based on the distribution of each worker's 95th percentile P value and represented the P value experienced at least 5 percent of the time by 95 percent of workers in the cohort. If κ is set to some minimum acceptable P value, the estimated probability that a respirator wearer could fail to achieve the minimum P value at least 5% of the time is Pr(Z>z), where

$$(10) \qquad z = \frac{\ln \kappa - \left[\ln \mu_p + \ln GM[B] + (1.645 \ln GSD[W]) - \left(0.5 \ln^2 GSD[W]\right)\right]}{\ln GSD[B]}$$

and Z is the standard normal deviate. Thus, the proportion of workers who fail to achieve a P value of κ at least 5 percent of the time can be determined by estimating the parameters μ_p, GM[B], and GSD[W] from WPF data.

The following hypothetical example illustrates OSHA's use of the model to estimate the risk to workers of experiencing an overexposure while using respiratory protection. Suppose that the WPF values obtained from a group of workers using half-mask, negative-pressure respirators are found to have a geometric mean of 50 (i.e., GM[P] = 1/50 = 0.02) and a geometric standard deviation of 3.0 (GSD[P] = 3.0). Furthermore, from one of the WPF studies reviewed by OSHA (Galvin et al.) (Ex. 64–22), it was reported that within-worker variability exceeded between-worker variability in workplace protection factors, with the ratio GSD[W]/GSD[B] = 1.5. From equations 4 through 7 above, and assuming that R = 1.5, then GSD[B] = 1.73, GSD[W] = 2.60, GM[W] = 0.63, and GM[B] = 0.86. The arithmetic average of the cohort's P values, μ_p, is estimated from equation 8 to be 0.037. If a protection factor of less than 10 (the NIOSH minimum assigned PF for half-mask respirators) is considered to place the worker at risk of an overexposure, then equation 9 predicts a probability of 1.8 percent that a worker in the group would be expected to have an average WPF value of 10 or less (i.e., δ is set to 0.1 in equation 9); that is, 1.8 percent of the group of respirator wearers would frequently encounter situations where they are working in a hazardous environment without the minimum protection expected from the respirators being used. By equation 10, there is a substantial probability (47 percent) that a worker in the cohort would not achieve a minimum protection factor of 10 at least 5 percent of the time that respirators are used (i.e., κ is set to 0.1 in equation 10).

OSHA used the Nicas and Spear model, the summary data from the WPF studies reviewed above, and the method outlined in the example described above to estimate the probability that a respirator wearer would fail to receive adequate protection from their respirator; the detailed results of this analysis appear in Table V–1, and summary findings are listed in Table V–2. From the studies that reflect the lack of an adequate respiratory protection program, the Nicas and Spear model predicts a high probability (between 36 and 100 percent) that a wearer would

not achieve an average protection factor of 10. Data from two of these studies by Toney and Barnhart (Ex. 64–68), and Harris *et al.* (Ex. 27–11), when used in the model, suggest a probability of between 13 and 39 percent that the average WPF for a respirator wearer could be 2 or less, which may be considered equivalent to receiving no long-term protection at all. In contrast, workers included in the studies reflecting good respirator program elements would be expected to experience low WPFs much less frequently. The probability that a wearer would attain an average WPF of 10 or less is estimated to be between <0.01 and 3 percent. Results from the studies that reflect good respiratory program practices also indicate that long-term average WPF values at or below 2 would rarely occur. The results from this analysis demonstrate that deficiencies in implementing a good respirator program can greatly increase the chance that the wearer of a negative-pressure respirator will receive less than the minimum expected average protection from the respirator over the long-term, thus increasing the chance that the worker will be exposed to a higher chronic health risk.

TABLE V–2.—SUMMARY ESTIMATES OF THE PROBABILITY OF ACHIEVING INADEQUATE FITS FOR HALF-MASK, NEGATIVE-PRESSURE RESPIRATORS UNDER DEFICIENT AND GOOD RESPIRATORY PROTECTION PROGRAMS

Quality of respirator program	Percent probability that wearer will achieve	
	Average workplace fit factor of less than 10	Workplace fit factor of less than 10 at least 5 percent of time that respirator is worn
Deficient	36–100	99–100
Good	<0.01–3	<0.01–32

OSHA's analysis (Tables V–1 and V–2) also demonstrates that workers using respiratory protection under a deficient program will be exposed more frequently to higher concentrations of airborne contaminants, which may increase the risk that the worker will experience acute health effects. The Nicas and Spear model applied to the studies that reflect inadequate respirator programs predicts nearly a 100 percent chance that a protection factor of less than or equal to 10 would be experienced at least 5 percent of the time. Under conditions of a good respirator program, use of the model suggests no more than a 32 percent chance that WPFs of less than or equal to 10 will occur more than 5 percent of the time.

OSHA finds that, without an adequate respiratory protection program in place, a substantial fraction of respirator users are at risk of being overexposed to hazardous air contaminants due to poor respirator performance. The studies conducted under conditions of a poor respirator program, when analyzed using the Nicas and Spear model, suggest a greater than 50 percent probability that the wearer of a half-mask, negative-pressure respirator will regularly fail to attain the expected minimum level of protection, and that the chance of receiving essentially no protection is substantial. OSHA considers these risks of overexposure to be significant. The studies reviewed by Nelson and the Galvin study indicate that these risks are considerably lower in situations where respirators are used in conjunction with the implementation of strong respiratory protection program elements such as appropriate fit testing, adequate employee training, use of clean respirators in good working order, and regular monitoring of employees to ensure proper respirator use. Thus, OSHA finds that implementation of a comprehensive respiratory protection program, such as the one prescribed by the final rule, will substantially reduce the risk of overexposure that is due to respirator failure. Because such overexposures can place workers at a significant risk of health impairment, as described earlier in this section, OSHA also finds that promulgation of the final rule will substantially reduce the significant health risks associated with those overexposures.

VI. Summary of the Final Economic Analysis

In the Final Economic Analysis, OSHA addresses the significant issues related to technological and economic feasibility and small business impacts raised in the rulemaking process. This analysis also explains in detail the Agency's findings and conclusions concerning pre-standard (baseline) conditions, such as respirator program practices, in establishments in the regulated community, and discusses how and why the requirements of the standard are expected to reduce employee exposures. The preamble to the revised rule and the Final Economic Analysis are integrally related and together present the fullest statement of OSHA's reasoning concerning this standard. The Final Economic Analysis has been placed in the rulemaking docket.

This analysis of OSHA's revised Respiratory Protection standard (29 CFR 1910.134) has been conducted in accordance with Executive Orders (EOs) 12866 and 12875, the Regulatory Flexibility Act (as amended in 1996), the Small Business Regulatory Enforcement Fairness Act (SBREFA), the Unfunded Mandates Reform Act (UMRA) and the Occupational Safety and Health Act. The standard is a ''significant'' rule as defined by EO 12866, a ''major'' rule as defined by Sec. 804 of SBREFA, and a ''significant'' rule as defined by UMRA.

The purposes of this Final Economic Analysis are to:

- Describe the need for a revised standard governing the use of respirators;
- Identify the establishments, industries and employees potentially affected by the standard;
- Evaluate the costs, benefits, economic impacts and small business impacts of the standard on affected firms;
- Assess the technological and economic feasibility of the standard for affected establishments, industries, and small businesses; and
- Identify the availability of effective non-regulatory and alternative regulatory approaches.

OSHA's final Respiratory Protection standard covers the use of respiratory protection in general industry, construction and shipyard employment, as well as marine terminals and longshoring. In all, about 5 million

employees are estimated to use respirators.[1] Workers use respirators to protect themselves from a wide variety of occupational exposures. Respirators are used, at least to some extent, in virtually every industry, although the extent of respirator use varies by industry. Manufacturing and construction have relatively heavy respirator use; in contrast, use in many service industries is very limited.

Chapter II of the economic analysis describes the pattern of respirator use within each affected industry. To develop this profile, the Agency analyzed the results of several OSHA-sponsored nationwide surveys. The results of OSHA's analysis appear in Table VI–1. The Agency estimates that approximately five percent of workers wear respirators at some time, and that approximately 1.3 million establishments, or about 20 percent of all establishments, have employees who use respirators. Approximately 900,000 of these establishments are very small, i.e., have fewer than 20 employees. For a discussion of the number of firms identified by the Small Business Administration (SBA) as small, see Chapter V.

TABLE VI–1.—NUMBER OF RESPIRATOR USERS AND THEIR EMPLOYERS BY INDUSTRY

SIC and industry	Total employment	Number of respirator wearers	Total number of establishments	Number of establishments with respirator wearers
07 Agricultural services	555,686	48,262	95,956	25,464
08 Forestry	17,716	2,764	2,251	950
13 Oil and gas extraction	257,694	46,180	18,502	3,313
15 General contractors and operative builders	1,096,289	202,284	180,998	70,835
16 Heavy construction, except building	679,578	99,668	34,332	13,403
17 Special trade contractors	2,731,774	491,928	382,528	115,380
20 Food and kindred products	1,498,078	87,589	21,049	8,899
21 Tobacco products	37,189	2,022	119	47
22 Textile mill products	615,683	66,989	6,245	1,937
23 Apparel and other textile products	972,060	26,431	24,293	5,238
24 Lumber and wood products	675,081	89,970	37,087	15,922
25 Furniture and fixtures	476,488	56,141	11,515	7,675
26 Paper and allied products	627,746	41,313	6,478	2,616
27 Printing and publishing	1,500,580	19,185	65,416	6,393
28 Chemicals and allied products	851,720	230,405	12,371	10,744
29 Petroleum and coal products	112,984	29,647	2,117	1,398
30 Rubbber and miscellaneous plastics products	915,166	53,800	16,048	6,805
31 Leather and leather products	104,747	4,406	2,025	324
32 Stone, clay, and glass products	471,639	69,904	16,208	8,798
33 Primary metal industries	655,556	133,012	6,726	4,105
34 Fabricated metal products	1,371,072	124,289	36,416	17,134
35 Industrial machinery and equipment	1,749,735	96,161	54,436	25,545
36 Electronic and other electronic equipment	1,424,351	65,930	17,073	6,895
37 Transportation equipment	1,601,554	185,783	11,420	7,649
38 Instruments and related products	878,379	35,188	11,419	4,207
39 Miscellaneous manufacturing industries	375,501	22,751	17,183	6,793
40 Railroad transportation	49,200	1,790	1,000	225
41 Local and interurban passenger transit	366,657	13,337	18,603	4,194
42 Trucking and warehousing	1,633,543	59,497	115,531	26,049
44 Water transportation	162,478	7,458	8,412	605
45 Transportation by air	344,822	12,543	11,436	822
46 Pipelines, except natural gas	17,143	2,808	811	521
47 Transportation services	363,103	22,428	47,858	3,441
48 Communication	1,299,658	15,176	40,399	3,457
49 Electric, gas, and sanitary services	924,373	187,298	21,040	10,148
50 Wholesale trade—durable goods	3,414,441	373,644	317,418	118,387
51 Wholesale trade—nondurable goods	2,504,260	289,619	185,908	70,196
52 Building materials and garden supplies	696,228	95,688	69,965	19,822
53 General merchandise stores	2,141,964	21,420	35,646	3,565
54 Food stores	3,027,828	30,278	181,850	18,185
55 Automotive dealers and service stations	1,992,774	245,662	198,905	80,121
56 Apparel and accessory stores	1,194,121	15,788	143,526	14,353
57 Furniture and homefurnishings stores	754,024	12,348	112,254	11,225
58 Eating and drinking places	6,727,618	67,276	441,512	44,151
59 Miscellaneous retail	2,422,923	38,734	352,129	35,213
60 Depository institutions	2,095,049	20,950	102,622	10,262
61 Nondepository institutions	483,133	4,831	41,869	4,187
62 Security and commodity brokers	449,826	4,498	34,325	3,433
63 Insurance carriers	1,570,356	15,704	43,784	4,378
64 Insurance agents, brokers, and service	656,007	13,452	122,292	12,229
65 Real estate	1,335,048	25,846	234,961	23,496
67 Holding and other investment offices	254,172	3,016	27,420	2,742
70 Hotels and other lodging places	1,527,126	15,271	52,874	5,287

[1] Approximately 5% of these respirator-using employees would be subject to OSHA's substance-specific health standards rather than to this standard.

TABLE VI–1.—NUMBER OF RESPIRATOR USERS AND THEIR EMPLOYERS BY INDUSTRY—Continued

SIC and industry	Total employment	Number of respirator wearers	Total number of establishments	Number of establishments with respirator wearers
72 Personal services	1,252,777	45,854	200,520	23,848
73 Business services	5,832,261	255,034	322,668	38,375
75 Auto repair, services, and parking	903,806	110,528	174,635	70,345
76 Miscellaneous repair services	439,495	5,103	72,763	3,810
78 Motion pictures	500,889	5,009	42,457	4,246
79 Amusements and recreation services	1,201,248	12,012	88,077	8,808
80 Health services	10,403,118	217,118	471,873	108,337
81 Legal services	962,374	17,417	158,335	15,834
82 Educational services	1,967,024	19,670	42,867	4,287
83 Social services	2,028,694	20,287	145,998	14,600
84 Museums, botanical, zoological gardens	73,874	739	3,607	361
86 Membership organizations	2,062,501	26,275	238,868	23,887
87 Engineering and management services	2,589,839	27,483	249,846	24,985
89 Services, n.e.c.	84,960	1,607	14,606	1,461
92 Fire Departments (State Plan States)	126,500	126,500	9,283	9,283
Other public sector (State Plan States)	7,677,000	114,570	203,158	20,316
Total	98,768,281	4,953,568	6,494,122	1,281,945

Sources: DOL, OSHA Office of Regulatory Analysis; County Business Patterns, 1993; OSHA's respirator, PEL, PPE, and Construction PEL surveys.

The new standard is programmatic in nature, reflects current practice at many facilities, and does not require the use of new technology. Thus, OSHA finds that the standard is clearly technologically feasible for affected firms of all sizes.

The benefits that will accrue to respirator users and their employers are substantial and take a number of forms. Chapter IV of the analysis describes these benefits, both in quantitative and qualitative forms. The standard will benefit workers by reducing their exposures to respiratory hazards. Improved respirator selection procedures, better fit test procedures, and improved training, all areas strengthened by the revised standard, will contribute substantially to greater worker protection. Estimates of the benefits of the standard are complicated by uncertainties about the effectiveness of the standard and the number of covered work-related illnesses. The Agency estimates that the standard will avert between 843 and 9,282 work-related injuries and illnesses annually, with a best estimate (expected value)[2] of 4,046 averted illnesses and injuries annually. In addition, the standard is estimated to 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.[3]

The annual costs employers in the affected establishments are estimated to incur to comply with the revised respirator standard total $111 million.[4] These costs, which are presented in detail in Chapter III of the full economic analysis, are annualized over a 10-year horizon at a discount rate of 7 percent; Table VI–2 shows annualized costs by provision of the standard. The most costly provisions are those requiring annual fit testing of respirators and annual refresher training. These two provisions together account for approximately 90 percent of the standard's compliance costs. As a rule, costs are largely determined by the extensiveness of respirator use in affected establishments. This analysis did not attempt to factor in the offsetting value of cost savings from regulatory changes, such as dropping the existing standard's prohibition against contact lens use, providing for greater uniformity for substance-specific health standard respirator provisions, or allowing employers to use licensed health care providers in addition to physicians to perform medical evaluations.

[2] OSHA believes that, for the purposes of this rulemaking, the most reasonable way to summarize the uncertainties in benefits estimates via a single numerical estimate is to use the expected value; that is, the average of all plausible values weighted by their relative probabilities. For simplicity's sake, OSHA will refer to this point estimate as the ''best estimate.''

[3] Because this regulation will not directly affect the benefits for the estimated 5% of employees who wear respirators as a result of OSHA's substance-specific health standards (except to the extent that uniformity of provisions improve compliance), and these respirator-wearing employees are included in the benefits estimates presented here, the benefits of the revised respiratory protection standard are somewhat overestimated. In particular, deaths and illnesses caused by exposures to such OSHA-regulated substances as asbestos and lead may in fact account for a disproportionate share (more than 5%) of the occupational illnesses and deaths attributed by this analysis to the respirator standard. This means that OSHA's benefits estimates are likely to be overstated by more than 5%. Nevertheless, OSHA believes that the substantial majority of the benefits resulting from appropriate respirator use can be properly attributed to the respirator standard.

[4] Because this regulation does not directly affect the costs for the estimated 5% of employees who wear respirators as a result of OSHA's substance-specific health standards, and these respirator users are included in the cost estimates, the costs are somewhat overestimated. Because costs are approximately proportional to the number of employees affected, the magnitude of this overestimate is likely to be about 5%.

TABLE VI–2.—ANNUAL COST OF RESPIRATOR STANDARD REVISIONS FOR RESPIRATOR-USING ESTABLISHMENTS, BY PROVISION

SIC and industry	Revision written plans	Annual fit testing	Annual training	Certification for emergency respirator inspections	Labeling for sorbent bed changes	Record-keeping	Total
07 Agricultural services	$31,755	$441,836	$298,047	$0	$0	$35,858	$807,497
08 Forestry	1,228	25,475	13,849	0	0	2,054	42,606
13 Oil and gas extraction	8,769	734,048	315,180	41,551	0	34,312	1,133,860
15 General contractors and operative builders	141,534	2,992,402	1,909,631	0	479	150,297	5,194,342
16 Heavy construction, except building	32,027	1,534,132	736,976	0	2,109	74,053	2,379,297
17 Special trade contractors	256,681	7,820,459	4,340,977	0	1,344	365,502	12,784,963
20 Food and kindred products	21,109	1,006,778	428,004	86,371	0	65,078	1,607,339
21 Tobacco products	210	37,254	16,252	0	0	1,502	55,218
22 Textile mill products	4,349	728,823	286,222	9,703	0	49,773	1,078,870
23 Apparel and other textile products	7,864	226,658	101,380	0	0	19,638	355,540
24 Lumber and wood products	27,997	972,293	489,510	16,750	0	66,848	1,573,397
25 Furniture and fixtures	13,119	623,774	289,781	53,627	0	41,712	1,022,013
26 Paper and allied products	8,373	877,037	280,715	66,279	105	30,696	1,263,205
27 Printing and publishing	15,217	221,275	139,295	0	0	14,255	390,041
28 Chemicals and allied products	33,159	4,194,240	1,656,678	741,170	763	171,191	6,797,201
29 Petroleum and coal products	4,699	646,431	277,684	108,927	16	22,028	1,059,785
30 Rubber and miscellaneous plastics products	14,100	676,734	284,187	2,068	0	39,974	1,017,063
31 Leather and leather products	456	37,208	15,800	1,502	0	3,274	58,239
32 Stone, clay, and glass products	20,743	1,018,192	464,833	28,365	11	51,939	1,584,083
33 Primary metal industries	14,028	2,263,416	951,396	44,664	28	98,828	3,372,360
34 Fabricated metal products	41,510	1,663,770	765,562	178,892	0	92,346	2,742,081
35 Industrial machinery and equipment	64,626	1,498,968	786,251	0	868	71,447	2,422,161
36 Electronic and other electronic equipment	17,103	917,414	388,929	24,483	657	48,986	1,397,572
37 Transportation equipment	23,876	3,413,486	1,568,463	100,401	8,775	138,037	5,253,038
38 Instruments and related products	10,299	516,278	230,813	1,626	333	26,145	785,493
39 Miscellaneous manufacturing industries	12,007	250,490	136,104	0	176	16,904	415,682
40 Railroad transportation	937	37,818	16,134	0	0	1,330	56,219
41 Local and interurban passenger transit	9,002	167,510	86,710	0	0	9,910	273,131
42 Trucking and warehousing	64,666	791,301	511,259	570	0	44,206	1,412,003
44 Water transportation	1,588	136,318	65,312	0	0	5,541	208,760
45 Transportation by air	2,015	199,061	85,196	0	0	9,320	295,592
46 Pipelines, except natural gas	1,637	87,121	31,182	0	15	2,086	122,041
47 Transportation services	6,150	256,532	135,948	0	0	16,664	415,294
48 Communication	9,141	282,097	141,518	0	0	11,276	444,032
49 Electric, gas, and sanitary services	32,542	3,736,483	1,662,243	359,209	4,581	139,162	5,934,220
50 Wholesale trade—durable goods	241,074	5,545,911	2,737,719	6,687	0	277,618	8,809,008
51 Wholesale trade—nondurable goods	134,760	3,979,336	1,728,752	126,854	0	215,187	6,184,888
52 Building materials and garden supplies	24,193	922,814	418,187	0	0	71,096	1,436,291
53 General merchandise stores	5,369	135,056	56,819	0	0	15,915	213,160
54 Food stores	27,336	208,820	154,036	0	0	22,497	412,689
55 Automotive dealers and service stations	112,276	1,920,333	1,281,723	0	0	182,527	3,496,858
56 Apparel and accessory stores	19,022	91,801	92,713	0	0	11,730	215,266
57 Furniture and homefurnishings stores	20,225	111,532	106,953	0	0	9,175	247,884
58 Eating and drinking places	47,123	257,557	214,860	0	0	49,986	569,526
59 Miscellaneous retail	53,098	275,565	269,808	0	0	28,780	627,250
60 Depository institutions	20,271	207,313	135,320	0	0	15,566	378,470
61 Nondepository institutions	10,608	51,626	53,951	0	0	3,590	119,776
62 Security and commodity brokers	10,508	64,998	58,550	0	0	3,342	137,397
63 Insurance carriers	13,360	226,063	123,889	0	0	11,668	374,979
64 Insurance agents, brokers, and service	36,394	200,209	199,277	0	0	9,995	445,875
65 Real estate	70,079	348,877	368,891	0	0	19,203	807,051
67 Holding and other investment offices	8,272	43,583	43,970	0	0	2,241	98,066
70 Hotels and other lodging places	8,119	101,853	57,381	0	0	11,347	178,699
72 Personal services	26,015	552,641	270,488	0	0	34,069	883,214
73 Business services	58,974	3,325,952	1,172,726	0	0	189,490	4,747,142
75 Auto repair, services, and parking	93,387	970,308	881,030	0	0	82,122	2,026,846
76 Miscellaneous repair services	5,735	61,214	54,759	0	0	3,791	125,499
78 Motion pictures	11,425	62,923	61,091	0	0	3,722	139,160
79 Amusement and recreation services	14,128	93,683	76,484	0	0	8,925	193,220
80 Health services	183,206	2,510,780	1,948,071	0	0	161,319	4,803,376
81 Legal services	47,661	253,320	256,703	0	0	12,941	570,625
82 Educational services	10,933	259,816	125,365	0	0	14,615	410,729
83 Social services	23,601	166,510	130,949	0	0	15,073	336,133
84 Museums, botanical, zoological gardens	891	8,995	6,036	0	0	549	16,471
86 Membership organizations	57,115	316,483	304,939	0	0	19,523	698,060
87 Engineering and management services	74,480	380,740	390,356	0	0	20,420	865,997
89 Services, n.e.c.	4,082	28,754	22,201	0	0	1,194	56,231

TABLE VI–2.—ANNUAL COST OF RESPIRATOR STANDARD REVISIONS FOR RESPIRATOR-USING ESTABLISHMENTS, BY PROVISION—Continued

SIC and industry	Revision written plans	Annual fit testing	Annual training	Certification for emergency respirator inspections	Labeling for sorbent bed changes	Record-keeping	Total
92 Fire Departments	24,723	2,265,377	1,005,792	0	0	93,990	3,389,882
Other public sector	48,361	49,739	1,147,899	0	0	85,126	1,331,125
Total	2,501,319	67,033,593	35,865,707	1,999,699	20,259	3,680,501	111,101,079

Source: Department of Labor, Safety and Health Administration, Office of Regulatory Analysis.

Chapter V of the economic analysis analyzes the impact of these compliance costs on establishments in affected industries. The standard is clearly economically feasible: the cost in the average affected establishment is 0.002 percent of sales and 0.03 percent of profits; in the most heavily impacted industry—business services, SIC 73—annualized compliance costs amount to only 0.1 percent of estimated sales and 1.22 percent of profits. In the next most heavily impacted industry—Special Trade Contractors, SIC 17—costs amount only to 0.02 percent of sales and 0.46 percent of profits. These results are shown in Table VI–3.

TABLE VI–3.—ANNUAL COST OF FINAL RESPIRATORY PROTECTION STANDARD AS A PERCENT OF SALES AND PROFITS OF RESPIRATOR-USING ESTABLISHMENTS

SIC and industry	Average compliance cost/establishment	Average sales/establishment	Average profit/establishment	Compliance cost as a percent of sales	Compliance cost as a percent of profits
07 Agricultural services	$32	$269,290	17,425	0.01	0.18
08 Forestry	45	897,908	69,720	0.00	0.06
13 Oil and gas extraction	364	11,234,630	1,021,330	0.00	0.04
15 General contractors and operative builders	73	1,131,765	52,585	0.01	0.14
16 Heavy construction, except building	178	2,709,660	146,028	0.01	0.12
17 Special trade contractors	111	476,348	24,098	0.02	0.46
20 Food and kindred products	192	20,620,629	999,788	0.00	0.02
21 Tobacco products	1,169	869,935,367	204,319,114	0.00	0.00
22 Textile mill products	578	7,611,245	438,223	0.01	0.13
23 Apparel and other textile products	68	3,228,588	194,177	0.00	0.03
24 Lumber and wood products	99	2,539,729	146,588	0.00	0.07
25 Furniture and fixtures	140	3,571,798	216,729	0.00	0.06
26 Paper and allied products	551	22,478,383	1,260,152	0.00	0.04
27 Printing and publishing	61	2,096,632	152,975	0.00	0.04
28 Chemicals and allied products	909	29,454,052	2,231,368	0.00	0.04
29 Petroleum and coal products	1,053	143,210,471	6,292,581	0.00	0.02
30 Rubber and miscellaneous plastics products	150	8,202,235	584,099	0.00	0.03
31 Leather and leather products	187	7,267,252	429,429	0.00	0.04
32 Stone, clay, and glass products	183	4,184,931	228,219	0.00	0.08
33 Primary metal industries	864	18,123,180	1,015,996	0.00	0.08
34 Fabricated metal products	170	4,348,383	266,070	0.00	0.06
35 Industrial machinery and equipment	95	6,924,099	482,589	0.00	0.02
36 Electronic and other electronic equipment	207	11,591,397	684,946	0.00	0.03
37 Transportation equipment	724	44,334,058	1,948,012	0.00	0.04
38 Instruments and related products	187	10,720,444	763,426	0.00	0.02
39 Miscellaneous manufacturing industries	61	1,568,937	111,245	0.00	0.06
40 Railroad transportation	249	NA	NA	NA	NA
41 Local and interurban passenger transit	65	1,014,732	43,699	0.01	0.15
42 Trucking and warehousing	54	1,286,872	58,437	0.00	0.09
44 Water transportation	345	NA	NA	NA	NA
45 Transportation by air	359	3,106,975	197,717	0.01	0.18
46 Pipelines, except natural gas	234	13,802,633	585,566	0.00	0.04
47 Transportation services	121	23,585,180	8,076,137	0.00	0.00
48 Communication	128	1,894,095	82,755	0.01	0.16
49 Electric, gas, and sanitary services	677	15,622,527	2,485,402	0.00	0.03
50 Wholesale trade—durable goods	74	14,371,043	1,350,007	0.00	0.01
51 Wholesale trade—nondurable goods	89	2,282,652	102,134	0.00	0.09
52 Building materials and garden supplies	72	4,447,849	172,734	0.00	0.04
53 General merchandise stores	60	1,075,912	36,708	0.01	0.16
54 Food stores	23	8,648,964	471,762	0.00	0.00
55 Automotive dealers and service stations	44	2,179,673	61,031	0.00	0.07
56 Apparel and accessory stores	15	2,010,075	47,296	0.00	0.03
57 Furniture and homefurnishings stores	22	737,603	47,246	0.00	0.05
58 Eating and drinking places	13	672,234	34,798	0.00	0.04

TABLE VI–3.—ANNUAL COST OF FINAL RESPIRATORY PROTECTION STANDARD AS A PERCENT OF SALES AND PROFITS OF RESPIRATOR-USING ESTABLISHMENTS—Continued

SIC and industry	Average compliance cost/establishment	Average sales/establishment	Average profit/establishment	Compliance cost as a percent of sales	Compliance cost as a percent of profits
59 Miscellaneous retail	18	734,358	34,558	0.00	0.05
60 Depository institutions	37	547,141	30,254	0.01	0.12
61 Nondepository institutions	29	8,651,403	NA	0.00	NA
62 Security and commodity brokers	40	9,094,686	1,419,322	0.00	0.00
63 Insurance carriers	86	6,131,429	631,723	0.00	0.01
64 Insurance agents, brokers, and service	36	65,412,387	NA	0.00	NA
65 Real estate	34	674,913	NA	0.01	NA
67 Holding and other investment offices	36	500,929	46,869	0.01	0.08
70 Hotels and other lodging places	34	5,183,873	573,368	0.00	0.01
72 Personal services	37	1,243,240	97,027	0.00	0.04
73 Business services	124	128,952	10,164	0.10	1.22
75 Auto repair, services, and parking	29	975,693	74,455	0.00	0.04
76 Miscellaneous repair services	33	358,494	22,775	0.01	0.14
78 Motion pictures	33	181,478	11,743	0.02	0.28
79 Amusement and recreation services	22	1,597,336	142,792	0.00	0.02
80 Health services	44	631,398	31,198	0.01	0.14
81 Legal services	36	1,167,682	71,435	0.00	0.05
82 Educational services	96	421,539	67,758	0.02	0.14
83 Social services	23	2,613,764	174,383	0.00	0.01
84 Museums, botanical, zoological gardens	46	351,713	16,137	0.01	0.28
86 Membership organizations	29	560,217	40,331	0.01	0.07
87 Engineering and management services	35	320,236	15,070	0.01	0.23
89 Services, n.e.c.	38	1,030,962	81,876	0.00	0.05
92 Fire Departments	365	NA	NA	NA	NA
other public sector	66	NA	NA	NA	NA

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

In the Preliminary Regulatory Impact Analysis developed in support of OSHA's 1994 Respiratory Protection proposal [Ex. 57], the Agency examined the impact of the proposal on different sizes of establishments. Based on that analysis, the Agency certified that the proposed standard would not have a significant economic impact on a substantial number of small entities. Upon review of comments and other data submitted to the record of this rulemaking, the Agency has analyzed the final rule's impact on small entities, as defined by the Small Business Administration (SBA) and in accordance with the Regulatory Flexibility Act. In addition, in order to ensure that even the smallest entities are not significantly impacted, the Agency performed an analysis of impacts on the smallest establishments, i.e., those with fewer than 20 employees.

The impacts of the standard on sales and profits did not exceed 1 percent for small firms in any covered industry, whether the analysis used the SBA's definitions or the fewer-than-20-employee size class definition. Because the incremental costs of the final rule are primarily related to the number of respirator users per establishment and because small entities do not have a higher percentage of respirator users than large establishments, the standard does not have a differential impact on small entities. If the costs of compliance were influenced by economies of scale, such effects would have been demonstrated by OSHA's analysis of the smallest firms, i.e., those with fewer than 20 employees. However, no such effects were seen, even among firms in this smallest size-class. Therefore, the Agency has no reason to believe that establishments or firms in intermediate size groupings, i.e., those in the range between 20 employees and the employment size cutoff for the applicable SBA definition, would experience larger impacts. Finding this, the Agency certifies that the final Respiratory Protection standard will not have a significant adverse economic impact on a substantial number of small entities. The results of OSHA's analysis of small business impacts on firms [5] within the SBA's size classifications are shown in Table VI–4.

TABLE VI–4.—ANNUAL COST OF THE RESPIRATORY PROTECTION STANDARD AS A PERCENT OF SALES FOR RESPIRATOR-USING SMALL FIRMS [1]

SIC and industry	Small business definition [1]	Number of affected firms	Average compliance cost per firm	Average sales per firm	Compliance cost as a percent of sales	Average profit per firm	Compliance cost as a percent of profits
07 Agricultural services	$5 million [2]	23,313	$36	$223,567	0.02	$14,466	0.25
08 Forestry	$5 million	860	41	470,247	0.01	36,513	0.11
13 Oil and gas extraction	500 employees	2,565	222	2,017,392	0.00	226,361	0.10

[5] The Agency also examined the impact of the costs of compliance on governmental entities serving communities with fewer than 50,000 people, and also found small impacts.

TABLE VI–4.—ANNUAL COST OF THE RESPIRATORY PROTECTION STANDARD AS A PERCENT OF SALES FOR RESPIRATOR-USING SMALL FIRMS [1]—Continued

SIC and industry	Small business definition [1]	Number of affected firms	Average compliance cost per firm	Average sales per firm	Compliance cost as a percent of sales	Average profit per firm	Compliance cost as a percent of profits
15 General contractors and operative builders	$17 million	70,232	75	954,486	0.01	43,794	0.17
16 Heavy construction, except building	$17 million	12,628	135	1,611,092	0.00	72,025	0.19
17 Special trade contractors	$7 million	114,097	117	490,343	0.02	24,806	0.47
20 Food and kindred products	500 employees	5,583	143	7,070,622	0.00	288,666	0.05
21 Tobacco products	500 employees	27	434	419,423,746	0.00	98,271,892	0.00
22 Textile mill products	500 employees	1,306	243	4,485,467	0.00	236,814	0.10
23 Apparel and other textile products	500 employees	4,227	49	1,717,339	0.00	84,857	0.06
24 Lumber and wood products	500 employees	13,854	96	1,520,435	0.00	80,494	0.12
25 Furniture and fixtures	500 employees	5,860	135	2,063,881	0.00	101,980	0.13
26 Paper and allied products	500 employees	1,082	364	7,356,895	0.00	389,269	0.09
27 Printing and publishing	500 employees	4,612	63	1,349,101	0.00	82,533	0.08
28 Chemicals and allied products	500 employees	3,794	388	7,758,606	0.00	573,110	0.07
29 Petroleum and coal products	500 employees	373	505	11,906,004	0.00	523,143	0.10
30 Rubber and miscellaneous plastics products	500 employees	3,926	192	4,132,970	0.00	252,124	0.08
31 Leather and leather products	500 employees	224	246	2,312,572	0.00	106,106	0.23
32 Stone, clay, and glass products	500 employees	5,529	209	2,337,003	0.00	101,728	0.21
33 Primary metal industries	500 employees	2,260	530	6,447,895	0.00	359,703	0.15
34 Fabricated metal products	500 employees	12,435	167	2,782,599	0.00	138,568	0.12
35 Industrial machinery and equipment	500 employees	18,625	152	2,001,196	0.00	118,786	0.13
36 Electronic and other electronic equipment	500 employees	4,356	237	3,836,835	0.00	184,646	0.13
37 Transportation equipment	500 employees	5,999	281	3,362,262	0.00	120,155	0.23
38 Instruments and related products	500 employees	3,266	163	3,239,263	0.00	211,242	0.08
39 Miscellaneous manufacturing industries	500 employees	5,149	102	1,539,311	0.00	95,981	0.11
40 Railroad transportation	1500 employees	NA	NA	NA	NA	NA	NA
41 Local and interurban passenger transit	$5 million	2,582	106	417,934	0.01	17,701	0.60
42 Trucking and warehousing	$18.5 million	15,626	79	670,885	0.01	29,993	0.26
44 Water transportation	500 employees	187	243	1,781,166	0.01	90,917	0.27
45 Transportation by air	1500 employees	157	449	2,031,762	0.00	70,300	0.64
46 Pipelines, except natural gas	1500 employees	11	888	15,403,556	0.00	5,274,551	0.02
47 Transportation services	$5 million	879	55	377,507	0.02	15,544	0.35
48 Communication	1500 employees	1,279	172	2,132,980	0.01	335,309	0.05
49 Electric, gas, and sanitary services	$5 million	3,809	65	883,319	0.01	72,099	0.09
50 Wholesale trade—durable goods	100 employees	52,553	43	1,828,263	0.00	73,131	0.06
51 Wholesale trade—nondurable goods	100 employees	30,785	44	2,682,104	0.00	85,196	0.05
52 Building materials and garden supplies	$5 million	13,619	19	712,058	0.01	24,294	0.08
53 General merchandise stores	$5 million	482	14	398,828	0.01	16,892	0.08
54 Food stores	$5 million	6,419	140	763,042	0.00	20,647	0.68
55 Automotive dealers and service stations	$5 million	38,985	26	774,574	0.01	18,225	0.14
56 Apparel and accessory stores	$5 million	289	41	1,346,240	0.00	85,526	0.05
57 Furniture and homefurnishings stores	$5 milion	438	71	1,685,231	0.00	87,235	0.08
58 Eating and drinking places	$5 million	16,852	24	374,691	0.00	17,633	0.14
59 Miscellaneous retail	$5 million	12,619	18	406,958	0.01	22,502	0.08
60 Depository institutions	$5 million	788	123	1,060,910	0.00	NA	NA
61 Nondepository institutions	$5 million	840	25	728,626	0.00	106,401	0.02
62 Security and commodity brokers	$5 million	921	33	631,139	0.01	55,488	0.06
63 Insurance carriers	$5 million	365	92	740,731	0.01	NA	NA
64 Insurance agents, brokers, and service	$5 million	5,583	54	335,823	0.01	NA	NA
65 Real estate	$5 million	10,714	56	533,940	0.01	48,369	0.12
67 Holding and other investment offices	$5 million	1,036	36	889,373	0.00	95,534	0.04
70 Hotels and other lodging places	$5 million	2,163	41	472,311	0.00	32,784	0.13
72 Personal services	$5 million	9,786	80	190,546	0.02	15,019	0.53
73 Business services	$5 million	14,343	160	517,986	0.01	37,783	0.42
75 Auto repair, services, and parking	$5 million	43,985	47	342,341	0.01	21,749	0.22
76 Miscellaneous repair services	$5 million	2,631	34	340,605	0.01	22,039	0.15
78 Motion pictures	$5 million	1,494	29	350,142	0.01	24,304	0.12
79 Amusement and recreation services	$5 million	4,052	46	469,977	0.00	23,222	0.20
80 Health services	$5 million	39,536	82	521,074	0.01	31,877	0.26
81 Legal services	$5 million	7,288	41	314,988	0.01	48,175	0.09
82 Educational services	$5 million	1,739	99	649,462	0.01	35,911	0.28
83 Social services	$5 million	5,194	43	354,060	0.01	16,245	0.26
84 Museums, botanical, zoological gardens	$5 million	158	80	492,341	0.01	35,333	0.23
86 Membership organizations	$5 million	11,589	55	296,761	0.01	13,965	0.39
87 Engineering and management services	$5 million	11,383	62	457,931	0.01	34,480	0.18
89 Services, n.e.c	$5 million	679	58	423,854	0.01	36,402	0.16

[1] As defined by the Small Business Administration, 61 FR 3289.
[2] Annual receipts.

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

Unfunded Mandates Analysis

The final Respiratory Protection standard has been reviewed by OSHA in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 USC 1501 et seq.) and Executive Order 12875. As discussed in Chapter V, OSHA estimates that compliance with the revised Respiratory Protection standard will require expenditures of more than $100 million each year by employers in the private sector. Therefore, the Respiratory Protection final rule establishes a Federal private sector mandate and is a significant regulatory action within the meaning of Section 202 of UMRA (2 U.S.C. 1532). OSHA has included this statement to address the anticipated effects of the final rule pursuant to Section 202.

OSHA standards do not apply to state and local governments except in states that have voluntarily elected to adopt an OSHA State plan and have then adopted the specific standard in question or one that has been deemed by OSHA to be equally effective. Consequently, the Respiratory Protection standard does not impose a ''federal intergovernmental mandate'' as defined by Section 421(5) of UMRA (2 USC 658 (5)). The revised Respiratory Protection standard therefore does not impose an unfunded mandate on state and local governments.

Further, OSHA has found that the costs incurred by state and local governments in those states that choose to adopt the standard will be small compared to corresponding state and local government expenditures. If State-plan states adopt the standard, the greatest impact in some states would be on public fire departments. Bureau of the Census data on the amount of revenue dedicated to fire protection by local governments indicate that $14.4 billion was spent on this service in 1992, the latest year for which such data are available [*Government Finances*]. NFPA data indicate that 75.3 percent of the U.S. population is served by fire departments that employ at least some career firemen [NFPA, p. 15]. This means that approximately 37.7 percent of the population (approximately half of all state and local government employees work in State-plan states) is served by at least partly career fire departments in State-plan states. Assuming the expenditures for fire protection are spread fairly evenly across the population, approximately $5.3 billion is spent on fire protection annually by affected fire departments. As indicated in the cost analysis (see Table VI–2), the total annual cost of the standard for public fire departments in State-plan states is approximately $3.5 million, which means that the costs of compliance constitute less than 0.1 percent of the revenue devoted by these states to fire protection. Costs of this magnitude are clearly an insignificant portion of the total fire protection budget.

The remainder of this section summarizes OSHA's findings, as required by Section 202 of UMRA (2 USC 1532):

This standard is issued under Section 6(b) of the OSH Act.

This standard has annualized costs estimated at $111 million, primarily in the private sector, and is estimated to save hundreds of lives per year from cancer and cardiovascular disease. Compliance will also prevent thousands of illnesses annually that would have been caused by acute and chronic overexposures. The standard will impose no more than minimal costs on state, local or tribal governments, substantially less than $100 million. OSHA pays 50 percent of State plan costs, although the Agency does not provide funding for state, local or tribal governments to comply with its rules as employers.

OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation or particular state, local, or tribal governments, or urban or rural or other types of communities. The principal costs of this standard are to control worker exposures associated with programmatic provisions such as annual fit testing and training, activities that are engaged in by thousands of establishments in hundreds of SIC codes that are widely distributed throughout the country. Chapters III and V have provided detailed analyses of the costs and impacts of the standard on particular segments of the private sector. OSHA has analyzed the economic impacts of the standard on the industries affected and found that compliance costs are no more than 0.1 percent of sales for establishments in any industry, and consequently that no plant closures or job losses are anticipated in the affected industries. As a result, impacts on the national economy would be too small to be measurable by economic models.

Pursuant to Section 205 of the UMRA (2 USC 1535), after having considered a variety of alternatives outlined in the Preamble and in the Regulatory Flexibility Analysis, the Agency has concluded that the final rule is the most cost-effective alternative for implementation of OSHA's statutory objective of reducing significant risk to the extent feasible.

Environmental Impact Analysis

The final Respiratory Protection standard has been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), the regulations of the Council of Environmental Quality (CEQ) (40 CFR part 1500), and DOL NEPA procedures (29 CFR part 11). As a result of this review, OSHA has concluded that the rule will have no significant environmental impact.

References

Bureau of the Census, *Government Finances*, Series GF, No. 5, annual, as reported in the *Statistical Abstract of the United States, 1995*. GPO, 1995.

VII. Summary and Explanation

This section of the preamble summarizes and explains the provisions of the final respiratory protection standard. It describes changes made to the rule since the proposal was issued, discusses the comments received by the Agency on the proposal, and presents OSHA's rationale for making these changes. The record evidence supporting each of the requirements of the final rule is also described in detail in this section.

This final rule clarifies, updates, and strengthens OSHA's previous respiratory protection standard, which was adopted by the Agency in 1971 and has remained essentially unchanged since that time. This rulemaking is thus the first major revision to OSHA's respiratory protection standard in more than 25 years. As discussed in connection with several of the individual paragraphs of the revised standard, not all of the provisions of the standard have been revised; in some cases, OSHA found, and the record supported, leaving individual provisions unchanged.

The final respiratory protection standard applies to respirator use in general industry, construction, shipyards, marine terminals, and longshoring operations. When used properly, respirators can help to protect employees from the acute and chronic effects of exposure to hazardous airborne contaminants, whether in the form of particulates, vapors, or gases. Generally, OSHA requires respirators to be used to protect employee health in

situations where engineering controls and work practices are not feasible, where such controls have not yet been instituted, in emergencies, or where such controls are not sufficient, by themselves, to protect the health of employees.

As noted above, this final standard applies to respirator use in general industry, construction, shipyards, marine terminals, and longshoring operations. In the 1994 proposal, OSHA proposed to cover general industry, shipyards and construction. The longshoring and marine terminals final rule (48 FR 30908) already made this standard applicable to those industries as well. To provide clarity, the final respiratory standard explicitly contains a note setting forth the scope of the respirator standard.

The preamble to the proposed rule asked for comments about the appropriateness of applying the final rule to construction and maritime workplaces. In the case of the construction industry, OSHA specifically provided the Advisory Committee for Construction Safety and Health (ACCSH) with a copy of the proposal for review and comment, and ACCSH recommended that the revised standard apply to construction industry workplaces. OSHA's responses to these comments are discussed above in the introduction to this preamble.

In response to the question raised about the applicability of the standard to the construction and shipyard industries, OSHA received several comments from participants concerned about the rule's impact on the construction industry (Exs. 54–102, 54–231, 54–288). These commenters noted that the costs of the standard for construction employers may be higher than for their counterparts in general industry because of the higher turnover, decentralization of workplaces, and multi-employer work arrangements typical of construction sites. However, as reported in the Final Economic Analysis (Ex. 196), OSHA has determined that the final rule is both technologically and economically feasible for employers in the construction industry. There is no question that many workers in this industry need respiratory protection to prevent material impairment of their health; in fact, some of the most hazardous exposures occur in this industry. For example, workers engaged in the abrasive blasting of bridges are often exposed to high concentrations of silica and other hazardous substances (contained in the abrasive blasting media), as well as to lead, chromates, and other toxic materials (contained in the paints, coatings, or preservatives covering the substrate). Welders, demolition workers, tunnel workers, and painters are other examples of construction trades that often involve overexposure to toxic substances and require respirators for control. In fact, respirators may be even more necessary in construction than in general industry because the transient and constantly changing nature of many construction worksites makes the use of engineering controls more difficult in these environments. Finally, OSHA's previous respiratory protection standard has applied to the construction industry since 1971 (it is codified at 29 CFR 1926.103); removing this protection for construction workers would thus decrease existing safety and health protections despite the significant risk confronting construction workers in many situations. Decreasing feasible worker protections in the face of significant risk of material impairment of health would clearly be contrary to the Agency's mandate.

OSHA received no comments on the applicability of the final rule to shipyard employment. Like construction workers, shipyard workers have been covered by the Agency's previous standard since 1971. In addition, employees in shipyards engage in many of the same highly hazardous operations as construction workers, including abrasive blasting, welding, painting, and drilling. The Final Economic Analysis (Ex. 196) has determined that it is both technologically and economically feasible for employers in shipyard operations to achieve compliance with the final rule.

OSHA has recently issued a revised final rule for the Longshoring (shipboard) portion of marine cargo-handling operations, along with revisions to the Agency's Marine Terminals (dockside) marine cargo-handling standard. The scope and application sections of both final maritime rules specifically incorporate OSHA's respiratory protection standard (29 CFR 1910.134) by reference. Thus, consistent with the proposal, this final respiratory protection standard will apply to workplaces in general industry and in the construction, shipyards, longshoring, and marine terminals industries.

At the public hearing, the Brotherhood of Maintenance of Way Employees (BMWE) submitted testimony on the issue of OSHA's respiratory protection standard's coverage of railroad construction and maintenance employees (Ex. 122). The BMWE stated:

> * * * the BMWE respectfully requests that * * * formal recognition of the applicability of OSHA 1910.134 for railroad employees be published in the **Federal Register** to remove any lingering questions regarding the applicability of OSHA's respiratory protection standards to working conditions which, although located within the railroad industry, are in fact similar to those of any industrial workplace.

In response to this comment, OSHA notes that both the prior respiratory protection standard and the final revised standard being published will apply to railway workers unless the Federal Railroad Administration (FRA) exercises statutory authority to issue a separate respirator standard for those workers. To date, the FRA has not issued a respiratory protection standard applicable to railway workers. Unless and until it does, this standard will apply to those workers.

This Summary and Explanation section follows the order of the final rule. The abbreviation ''Ex.'' denotes exhibits in the docket for this rulemaking, Docket H–049. The abbreviation ''Tr.'' denotes the transcripts of the hearings conducted in connection with this rulemaking.

Paragraph (a)—Permissible practice

Paragraphs (a)(1) and (a)(2) of the final rule are essentially unchanged from the corresponding paragraphs of the prior rule and the proposed rule. Indeed, in the proposal OSHA explained that this rulemaking was not intended to address the substantive portion of paragraph (a)(12). The only changes proposed by OSHA to the regulatory language of paragraph (a) were non-substantive: (1) In the proposal, the Agency titled this paragraph ''Scope and Application'' rather than ''Permissible Practice,'' which had been the title of this paragraph since 1971; and (2) a cross-reference to paragraph (b) in the prior standard was proposed to be changed to paragraph (c), because a new paragraph (b), ''Definitions,'' was proposed to be added to the final rule. In the final rule, OSHA has determined that the original title of paragraph (a), ''Permissible Practice,'' better describes paragraph (a), and thus this continues to be the title of this paragraph. The proposed cross-reference to paragraph (c) is retained in the final rule.

Paragraph (a)(1) requires the use of appropriate respiratory protection when ''effective engineering controls are not feasible, or while they are being instituted.'' This paragraph also stipulates that the prevention of atmospheric contamination caused by ''harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors'' shall

be accomplished, to the extent feasible, by the use of engineering control measures.

As stated in the preamble of the proposed rule (59 FR 58895), OSHA did not in this rulemaking open the record on the issue of the hierarchy of industrial hygiene controls; the hierarchy language is merely brought forward, verbatim, from this paragraph of the prior rule. Paragraph (a)(1), which was adopted by OSHA in 1971 from the 1969 American National Standards Institute (ANSI) standard, Z88.2–1969, established that a hierarchy of controls is to be used to protect employees from hazardous airborne contaminants. According to this hierarchy, engineering controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. According to paragraph (a)(1), respirators are permitted to be used only where engineering controls are not feasible or during an interim period while such controls are being implemented.

Paragraph (a)(2) requires employers to provide employees with respirators ''when such equipment is necessary to protect the health of the employee.'' In addition, this paragraph specifies that the employer must provide employees with respirators that are ''applicable and suitable'' for the purpose intended, i.e., for the protection of employee health. This paragraph thus clearly recognizes that, when properly selected, used, and maintained, respiratory protection can play an essential role in preventing adverse effects on the health of employees exposed to hazardous airborne contaminants.

By leaving paragraphs (a)(1) and (a)(2) of the final rule unchanged from the corresponding paragraphs of the respiratory protection standard that has been in effect since 1971, OSHA accomplishes several objectives. First, it continues the protection that employees have relied on throughout OSHA's history. Second, it retains the language that employers are familiar with and thus will not require them to become familiar with new regulatory language. Third, leaving the regulatory text of paragraphs (a)(1) and (a)(2) unchanged allows OSHA and the affected public to continue to rely on OSHA interpretations, decisions, and case law that have developed over the years.

As noted above, this standard is a respiratory protection standard. OSHA has enforced this standard when employers fail to provide respirators, when the respirators that are provided are inappropriate for the form of the contaminant or for the atmospheric concentration of the contaminant, when they are inappropriately used, and when they are improperly maintained.

Although OSHA clearly stated in the preamble to the proposal that the hierarchy of controls was not an issue in this rulemaking, the Agency did receive comment on this provision. For example, one commenter stated that, in its opinion, OSHA has ''a legal obligation to provide interested parties with an opportunity to comment on the methods of compliance provisions'' (Ex. 54–307). In the opinion of this commenter, the American Iron and Steel Institute (AISI), ''Section 6(b)(2) of the OSH Act requires that OSHA provide interested persons an opportunity to submit written data and comments on a proposed rule *in total*'' [emphasis added].

The unchanged language of paragraph (a)(1) was included in the proposed rule only to enable interested parties to view the rule as it would ultimately appear in the Code of Federal Regulations in its entirety. Since OSHA neither proposed nor adopted modifications to paragraph (a)(1), the Agency believes that it is not legally required to reconsider this issue at this time. OSHA has the authority to identify which regulatory requirements it is proposing to revise and which issues are to receive regulatory priority. Limiting this rulemaking to issues concerning respirator programs is appropriate because such programs are the exclusive focus of this rulemaking and to collect comments and data on additional issues would divert resources from the task at hand.

The preference for engineering controls has been reaffirmed in each substance-specific health standard OSHA has published, most recently in the Methylene Chloride standard (29 CFR 1910.1052). OSHA does not believe that it is necessary or appropriate, in a rulemaking dealing with respiratory protection, to reconsider its long-established policy with regard to the hierarchy of controls.

A number of commenters raised another issue in connection with paragraph (a)(1), and that is whether biological hazards, such as the hazard posed by exposure to *Mycobacterium tuberculosis,* the infectious agent that causes tuberculosis (TB), are covered by this paragraph (Exs. 54–213, 54–239, 54–249). In response, OSHA emphasizes that this respiratory protection standard does apply to biological hazards (see *Mahone Grain Corp.,* 10 OSHRC 1275, 1981). However, specifically with regard to the use of respirators to protect employees from the risk of occupational exposure to *M. tuberculosis,* OSHA stated at the public hearing on this respiratory protection standard (Tr. 16–17), that the Agency's tuberculosis standard, which has just been proposed (62 FR 54160) would contain specific requirements covering all aspects of respirator use in environments where occupational transmission of tuberculosis is possible. As explained in the preamble to that standard, OSHA is committed to ensuring consistency between the respirator requirements in the two standards.

As stated at the hearing, ''until the final tuberculosis standard is promulgated, we will continue to enforce respirator usage for TB under the current, unrevised respirator standard, 1910.134.'' (Tr. 18). There was little comment on this issue during the rulemaking. The entire previous respiratory protection standard is being redesignated as 29 CFR 1910.139. It will be published in the next edition of the Code of Federal Regulations under that designation. OSHA's enforcement policy concerning required respirator use for TB is set out in OSHA's Compliance Directive, ''Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis'' (OSHA Instruction CPL 2.106). These enforcement procedures are based, in part, on the Centers for Disease Control and Prevention's (CDC) ''Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Settings, 1994.'' Like the CDC recommendations, OSHA's directive clarifies that respiratory protection for employees exposed to TB is required when: (1) Workers enter rooms housing individuals with suspected or confirmed infectious TB; (2) workers are present during the performance of high-hazard procedures on individuals who have suspected or confirmed infectious TB; and (3) emergency medical response personnel or others transport, in enclosed vehicles, an individual with suspected or confirmed infectious TB. Under the directive, OSHA also enforces the performance criteria recommended by CDC for selecting a respirator suitable for use against TB. OSHA's directive further specifies that where respirator use is required against TB, the program elements of OSHA's respiratory protection standard apply. A copy of OSHA's Compliance Directive can be obtained from OSHA's Office of Publications (Telephone Number, 202–219–4667). Copies of the CDC Guidelines can be obtained by calling CDC (Telephone Number, 1–800–342–2437).

As noted above, paragraph (a)(2) of the final rule is identical both to the corresponding paragraph of the respiratory protection standard in place

since 1971 and to proposed paragraph (a)(2). It specifies that respirators must be provided by the employer ''when such equipment is necessary to protect the health of the employee.'' OSHA considers respirators to be necessary to protect the health of the employee whenever feasible engineering and work practice controls are not available, are not sufficient to protect employee health, have not yet been instituted, in emergencies, and where the health of an employee is at risk (e.g., whenever employee exposure exceeds an OSHA permissible exposure limit (PEL)).

A violation of paragraph (a)(2) could exist, for example, if it can be shown that exposure to an airborne contaminant could result in illness or injury to the employee's health and that this could be prevented by the appropriate selection and use of a respirator. An OSHA Review Commission case illustrates such a situation: an employer was held to have violated paragraph (a)(2) because his employees either did not use respirators when working in an atmosphere contaminated with grain dust or used respirators that were ''so caked with dust that employees could not breathe through them'' and contracted a potentially fatal disease caused by the inhalation of grain dust contaminated with *Histoplasma capsulatum* spores (*Mahone Grain Corporation,* 10 OSHRC 1275, 1981). Paragraph (a)(2) was cited in this case even though OSHA has no specific PEL for grain dust or for *H. capsulatum* spores.

In the past 5 years, OSHA has issued 99 citations for violations of paragraph (a)(2) in conjunction with a citation of the General Duty Clause (i.e., Sec. 5(a)(1) of the Act). These citations concerned various situations involving the failure of the employer: (1) To control exposures in emergencies; (2) to control exposure to unknown concentrations of a toxic substance; (3) to control exposure to a contaminant that was clearly a recognized hazard even though no OSHA PEL existed; (4) to provide and require the use of a respirator for a confined space entry; or (5) to ensure the proper use of a respirator in a situation involving the improper storage of a chemical(s). OSHA will continue to view these situations as citable under this standard because they involve failure to implement the appropriate exposure control necessary to protect the health of the employee from adverse effects.

As proposed, paragraph (a)(3) of OSHA's prior standard does not appear in the final rule. This paragraph, which was adopted by OSHA in 1971 from the ANSI Z88.2–1969 standard, stated that employees must use the respiratory protection provided in accordance with instructions and training they have received.

Several commenters (Exs. 54–79, 54–181, 54–226, 54–234, 54–295, 54–307, 54–334) urged OSHA to retain this paragraph in the final rule. According to these commenters, this paragraph is necessary to ensure that employees take responsibility for their actions and that employees are actively involved in the respirator program and conform to program procedures. OSHA agrees that active employee involvement in the respirator program is essential to program effectiveness but does not believe that this principle should be stated in the standard, for a number of reasons. First, the OSH Act itself, at Sec. 5(b), states that ''Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to the OSH Act which are applicable to his own actions and conduct.'' In addition, the courts have repeatedly held that employers are responsible under Section 5(a)(2) of the Act (29 U.S.C. 654(a)(2)) for ensuring worker protection (see, e.g., *Brock v. City Oil Well Service Co.,* 795 F.2d 507, 511 (5th Cir. 1986)). In this case, the court held, ''it is the employer's responsibility to ensure that the employees are protected. It may accomplish this objective through others if it chooses, but the duty to provide the protection remains the employer's.'' Accordingly, the final rule does not contain this paragraph.

An issue raised by OSHA in connection with paragraph (a) of the proposal, the use of respirators by employees when such use is required by an individual employer or is chosen voluntarily by employees but not mandated by OSHA in this final rule, is addressed below in connection with paragraph (c) of this Summary and Explanation.

Paragraph (b)—Definitions

The final standard includes definitions of important terms used in the regulatory text of the final rule. The previous and proposed respiratory protection standards contained no definitions; however, OSHA is adding a number of definitions to the final rule because the Agency believes that employers and employees will benefit from this additional information. This is consistent with the Agency's desire to clarify its respiratory protection requirements, including those that are not being substantively changed in this rulemaking.

A number of the definitions relate to specific types of respiratory protection devices or to components or design characteristics of those devices. For example, the terms ''air-purifying respirator,'' ''filter or air-purifying element,'' and ''positive pressure respirator'' are defined in the final rule. These definitions, which are derived from generally recognized sources such as the current ANSI Z88.2–1992 respiratory protection standard, the NIOSH requirements for particulate respirators in 42 CFR part 84, and the 1987 NIOSH Respirator Decision Logic (Ex. 38–20), have been revised for clarity, consistency with compliance interpretations of the Agency's respiratory protection standard, and to respond to comments received during the rulemaking.

A number of commenters (Exs. 54–208, 54–218, 54–219, 54–410, 54–424) suggested that OSHA adopt several of the definitions in the ANSI Z88.2–1992 respiratory protection standard. The regulated community is already familiar with the ANSI definitions of these terms, and OSHA agrees that the potential for confusion will be reduced if terms mean the same thing in both the OSHA and ANSI standards. Therefore, the ANSI definitions of ''airline respirator (supplied-air respirator or airline respirator),'' ''canister or cartridge,'' ''demand respirator,'' ''end-of-service-life indicator,'' ''escape-only respirator,'' ''filter,'' ''fit check (user seal check),'' ''fit test,'' ''helmet,'' ''hood,'' ''loose-fitting facepiece,'' ''negative pressure respirator,'' ''pressure demand respirator,'' ''powered air-purifying respirator (PAPR),'' ''respiratory inlet covering,'' ''self contained breathing apparatus (SCBA),'' ''service life,'' and ''tight-fitting facepiece'' have all been added to the final standard, with some minor word changes to improve clarity and to recognize the mandatory nature of OSHA standards. In other cases, OSHA has substituted an ANSI definition for one the Agency originally proposed.

Several commenters urged OSHA to add other definitions to those in the proposal (Exs. 54–208, 54–218, 54–219, 54–222, 54–251 54–267, 54–283, 54–289, 54–363, 54–410, 54–437, 54–455). OSHA did not add some of the suggested definitions, such as one for ''health screening,'' because the term is no longer used in the standard. Other terms, such as ''medical evaluation,'' are defined where they appear in the regulatory text.

The following discussion addresses changes made since the proposed standard.

Adequate warning properties. The proposed definition of ''adequate warning properties'' has not been

retained in the final standard because the term is no longer used in the regulatory text. OSHA deleted the term after concluding that the two major warning properties, odor and irritation, are unreliable or inappropriate to use as indicators of sorbent exhaustion. This issue is discussed further in this Summary and Explanation in connection with paragraph (d).

Air-purifying respirator. The final standard defines the term ''air-purifying respirator'' as ''a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.'' Marc Evans of Baxter Diagnostics, Inc. (Ex. 54–38) stated that the proposed definition, ''a respirator which is designed to remove air contaminants [i.e., dust, fumes, mists, gases, vapors, or aerosols] from the ambient air or air surrounding the respirator,'' was inaccurate since filter elements can only remove air contaminants when air passes through the filters; he stated that the ANSI definition was more accurate in this regard.

Another commenter wanted to add the term ''biologicals'' to the list of air contaminants removed by air-purifying respirators (Ex. 54–249). In response, the definition has been revised to state more clearly that an air-purifying respirator removes specific contaminants from the ambient air by drawing air through appropriate filters, cartridges, or canisters. Deleting the proposed definition's examples of air contaminants makes clear that no type of air contaminant, including biological agents, is excluded from the definition. Also, the term ''filter'' has been changed to ''filter or air-purifying element,'' which is also defined in the standard, and includes the broad range of filters, cartridges, canisters and other air-purifying elements used with respirators.

Assigned protection factor. The definition of ''assigned protection factor'' has been reserved as part of OSHA's decision to address the entire Assigned Protection Factor (APF) issue in a subsequent phase of this rulemaking. OSHA proposed to reference the NIOSH assigned protection factors from the 1987 NIOSH Respirator Decision Logic in the respiratory protection standard and then to adopt new APF values issued by NIOSH after that Agency had conducted rulemaking on APFs. In the course of this rulemaking, OSHA has concluded that it should instead develop its own set of assigned protection factors based on a thorough review and analysis of all relevant evidence. Both the NIOSH and the ANSI APFs, as well as all relevant data and information, will be considered by OSHA at that time.

Atmosphere-supplying respirator. This term means ''a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.'' As it has done in many of the definitions in this section, OSHA has substituted the term ''breathing air'' for a number of synonymous, but confusingly diverse, terms used in the proposal and in the ANSI Z88.2–1992 standard. The minor changes from the proposed definition have been made solely to enhance clarity.

Canister or cartridge. The final standard adopts the ANSI Z88.2–1992 standard's definition: ''a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.'' Several commenters suggested that this definition be added to the final rule (Exs. 54–208, 54–218, 54–219, 54–410, 54–424).

Demand respirator is defined as ''an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.'' This term was not defined in the proposal but is defined by ANSI, and several commenters (Exs. 54–208, 54–218, 54–219, 54–410, 54–424) urged that it be included in the final rule. As in other definitions, the phrase ''breathing air'' has been substituted for ''respirable gas'' for clarity.

The proposal's definition of ''demand'' has been deleted from the final standard because the addition of a definition for ''demand respirator'' makes its inclusion unnecessary. (See the definition of pressure demand respirator below for the distinction between the two types of respirator.)

Dust mask. See the definition for ''filtering facepiece'' below.

Emergency situation. In the final rule, OSHA is adding this term to paragraph (b) to clarify its use in the regulatory text. ''Emergency situation'' is defined as ''any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled substantial release of an airborne contaminant.'' Under this definition, OSHA intends that a potential release, and not just an actual release, be considered an emergency situation requiring appropriate respiratory protection. This definition is the same or similar to those used to define emergency situations in other OSHA health standards (e.g., 1910.1051, Butadiene; 1910.1028, Benzene; 1910.1048, Formaldehyde).

Employee Exposure. OSHA has added this term to paragraph (b) of the final rule and has defined it to mean ''exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.'' This is the same definition that has been used in many of OSHA's substance-specific health standards. It is included to clarify that employee exposure is measured outside any respiratory protection worn.

End-of-service-life indicator (ESLI) means ''a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.'' This definition was not in the proposal, but has been derived from the definition in the ANSI Z88.2–1992 standard, as requested by several commenters (Exs. 54–208, 54–218, 54–219, 54–410, 54–424). OSHA has included the example at the end of the definition to clarify the function of an ESLI.

Escape-only respirator. This term was not defined in the proposal, but the final standard defines an escape-only respirator as ''a respirator intended to be used only for emergency exit.'' The Dow Chemical Company (Ex. 54–278) and the Chlorine Institute (Ex. 54–439) recommended adding definitions for an ''escape'' respirator and an ''emergency'' respirator. Partially in response to these comments, and to clarify OSHA's intent, OSHA has described in paragraph (d) the narrow function of an ''escape-only respirator,'' and has added a definition for ''escape-only respirator'' to this paragraph (b). The definition of ''escape-only respirator'' derives from the ANSI Z88.2–1992 standard, with the phrase ''egress from a hazardous atmosphere'' replaced by the word ''exit.''

Filter or air-purifying element. The final standard's definition of this term is ''a component used in respirators to remove solid or liquid aerosols from the inspired air.'' The parallel definition in the proposal used ''filter'' instead of ''filter or air-purifying element'' and has been changed in response to comments (Exs. 54–208, 54–218, 54–219, 54–410, 54–424). The phrase ''or air-purifying element'' has been added to clarify that this definition applies to all filtration mechanisms, not only to mechanical or electrostatic filtration of particulates. The new definition derives from the definition of ''filter'' in the ANSI Z88.2–1992 standard.

Filtering facepiece (dust mask). The definition of ''filtering facepiece'' in the final rule is ''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.'' This new definition is derived from the definition of ''filtering facepiece'' in the NIOSH Respirator Decision Logic (Ex. 38–20). As described in the discussion of paragraph (c) below, employers who allow the use of these respirators when such use is not required need to comply with only paragraph (c)(2) of this standard, which requires that the employer provide the employee with the information contained in Appendix D.

Fit factor. The definition of ''fit factor'' in the final rule is 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. In the proposal, OSHA's definition included the terms ''challenge agent'' and ''test chamber.'' Several commenters (Baxter Diagnostics, Ex. 54–38; American Subcontractors Association, Ex. 54–293) stated that using these terms would have the unintended effect of prohibiting the use of several existing QNFT test methods, such as the TSI Portacount,™ and recommended that OSHA rely on the ANSI definition of ''fit factor'' instead. OSHA agrees with this point, and the final standard's definition derives primarily from the ANSI Z88.2–1992 standard's definition, as commenters suggested (Exs. 54–208, 54–218, 54–219, 54–410, 54–424). The final definition uses the word ''estimate'' instead of the ANSI definition's word ''measure'' because fit factors estimate, rather than measure, the fit obtained during use. The phrase ''specific individual'' has been substituted for ''particular individual'' for clarity.

Fit test. A definition of ''fit test'' has been added to the final rule and is defined as ''the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.'' (See also QLFT and QNFT.) This definition has been added because OSHA is of the opinion, based on comments to the record, that such a definition is needed (Exs. 54–208, 54–218, 54–219, 54–410, 54–424). ANSI also has a definition of fit test, but OSHA's definition differs from that in the ANSI Z88.2–1992 standard in that the term ''challenge agent'' has been eliminated and replaced by the phrase ''protocol to quantitatively or qualitatively evaluate.'' The use of the term ''challenge agent'' would limit the development of future fit test technologies that do not involve a test agent (Exs. 54–208, 54–250, 54–330, 54–424).

Hazardous exposure level. Because the final standard does not use the term ''hazardous exposure level,'' it is not defined. The proposal defined such levels as including the Permissible Exposure Limits (PELs) contained in OSHA's Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000; the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), as published in the latest edition of that organization's ''Threshold Limit Values for Chemical Substances and Physical Agents,'' for those substances without an OSHA PEL; the NIOSH Recommended Exposure Limits (RELs) for those hazardous chemicals without either an OSHA PEL or ACGIH TLV; and any exposure level based on available scientific information, including Material Safety Data Sheets, for those hazardous chemicals for which no OSHA PEL, ACGIH TLV, or NIOSH REL has yet been published.

The proposed rule would have required employers to identify the ''hazardous exposure level'' applicable to each hazardous chemical in the workplace and then to use this information in selecting the appropriate respirator to provide protection against exposure to that chemical. The final rule takes a different and much simpler approach to assisting employers in the selection of appropriately protective respirators in those cases where OSHA has not yet promulgated a PEL for a hazardous chemical. OSHA has taken the approach reflected in the final standard because there was widespread objection to the proposed approach (Exs. 54–94, 54–175, 54–212, 54–226, 54–232, 54–275x, 54–283, 54–293, 54–306, 54–312, 54–324, 54–334, 54–347, 54–352, 54–361, 54–397, 54–443, 54–445). Some commenters (Exs. 54–91, 54–165, 54–181, 54–291, 54–316, 54–347, 54–397, 54–445) interpreted the proposed approach as an attempt by OSHA to expand the number of hazardous chemicals with OSHA-enforceable exposure limits, while others believed that implementing the proposed approach would require employers to have risk assessment expertise or to perform complex analyses, and pointed out that many employers lacked such expertise (Exs. 54–106, 54–175, 54–210). In general, rulemaking participants stated that OSHA's approach to this problem should rely on the professional judgment of employers, based on readily available information (Exs. 54–206, 54–210).

OSHA has decided, after a thorough review of the record, to follow these recommendations, and in the final rule has adopted an approach that requires employers to select appropriately protective respirators on the basis of informed professional judgment. Accordingly, the final rule does not identify the ACGIH TLVs or the NIOSH RELs as references that would trigger required respirator use. The approach taken in the final rule provides employers with the flexibility to rely on professional judgment and available data sources when selecting respirators for protection against hazardous chemicals that have no OSHA PEL.

OSHA believes that it is prudent in such cases for employers to select more rather than less protective respirators, i.e., to select a respirator that will reduce employee exposure to a level below the concentration indicated as hazardous by the scientific literature. OSHA also believes that many employers will choose to rely on the ACGIH TLV or NIOSH REL in those cases where OSHA has no PEL at the present time. However, whatever approach employers choose to take, the respirator selected must ''be applicable and suitable for the purpose intended,'' as required by paragraph (a).

Helmet. The final standard defines a helmet as ''a rigid respiratory inlet covering that also provides head protection against impact and penetration.'' This definition, which was not in the proposal, has been added to the final standard at the request of several commenters (Exs. 54–208, 54–218, 54–219, 54–410, and 54–424). The OSHA definition uses the term ''respiratory inlet covering'' instead of the word ''hood'' used in the ANSI definition in order to include helmet-style powered air-purifying respirators (PAPRs).

High efficiency particulate air (HEPA) filter is defined as ''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.'' Although NIOSH has revised the particulate filter descriptions under the new 42 CFR Part 84 respirator certification regulation, and no longer uses the term HEPA, this definition is included because ''HEPA filter'' is used in many of OSHA's substance-specific standards. The definition, which is similar to that used by ANSI, lists the NIOSH 42 CFR part 84 particulate filters that are equivalent, in terms of

efficiency, to the HEPA filter, i.e., the N100, R100, and P100 filters.

Hood. The final standard includes the following definition of ''hood'': ''a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.'' This definition has been added to the final standard in response to commenters (Exs. 54–208, 54–218, 54–219, 54–410, and 54–424). The definition derives from the ANSI Z88.2–1992 standard; the word ''also'' has been added for clarity.

Immediately dangerous to life or health (IDLH). The final standard defines IDLH as ''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.'' In the proposal, the definition of IDLH was ''an atmospheric concentration of any toxic, corrosive, or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health effects or would interfere with an individual's ability to escape from a dangerous atmosphere.'' In the final rule, OSHA has decided that including all atmospheres capable of causing the listed health effects is more consistent with OSHA's intent than limiting the definition to toxic, corrosive, and asphyxiant atmospheres and has also deleted the word ''delayed'' from the definition because including it caused considerable confusion among commenters.

Under the final standard's definition, atmospheres where a short, one-time exposure (i.e., an acute exposure) may cause death or irreversible adverse health effects immediately, within a few hours, or within a few days or weeks are considered IDLH atmospheres. The severity of the adverse effects and the certainty that health impairment will occur following an acute exposure are more important considerations in defining a potential IDLH situation than is the time course of the health effect. For example, an atmosphere containing life-threatening or health-impairing concentrations of fluorides, cadmium fumes, or radioactive substances would be considered IDLH even though a single exposure might not cause death or permanent impairment for as long as days or even weeks after the exposure. On the other hand, many situations involving atmospheres exceeding short-term or ceiling exposure limits are not IDLH atmospheres; most short-term or ceiling limits are designed to reduce the risk of less serious effects, such as sensory irritation. Thus, only those situations where the acute exposure would threaten life, initiate an irreversible process that threatens life or health, or impede the ability of the worker to escape from the atmosphere would constitute IDLH conditions. In contrast, if chronic exposure to a toxic atmosphere is required to produce health impairment or cause death, the atmosphere is not IDLH. Thus, the relatively low atmospheric concentrations of carcinogenic substances that cause work-related cancers are not considered IDLH atmospheres, even though the effect of long-term exposure at such concentrations is death or serious illness.

Paragraphs (d) and (g) of the final standard require employers whose employees are exposed to an IDLH atmosphere to provide them with the most protective and reliable respiratory protection, i.e., a full facepiece pressure demand SCBA certified by NIOSH for a minimum of a 30-minute service life, or a combination full facepiece pressure demand supplied-air respirator with auxiliary self-contained air supply, and to implement specific rescue precautions and communication procedures. Although OSHA's prior Respiratory Protection standard does not explicitly use the term ''IDLH,'' it does require that respirators used in ''immediately dangerous'' atmospheres keep inward leakage to a minimum and be highly reliable (See paragraph (c) of prior 29 CFR 1910.134, which incorporates this language from the ANSI Z88.2–1969 standard by reference).

Commenters raised a number of issues specifically related to the proposed definition of IDLH and to the IDLH concept in general. These comments addressed the following points:

- Whether the term IDLH should apply to all delayed effects, some delayed effects, or be restricted to immediate effects;
- How OSHA's definition of IDLH differs from those of other organizations and how it relates to the definition of IDLH used in other OSHA standards;
- How the presence of an IDLH or potential IDLH atmosphere affects respirator selection.

The following discussion addresses each of these points in turn.

The proposed definition of IDLH included the phrase ''delayed adverse health effects.'' OSHA has omitted this phrase from the final standard to respond to comments received and to remove a source of confusion. Many commenters argued that the term IDLH should cover only immediate, severe adverse health effects, such as those resulting from exposures to hydrogen fluoride or oxides of nitrogen (e.g., Exs. 54–208, 54–219; 54–316), while others favored taking chronic, delayed effects into consideration when making an IDLH decision (See, e.g., Exs. 54–202 and 54–437). For example, OCAW stated that ''OSHA's IDLH and acute hazard-based framework * * * does not properly emphasize the need to consider long-term and cumulative health effects.''

Most participants, however, argued against including chronic health effects in the IDLH definition because it would make the definition too broad. These participants feared that including this term would mean that exposures typically associated with chronic effects, such as cancer, would be designated IDLH (Exs. 54–67; 54–153; 54–175; 54–208; 54–218; 54–219; 54–232; 54–266; 54–278; 54–307; 54–314; 54–316; 54–326). Typical of these comments is one from the American Iron and Steel Institute: ''The proposed definition, which includes ''delayed health effects,'' is so broad that it goes far beyond the accepted IDLH concept, and would expand it beyond its intended purpose'' (Ex. 54–307). Arguing along the same lines, the Exxon Corporation stated that ''the phrase 'delayed health effects' could include chronic toxins like asbestos * * *'' (Ex. 54–266).

Other commenters urged OSHA to narrow the definition of IDLH by adding the word ''acute'' before ''adverse'' in the phrase ''delayed adverse health effects'' or by making other language changes that would achieve the same effect (Exs. 54–67, 54–278, 54–326, 54–208A). For example, the American Industrial Hygiene Association (Ex. 54–208A) stated that the only atmospheric contaminants with delayed effects that should be included in the definition are those, such as the oxides of nitrogen, that cause delayed-onset severe adverse health effects (such as pulmonary edema). Representatives of Pennzoil suggested that ''* * * the phrase 'immediate or delayed irreversible debilitating health effects', be used'' to achieve the same end (Ex. 54–287).

These commenters objected to the inclusion of ''delayed health effects'' in the proposed definition because the language suggested that effects typically associated with long-term exposures, such as cancer, would be included. The definition in the final standard recognizes that the effects of concern must be the result of an acute overexposure but does not specifically limit the length of time between that overexposure and the resulting effect.

Where very serious health effects may arise from a single acute exposure, even if such effects become apparent only after a relatively long latency period, e.g., hours, days, or even weeks, the atmosphere associated with the effect must be designated IDLH. OSHA is confident that deleting the word ''delayed'' from the IDLH definition in the final rule will reduce confusion but will not affect the level of employee protection provided by the standard.

Many commenters urged OSHA to adopt an IDLH definition developed by another organization, agency, or by OSHA itself in other standards. Some commenters (Exs. 54–153, 54–214, 54–234, 54–251, 54–266, 54–278, 54–290, 54–330, 54–361, 54–363, 54–424, 54–439) urged OSHA to adopt the ANSI Z88.2–1992 standard's definition of IDLH: ''any atmosphere that poses an immediate hazard to life or poses immediate irreversible debilitating effects on health'' (clause 3.33). For example, Bell Atlantic (Ex. 54–361) suggested that the ANSI definition be used to ensure that ''chronic toxins like asbestos would not be considered IDLH.'' However, OSHA believes that adopting the definition contained in the current ANSI standard could reduce employee protection because it states that atmospheres are IDLH only in cases where the adverse effects of exposure occur immediately. An example of an atmosphere that OSHA believes must be considered IDLH but arguably would not be so designated under the ANSI definition is one containing high concentrations of cadmium fume, which may result in fatal collapse as long as 48–72 hours after an acute overexposure.

The Exxon Corporation (Ex. 54–266) objected to the phrase ''ability to escape'' in OSHA's proposed definition, and suggested that OSHA instead adopt the ANSI definition, which does not refer to impairment of the ability to escape. OSHA wishes to clarify that the proposed terminology, ''interfere with an individual's ability to escape'' was not meant to cover a minor or even moderate degree of interference but to address interference of a kind sufficiently serious to impair the individual's ability to escape from exposure to a dangerous concentration of an air contaminant. To address Exxon's concern, the final rule's definition has been revised to read ''impair the individual's ability to escape.'' OSHA notes that it is imperative for employees to be able to escape. There are atmospheres, for example one contaminated with a severe eye irritant, that can effectively incapacitate an individual in the short term and prevent the individual from escaping in time to avoid more serious health consequences. OSHA has therefore retained in the IDLH definition language that addresses the need to protect workers escaping from dangerous atmospheres.

One commenter, Monsanto (Ex. 54–219), expressed concern about the consistency of IDLH definitions in different OSHA standards. In response, OSHA has reviewed the definitions of IDLH used in its standards and believes that the final standard's definition is largely consistent with those in the two OSHA safety standards that use the term: 29 CFR 1910.146, the Permit-Required Confined Space standard (''Confined Spaces standard'') and 29 CFR 1910.120, the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard.

Some commenters (Exs. 54–439, 54–330, 54–278) asked which IDLH values OSHA endorses or pointed to the limitations of the available information on IDLH concentrations. For example, OCAW noted that ''only a handful of IDLH limits have been determined. In most worker exposure, the IDLH limit is unknown. Even when [an] IDLH limit exists, workers do not have access to this information. MSDSs rarely include IDLH information'' (Ex. 54–202).

The final rule does not contain a prescribed list of IDLH values or require employers to rely on any particular list. Some commenters (Exs. 54–278, 54–330, 54–361, 54–424, 54–439) criticized the IDLH values listed in the 1994 NIOSH Pocket Guide to Chemical Hazards (Ex. 54–278) or recommended that the Emergency Response Planning Guidelines (ERPGs) developed under the auspices of the American Industrial Hygiene Association be used instead. OSHA is aware that published IDLH values are not available for many industrial contaminants and that employers must therefore rely on their own knowledge and judgment, and that of safety and health professionals, when deciding that a given atmosphere has the potential to cause health effects of the kind envisioned by OSHA's IDLH definition. During enforcement inspections, OSHA will continue to accept any published IDLH value that is based on sound scientific evidence; those published by NIOSH and the AIHA would clearly meet this test.

OSHA's final IDLH definition does not separately mention ''potential'' IDLH atmospheres. Many OSHA enforcement cases have involved the failure of employers to provide respirators in situations that were not IDLH at the time workers entered the area but became so thereafter. OSHA intends employers to interpret the respirator selection requirements in paragraph (d)(1) proactively, i.e., where employers are uncertain about the adequacy of a given respirator for a highly hazardous atmosphere, cannot identify the atmospheric concentration of a substance that poses a potentially life-threatening or health-impairing risk, or cannot maintain the concentration of such a substance below life-threatening or health-impairing levels, the employer must consider the atmosphere IDLH and select a respirator accordingly. For example, an employer in a chemical plant knows that inadvertent releases or spills of highly hazardous chemicals may occur at the facility and selects the most protective respirators available for employees who must enter a spill area because, in an emergency, there is no time to take airborne measurements to determine whether or not the concentration is IDLH. OSHA encourages this kind of proactive planning because it is protective of employee health.

Interior structural firefighting. The final respiratory protection standard uses the OSHA definition for ''interior structural firefighting'' contained in 29 CFR 1910.155, which applies to all situations covered by Subpart L—Fire Protection. The definition is as follows:

> *Interior structural firefighting* means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage.

Loose-fitting facepiece. The final standard now defines this term to mean ''a respiratory inlet covering that is designed to form a partial seal with the face.'' This definition was not in the proposal, and has been added in response to commenters such as the AIHA (Ex. 54–208), 3M (Ex. 54–218), Monsanto (Ex. 54–219), Martin Marietta Energy Systems, Inc. (Ex. 54–410), and ORC (Ex. 54–424), who recommended that OSHA adopt several of the ANSI Z88.2–1992 definitions for respirator terms. OSHA has adopted only part of the ANSI definition for loose-fitting facepiece. The phrase in the ANSI definition that states a loose-fitting facepiece ''does not cover the neck and shoulders, and may or may not offer head protection against impact and penetration'' has not been included. This phrase from the ANSI definition was not adopted as part of the OSHA definition because adding this phrase would not allow users to clearly distinguish between hoods, helmets, and loose-fitting respirators. It is important for employers to be able to distinguish loose-fitting from tight-

fitting respirators in order to correctly apply the fit testing requirements.

Maximum use concentration. OSHA is not defining this term at this time because the Agency has reserved the issue of Assigned Protection Factors, which is associated with Maximum Use Concentrations, until a subsequent phase of this rulemaking.

Negative pressure respirator (tight fitting). The final standard defines this term as ''a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.'' The proposed definition was revised in response to comments (Exs. 54–208, 54–218, 54–219, 54–410, and 54–424) that recommended that OSHA adopt the ANSI Z88.2–1992 standard's definition. In the final rule, OSHA has accepted the ANSI definition, with two changes: (1) The word ''facepiece'' has replaced the term ''respiratory inlet covering'' to make clear that the facepiece is the area of interest with negative pressure respirators; and (2) the phrase ''outside the respirator'' has been added after the phrase ''ambient air pressure'' to clarify that negative pressure exists only when the outside air pressure is higher than the air pressure inside the negative pressure facepiece.

Oxygen-deficient atmosphere. The proposed definition of an ''oxygen deficient atmosphere'' was ''an atmosphere with an oxygen content of less than 19.5% by volume at altitudes of 8000 feet or below.'' OSHA is retaining the 19.5% definition of an oxygen-deficient atmosphere in the final rule, but is removing the reference to altitudes. The use of a 19.5% oxygen level is well established and has even been incorporated by Congress into other safety and health legislation (See Federal Mine Safety and Health Act, 20 USC 863 (b), discussed in *National Mining Association* v. *MSHA*, 116 F.3d 520 (D.C. Cir. 1997.) Paragraph d(2)(iii) of the final rule requires employers to consider all oxygen-deficient atmospheres to be IDLH and to require the use of pressure-demand SCBA or a combination full-facepiece pressure-demand SAR with an auxiliary self-contained air supply. However, this paragraph also contains an exception that would permit employers to use any atmosphere-supplying respirator in oxygen-deficient atmospheres where the employer can demonstrate that oxygen levels cannot fall below the altitude-adjusted concentrations prescribed in Table II of paragraph (d).

The ANSI Z88.2–1992 standard, NIOSH (Ex.164), and AIHA (Ex. 2098) use an altitude-adjusted definition for oxygen deficiency. Although there are some small differences, these organizations generally define oxygen deficiency as an oxygen level of less than 19.5% at altitudes up to 5,000 or 6,000 feet, and less than 20.9% at higher elevations. OSHA chose not to adopt this approach to defining oxygen deficiency for several reason. First, as was stated in the proposal (59 FR 58905), OSHA's concern is that employees not be exposed to environments in which the oxygen partial pressure is less than 100 mm Hg; this partial pressure of oxygen is generally regarded as an appropriate IDLH level (Exs. 164, 208). OSHA believes that using an oxygen concentration of 19.5 percent as a baseline oxygen level is appropriate because exposure to such an atmosphere does not pose a serious health risk at elevations below 8,000 feet, i.e., the oxygen partial pressure in such atmospheres will remain above 100 mm Hg (Ex.164). Although OSHA realizes that the partial pressure of oxygen may be at or above 100 mm Hg even at some lower altitudes and lower oxygen concentrations, these lower-altitude, lower-concentration situations are generally unstable and can quickly deteriorate to life-threatening atmospheres. OSHA has accounted for those rare situations where the employer controls the environment to maintain a constant altitude-adjusted oxygen level through the exception in paragraph (d)(2)(iii) of the final rule. OSHA's definition of oxygen deficiency is also consistent with the Compressed Gas Association's definition of Grade D breathing air as air containing a minimum of 19.5% oxygen. OSHA finds that defining oxygen deficiency as an atmosphere with an oxygen content below 19.5% is both protective and straightforward, and is consistent with the definition that has been used by the Agency in the past.

Oxygen-deficient IDLH atmosphere. The proposal originally included a definition of oxygen-deficient IDLH atmosphere. Because the term has not been used in the regulatory text of the final rule, OSHA is deleting this term from paragraph (b).

Physician or other licensed health care professional (PLHCP) is defined as ''an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section.'' This definition has been added because paragraph (e)(2) of the final standard requires that all medical evaluation procedures be performed by a PLHCP.

OSHA has long considered the issue of whether, and if so how, to specify the qualifications of the particular professionals who are permitted to perform the medical evaluations required by its standards. The Agency has determined that any professional who is licensed by state law to perform the medical evaluation procedures required by the standard may perform these procedures under the respiratory protection standard. The Agency recognizes that this means that the personnel qualified to provide the required medical evaluation may vary from state to state, depending on state licensing laws. Under the final rule, an employer has the flexibility to retain the services of a variety of qualified licensed health care professionals, provided that these individuals are licensed to perform a given service. OSHA believes that this flexibility will reduce cost and compliance burdens for employers and increase convenience for employees. The approach taken in this final standard is consistent with the approach OSHA has taken in other recent standards (e.g., cadmium, methylene chloride).

Positive pressure respirator. This term has been redefined in the final standard to mean ''a respirator in which the pressure inside the respiratory inlet covering is positive with respect to ambient air pressure outside the respirator.'' Consistent with the recommendations of several commenters (Exs. 54–208, 54–218, 54–219, 54–410, and 54–424), the final standard's definition adopts the ANSI Z88.2–1992 definition but adds the phrase ''outside the respirator'' for clarity.

Powered air-purifying respirator. The final standard defines this term as ''an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.'' This revision also reflects commenters' recommendations that OSHA adopt ANSI Z88.2–1992 standard definitions (Exs. 54–208, 54–218, 54–219, 54–410, and 54–424). The term ''ambient atmosphere'' in the ANSI definition has been replaced with the term ''ambient air'' for simplicity.

Pressure demand respirator. This type of respirator is defined as ''a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.'' This language has been taken verbatim from the ANSI Z88.2–1992 standard's definition, except that

the term ''breathing air'' has replaced the term ''respirable gas'' for clarity.

Qualitative fit test (QLFT). This definition has been revised to read ''a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.'' OSHA has replaced the proposal's QLFT definition with one derived from the ANSI Z88.2–1992 standard but has added the phrase ''to assess the adequacy of respirator fit'' to emphasize the purpose of QLFT. In addition, the OSHA definition uses the phrase ''the individual's response'' instead of the ANSI definition's phrase ''subject's sensory response'' for clarity.

Quantitative fit test (QNFT). This definition has been revised and simplified to accommodate both current and yet-to-be-developed fit test technology. The final standard defines a quantitative fit test (QNFT) as ''an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.'' Commenters generally opposed the proposed definition of QNFT, which made reference to challenge agents, because they feared that it might interfere with the development of new fit test methods (Exs. 54–5, 54–222, 54–251, 54–266, 54–275x, 54–350, 54–208, 54–218, 54–219, 54–278, 54–316, 54–424). OSHA agrees and has revised the definition accordingly. OSHA believes that the definition of QNFT must be usable, enforceable, and understandable, and accommodate evolving technology.

Respiratory inlet covering. The final standard defines this term, which is often used in descriptions of respiratory equipment, as ''that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with nose clamp.'' This definition is adapted from that in the ANSI Z88.2–1992 standard; the phrase ''that connects the wearer's respiratory tract'' in the ANSI definition has been modified to read ''that forms the protective barrier between the user's respiratory tract'' in the OSHA definition for clarity.

Self-contained breathing apparatus (SCBA). The proposed definition of self-contained breathing apparatus (SCBA) has been revised slightly in the final standard to read ''an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.'' This revised definition was adopted from the ANSI Z88.2–1992 standard's definition of SCBA.

Service life. The final standard defines service life as ''the period of time that a respirator, filter, or sorbent, or other respiratory equipment provides adequate protection to the wearer.'' This definition eliminates a reference in the proposal to substances ''breaking through'' the cartridge or canister, and deletes a statement that respirator manufacturers are to determine service life concentrations, since this is the employer's responsibility. The new definition parallels ANSI's except that it contains additional language covering filters, sorbents, and other respiratory equipment. This definition is further explained in the discussion of paragraph (d) of the Summary and Explanation.

Supplied-air respirator (SAR) or airline respirator. OSHA has elected to retain a definition for supplied-air respirators, since the term is used by NIOSH in the 42 CFR part 84 regulations. The final standard's definition reads: ''Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.'' Participants (Exs. 54–208, 54–249) were more familiar with this term than with the term ''air-supplied respirator'' recommended as an alternative by some commenters (Exs. 54–218, 54–219, 54–363, 54–434). The language of this definition is derived from the ANSI Z88.2–1992 definition for ''airline respirator,'' but also applies to supplied-air respirators, a term that NIOSH uses to certify this class of respirators. OSHA believes that using both names in the definition will reduce confusion for respirator users.

Tight-fitting facepiece is defined as ''a respiratory inlet covering that forms a complete seal with the face.'' This term was not defined in the proposal, but numerous commenters requested that OSHA add this definition (Exs. 54–222, 54–283, 54–363, 54–410, 54–424, 54–428, 54–433, 54–455) to the final standard.

User seal check is defined as ''an action conducted by the respirator user to determine if the respirator is properly seated to the face.'' Such a check is performed by the user each time the respirator is donned or adjusted to ensure that the tight-fitting respirator is properly seated on the user's face, i.e., that the proper seal has been achieved. Several commenters recommended that OSHA add the definition for ''fit check'' from the ANSI Z88.2–1992 standard to replace the term ''facepiece seal check'' that was used in Appendix B of the proposal (Exs. 54–208, 54–218, 54–219, 54–410, 54–424). The term ''fit check'' has proven confusing to those respirator users who do not realize that a daily fit check is not a substitute for an annual fit test. The AIHA (Ex. 54–208) recommended that OSHA add a statement to Appendix B to the effect that: ''Fit checks are not substitutes for qualitative or quantitative fit tests,'' and OSHA has done so in this final standard. Because OSHA believes that the similarity between the terms ''fit check'' and ''fit test'' is responsible for this confusion, OSHA has used the term ''user seal check'' rather than ''fit check'' in the final standard. The definition of ''user seal check'' derives from the ANSI Z88.2-1992 standard's definition for ''fit check,'' except that the word ''action'' has been substituted for ''test'' to avoid any possible confusion among respirator users.

Paragraph (c)—Respiratory Protection Program

This paragraph of the final standard requires employers to develop and implement a written respiratory protection program, with workplace-specific procedures addressing the major elements of the program, whenever respirators are necessary to protect the health of the employee. In addition, where an employer requires an employee to wear a respirator, i.e., in a situation where the standard does not otherwise require such use, a written program must be developed and implemented. Employers who provide respirators at the request of their employees or who allow their employees to bring their own respirators into the workplace must ensure that the respirator used does not present a hazard to the health of the employee. However, if the respirator voluntarily worn is a filtering facepiece (dust mask), the employer is not required to implement a written program. Paragraph (c)(1) also requires employers to update the program when changes in the workplace or in respirator use make such updating necessary.

As in the proposed rule, the final standard requires that the respiratory protection program be written. OSHA's experience and that of the industrial hygiene community have demonstrated that health and safety programs can best be effectively implemented and evaluated when written. In addition, because workplaces differ substantially, each program must be tailored to the specific conditions of the workplace if it is to protect employee health, and developing a written program is the most efficient way of ensuring that the program reflects the unique characteristics of each workplace. Developing and writing down worksite-

specific procedures requires employers to design their respiratory protection programs to address the respiratory hazards in their particular workplace, and this process requires employers to think about and document all relevant information pertaining to the hazardous atmospheres that their employees may encounter under normal operating conditions or during reasonably foreseeable emergencies that may occur in the workplace. Finally, OSHA's enforcement data indicate that compliance with the previous standard has not been optimal, particularly in smaller workplaces, and a written program will help employers, employees, and compliance officers gauge the adequacy of a given program.

Paragraphs (c)(1)(i) through (c)(1)(ix) identify the elements that must be included in the employer's program unless the particular element does not apply to the employer's workplace. The previous OSHA respiratory protection standard also required employers to develop written standard operating procedures that covered the selection, use, cleaning, maintenance, inspection, and storage of respirators and the training and medical evaluation of respirator users (paragraphs (b)(1), (e)(1), and (e)(3), among other provisions of the previous standard). In the final standard, the general elements of the written program have been expanded, reordered and updated, and the term ''written standard operating procedures (SOP)'' used in the previous standard has been replaced with the words ''worksite-specific procedures.'' Thus, the standard identifies the basic elements of written programs for all workplaces, but the employer has the flexibility to tailor these general program elements to match the specific workplace conditions and processes that occur in that workplace. In the Agency's previous respiratory protection standard, the requirement for written standard operating procedures tended to lead to the adoption of generic procedures. Changing the terminology from ''SOPs'' to ''worksite-specific procedures'' gives employers the incentive to develop procedures that are unique and specific to the employer's workplace, to describe the particular respirator selection process used in that workplace, and to explain how employees are to use respirators in that setting.

OSHA has also revised the required program elements themselves, for several reasons. First, they have been modified to reflect those provisions of the final standard that have been added or enhanced to reflect advances in respiratory protection technology, such as the development of atmosphere-supplying respirators and the widespread use of modern methods of fit testing. Second, several of the provisions of the previous standard were vague and had caused compliance difficulties for employers over the years. OSHA wishes to provide employers with clear notice of what elements OSHA considers essential to an effective respirator program. Third, OSHA has adopted several changes suggested by commenters.

OSHA also believes that clearer program elements will improve employer compliance. According to the Minnesota Department of Labor and Industry (Ex. 54–204), for example, many employers have had difficulty complying with OSHA's previous standard because they were unsure what elements a program was required to include. Several other data sources also point to the lack of clarity in OSHA's previous standard; these include OSHA's inspection data and compliance experience, comments to the record (Ex. 54–219), and studies of workers (Ex. 64–65). As noted in the NPRM, data collected on current respirator practices and procedures in over 2300 manufacturing plants classified in 15 SIC codes were reviewed by the Agency (See Summary of the Preliminary Regulatory Impact Analysis, 59 FR 58892). This survey sample was used to produce estimates of respirator-related practices for about 123,200 manufacturing plants with regular and occasional respirator use. Only 25.5% of these plants were estimated to have written standard operating procedures, and only 7.9% had procedures that addressed all eight of the program elements required by the previous standard (selection, use, cleaning, maintenance, inspection and storage of respirators, and the training and medical evaluation of respirator users). More than 80% of the very large plants (those with 1000 or more employees) had written procedures, while in small plants (those with fewer than 50 employees), only about 22% had written procedures. This survey clearly showed that improving the clarity of the elements to be addressed in standard operating procedures would help employers to develop and implement better respiratory protection programs and thus would provide greater protection to workers as well.

Similarly, a study of OSHA citations for violations of the previous OSHA respirator standard from 1977 to 1982 showed that 13% of these citations were issued because standard operating procedures were either inadequate or missing (Rosenthal and Paull; Ex. 33–5). OSHA's latest citation data for the respiratory protection standard, for the period October 1990 to December 1995, show that the number of citations issued for inadequate or missing written respirator programs in general industry has increased to 18.4% of all respirator standard-related citations. These data indicate that the conclusions reached by Rosenthal and Paull are still valid. The citation history for the construction industry respiratory protection standard, 29 CFR 1926.103, is similar, with citations for inadequate respirator programs representing 10.5% of all respirator standard-related citations in that industry. OSHA believes that the percentages of respirator standard-related citations reported in these reviews substantially underestimate the real incidence of deficient programs because it is OSHA policy not to issue citations for an inadequate program unless an overexposure is also documented.

Paragraphs (c)(1)(i) through (c)(1)(ix) of the final standard provide additional detail about each of the required program elements but remain performance based to enable employers to adapt them to their workplaces. The program elements have been reorganized from those in the previous standard so that they track the order of the major paragraphs of the standard. OSHA believes that reordering the elements, as suggested by one commenter (Ex. 54–204), is logical and should make program development easier. OSHA also believes that the additional detail and greater clarity provided by the final rule's program elements will reduce confusion over the intent of these provisions, lead to higher compliance rates, and result in better respiratory protection for employees.

The ANSI Z88.2–1992 standard for respiratory protection also states that written procedures covering the complete respirator program must be established and implemented (Ex. 81). Thus, like OSHA, ANSI recognizes the need for a written respiratory protection program and implementing procedures to provide complete and consistent protection to employees wearing respirators. Although the ANSI standard does not contain detailed instructions on the content of these procedures, it does describe, in clause 6, the elements to be included in the program to cover routine and emergency use of respirators.

The program elements in the ANSI Z88.2–1992 standard (i.e., program administration, respirator selection, training, respirator fit, maintenance, inspection and storage) are similar to those in paragraphs (c)(1)(i) through

(c)(1)(ix) of OSHA's final standard. The specific content of each element of the written procedures is left to the employer, who can tailor them to match the conditions that occur in his/her worksite. Although many of the program elements are common to all respiratory protection programs, such as respirator selection, care, use, and program evaluation, some elements, such as the one addressing specifications for air quality for atmosphere-supplying respirators, apply only in workplaces in which those types of respirator are used.

OSHA received many comments, both on written programs in general and on specific program elements. Some commenters (Exs. 54–160, 54–187, 54–238), questioned the need for a written respirator program with worksite-specific procedures. For example, Transtar Railroads (Ex. 54–160) stated that written procedures do not guarantee an effective respiratory protection program and argued that requiring additional written program elements would not cause those companies who presently disregard OSHA's existing standard to become more conscientious. Motorola (Ex. 54–187) urged OSHA to delete the requirement for a written program and instead simply to require that employers ensure that respirators are properly selected, fitted, used, and maintained as necessary to protect employees when respirators are required. However, the requirement for a written respirator program was widely supported by many other participants in the rulemaking (Exs. 54–204, 54–219, 54–304, 54–387, 54–389, 54–428, 54–435). For example, the United Automobile Workers (Ex. 54–387) agreed that a written respiratory protection program that is site-specific and detailed (for example, that includes specific procedures for determining when a cartridge or filter needs to be changed) should be required. The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) (Ex. 54–428) strongly supported the requirement for a written respiratory program and identified such a program as the fundamental core of the standard:

> The AFL–CIO strongly supports the Agency's proposal that employers who are required to use respirators or voluntarily use respirators in the workplace establish a written respiratory protection program. The written program constitutes an employer's plan for dealing with worker protection from hazardous airborne contaminants that may be present in the workplace, and as such, we view these provisions as the fundamental core of the standard. Requiring a written program is essential in providing uniformity and consistency while supplying the maximum protection for workers who use respirators in the workplace. (Ex. 54–428)

OSHA's expert witness, James Johnson of the Lawrence Livermore National Laboratory, testified that respiratory protection programs must be written because of their complexity:

> * * * A respirator program involves many decisions. What kind of respirator do I use, what kind of concentrations were measured, what kind of contaminants were in the workplace
>
> * * * So all this information is important to provide documentation and understanding so that you can make sure the program is adequate and you can make changes to it, to improve it and to have it be a dynamic operation as the workplace changes * * * (Tr. 212)

Commenting in the same vein, the National Pest Control Association (Ex. 54–435), which represents many small businesses, agreed that requiring employers to provide a written respiratory program was sensible, and the Cambrex Corporation (Ex. 54–389) noted that ''A performance approach in defining written program requirements will provide needed flexibility to employee protection programs.'' David Lee, CIH, CSP (Ex. 54–304), strongly supported the approach OSHA has taken in the final rule; he stated that a written respiratory protection program should be required in all places where respirators are used, regardless of the circumstances, and that the program's contents should be specifically tailored to conditions of use at the place of employment.

OSHA agrees with these commenters that it is appropriate to retain the previous standard's requirement for a written program, and that the program must be flexibly tailored to worksite conditions. OSHA finds that comments to the record, and the Agency's own compliance experience, strongly suggest that many employers wish to comply but are unsure about what is required; for these employers, greater clarity and guidance will enhance compliance and enable them to provide their employees with needed protection.

Paragraph (c)(1) of the final rule requires employers to update the program as necessary to reflect changes in the workplace. This requirement has been revised somewhat from the proposal. The proposed standard stated that ''[t]he written program shall reflect current workplace conditions and respirator use'' (59 FR 58939). OSHA received several comments on this provision (Exs. 54–278, 54–213, 54–249). For example, the Dow Chemical Company (Ex. 54–278) urged OSHA to revise this language to require that the program reflect only those current workplace conditions ''significantly impacting respirator use.'' In the final rule, OSHA has moved this provision to paragraph (c)(1) and revised it to require that the program be ''updated as necessary to reflect those changes in workplace conditions that affect respirator use.'' OSHA believes that this change is responsive to Dow's point. As now written, when the workplace changes in a way that may affect respirator use, such as when new processes are introduced, changes are made in the types of chemicals used, or the types of respirators being used changes, employers must revise the program as necessary to reflect these new conditions.

One of the major issues raised in the rulemaking dealt with situations in which respirator use is not specifically required by 29 CFR 1910.134 or other OSHA statutory or regulatory requirements, but instead is required by employers as a condition of employment or is permitted by employers upon the request of employees (i.e., voluntary use). The preamble discussion for proposed paragraph (a) stated that employers who required employees to use respirators would be covered by the standard (59 FR 58895). OSHA also recommended in the NPRM that employers who permit voluntary respirator use in their workplaces implement the full respiratory protection program. In the final rule, paragraph (c)(1) requires that a respiratory protection program be developed and implemented ''wherever respirators are required by the employer,'' but has greatly reduced the obligations of employers who allow their employees to use respirators when such use is not required.

In the preamble to the proposal, OSHA discussed the reasoning behind including employer-required respirator use within the scope of the standard (59 FR 58895). OSHA stated that the requirement was appropriate both because the use of a respirator could in itself present a health hazard to the wearer, and because improper use of a respirator in environments where respiratory hazards are present would not sufficiently protect employees from those hazards. OSHA finds that these are still valid reasons for requiring that a respiratory protection program be implemented where employers require respirator use. All of the elements of a respiratory protection program apply to this situation. Employers must still select respirators that are appropriate to the workplace conditions and types of respiratory hazards present to ensure that respirators offer adequate protection. Improperly selected

respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.

Employees who are required by their employers to wear respirators must also be medically evaluated to determine that they are capable of tolerating the increased physiological load associated with some respirator use. Proper fit testing is necessary to ensure that discomfort is minimized and that the respirator selected is offering sufficient protection. It is also necessary that respirators required by employers be cleaned, disinfected, stored, inspected, and repaired according to the procedures contained in the final rule to ensure proper respirator functioning and protection of employees from dermatitis or exposure to hazardous contaminants that may result from using a dirty respirator. Compliance with the provisions of the standard dealing with supplied air quality and use is also essential where employers require the use of supplied-air respirators. When employers require employees to use respirators, OSHA believes it necessary that employees be properly trained in their use and care, and be informed of the limitations of using respirators. Paragraph (k) of the final rule makes clear that employers must implement the employee training requirements contained in paragraph (k) if they require their employees to use respirators.

In contrast, not all of these protections are necessary in the situation where an employer allows, but does not require, respirator use. OSHA has therefore added a new paragraph (c)(2) to the final rule, which applies when employers allow employees to use respirators when such use is not required by the employer or by the standard. This paragraph applies when employers either provide respirators to employees who request them or allow employees to use their own respirators. In both situations, paragraph (c)(2)(i) states that employers must determine that the employees that they allow to use respirators are medically able to do so, and that there are no other conditions that could cause the respirator use to create a hazard.

If the employer allows voluntary respirator use, paragraph (c)(2)(i) requires that the employer provide the employee with the information contained in Appendix D to this standard, entitled ''Information for Employees Using Respirators When Not Required Under the Standard.'' In the rare case where an employee is voluntarily using other than a filtering facepiece (dust mask) respirator (paragraph (c)(2)(ii)), the employer must implement some of the elements of a respiratory protection program, e.g., the medical evaluation component of the program and, if the respirator is to be reworn, the cleaning, maintenance, and storage components. An exception to this paragraph makes clear that, where voluntary respirator use involves only filtering facepieces (dust masks), the employer is not required to implement a written program.

Paragraph (c)(2) is necessary because the use of respirators may itself present a health hazard to employees who are not medically able to wear them, who do not have adequate information to use and care for respirators properly, and who do not understand the limitations of respirators. Paragraph (c)(2) is intended to allow employers flexibility to permit employees to use respirators in situations where the employees wish to do so, without imposing the burden of implementing an entire respirator program. At the same time, it will help ensure that such use does not create an additional hazard and that employees are provided with enough information to use and care for their respirators properly. This provision does not, of course, preclude employers from adopting additional program elements if they believe such elements are appropriate.

The great majority of voluntary use situations involve the use of dust masks, i.e., filtering facepieces, which are provided for the employee's comfort. For example, some employees who have seasonal allergies may request a mask for comfort when working outdoors, or an employee may request a dust mask for use while sweeping a dusty floor. There are no medical limitations on the use of these respirators, so employers who allow their use need only ensure that the masks are not dirty or contaminated, that their use does not interfere with employees' ability to work safely, and that they provide the employees with the information contained in Appendix D, as required by paragraph (k) of the final rule.

In rare cases where the employee requests and the employer allows the use of a negative-pressure respirator (tight-fitting), or where the employee brings such a respirator into the workplace, the employer must implement some provisions of the respirator program described in paragraph (c)(1) to ensure that such respirator use will not affect the employee's health adversely. The employer can include these elements in its existing respiratory protection program, if it is required to maintain one. Some medical evaluation is necessary to determine that the employee is physically able to use a tight-fitting negative pressure respirator. In addition, if the respirators being used voluntarily are reused, it is necessary to ensure that they are maintained in proper condition to ensure that the employee is not exposed to any contaminants that may be present in the facepiece, and to prevent skin irritation and dermatitis associated with the use of a respirator that has not been cleaned or disinfected. OSHA believes it unlikely that voluntary use situations will involve the use of supplied-air devices, but such use would also trigger these requirements of the standard.

These requirements are necessary because use of a negative pressure (tight-fitting) respirator imposes a significant physiologic burden on a respirator user, and it is crucial to determine that the user can withstand that burden without suffering adverse health consequences. Similarly, reusable tight-fitting negative pressure respirators can become contaminated if they are not cleaned, maintained, and stored properly. Thus if an employer allows use of this type of respirator, the employer must implement the program elements necessary to ensure that contamination does not harm the employee.

The hazards addressed by this requirement are the same ones that are already considered under OSHA's longstanding enforcement policy. The Agency generally does not issue citations for violations of its respirator standards unless there is also evidence of overexposure to a hazardous substance, or some other hazard caused by improper or inadequate respirator use. (OSHA Field Inspection Reference Manual (FIRM), Ch. III. Sec. C.3.c). Other hazards referenced in the FIRM include ingestion of harmful substances that may remain on improperly cleaned and maintained respirators, or dermatitis caused by the same condition. These are precisely the hazards that the requirements of paragraph (c)(2) are designed to prevent. They can occur whether respirator use is voluntary or required, and OSHA does not believe it would be consistent with the OSH Act to allow employees to expose themselves to preventable hazards, particularly where there are fairly undemanding measures available to prevent that exposure.

Requiring employers to undertake these minimal obligations when they allow voluntary respirator use is

consistent with the fact that employers control the working conditions of employees and are therefore responsible for developing procedures designed to protect the health and safety of the employees. Employers routinely develop and enforce rules and requirements for employees to follow based on considerations of safety. For example, although an employer allows employees discretion in the types of clothing that may be worn on site, the employer would prohibit the wearing of loose clothing in areas where clothing could get caught in machinery, or prohibit the use of sleeveless shirts where there is a potential for skin contact with hazardous materials. Similarly, if an employer determines that improper or inappropriate respirator use presents a hazard to the wearer, OSHA finds that the employer must exert control over such respirator use and take steps to see that respirators are safely used under an appropriate program. It has been OSHA's experience that employers will be able to determine whether employees are using their own respirators in the workplace, just as they are able to determine that employees are adhering to all other procedures and requirements established by the employer.

Concomitantly, OSHA's decision to impose fewer requirements on voluntary respirator use than on required use is supported by the record. Many comments addressed the issue of how the final standard should treat these two types of respirator use. Many commenters (Exs. 54–96, 54–109, 54–196, 54–222, 54–272, 54–341, 54–424, 145, 176, Tr. 2127, Tr. 2174) supported the inclusion of employer-required respirator use, but not of voluntary use, within the full scope of the standard. Many of these rulemaking participants believed that voluntary respirator use should require a minimal program designed to provide information and training to the employee, and that other elements of the program should not be made mandatory. Typical of these was the post-hearing comment of Organization Resources Counselors, Inc. (ORC):

> OSHA should not require a complete respirator program for the voluntary use of respirators by employees, when not required by an OSHA standard, or by the employer. Some employees will wish to use respirators even though they are not required to protect against overexposure to a toxic hazard. In these instances the employer should be required only to inform the employee of the safe and proper use of such respirators and any associated limitations on the particular device chosen (Ex. 145).

In addition, some of these commenters (Exs. 54–341, 176, Tr. 594, Tr. 2100) suggested that requiring employers to comply with all or most of the requirements would discourage employers from permitting voluntary respirator use in their workplaces. For example, in its post-hearing submission, the North American Insulation Manufacturers Association (NAIMA) commented as follows:

> NAIMA agrees with many other hearing participants that employers should be required to train voluntary respirator users in the proper function and use of respirators * * * OSHA should, however, tailor other aspects of the Proposed Rule to ensure that the more onerous and unnecessary additional requirements, such as comprehensive medical examinations, are not imposed in truly voluntary use situations. Applying unnecessary ancillary requirements to voluntary use situations would discourage employers from allowing workers such use (Ex. 176).

OSHA believes that the final rule provides for the kind of tailoring suggested by NAIMA's comment. Employers who permit the voluntary use of tight-fitting negative-pressure respirators must utilize the procedures necessary to address the health hazards associated with the use of such respirators, but in the vast majority of voluntary-use situations where employees are using dust masks (filtering facepieces), the standard does not require the employer to implement a written respirator program to ensure employee health. Thus, the final rule does not require employers providing dust masks (filtering facepieces) to their employees to comply with the requirements that NAIMA considers ''onerous and unnecessary'' in this situation. However, where respirators are used voluntarily by employees, and the use of a given type of respirator, e.g., a tight-fitting negative pressure respirator, is associated with an increased health risk, OSHA finds that applying relevant portions of the respiratory protection program is essential to ensure worker protection.

Other commenters (Exs. 54–214, 54–218, 54–278, 54–389) believed that application of the standard should be limited in situations where there was no exposure to a respiratory hazard, regardless of whether respirator use is required by employers in this situation or is voluntary. In discussing this issue, the 3M Company commented as follows:

> 1. Any use of respirators or masks in the workplace should trigger a requirement for at least a minimal respiratory protection program. Regardless of whether use is required or recommended by an employer or is self-imposed by an employee, the employer should be responsible for the safe use of respirators and masks in the workplace.
>
> 2. Where it is documented by an employer that no hazard exists—such as when used against non-toxic materials, exposures well below the permissible exposure limit (PEL) or hazard level, or voluntary use against such conditions as discomfort or allergies—the rule should only require an abbreviated respiratory protection program * * *. (Ex. 54–218)

In a similar argument, the Dow Chemical Company (Ex. 54–278) suggested that employers be exempt from the standard's requirements if they require employees to use respirators as a precautionary measure where exposures are below the PELs.

OSHA did not adopt this approach in the final rule because the Agency believes that, in most cases of employer-required respirator use, respirators are being used as protection against actual or potential exposure to a respiratory hazard. In these cases, OSHA finds that it is necessary and appropriate that the employer implement all elements of the respiratory protection program that apply to the worksite-specific conditions under which respirators are used. If respirators are used as protection against a real or potential risk caused by exposure to a respiratory hazard, OSHA believes it essential for the employer to provide for proper respirator selection, fit testing, medical evaluation, and care and maintenance to ensure that the respirator is providing sufficient protection against the hazard and that use of the respirator is not imposing an additional health risk. OSHA also believes that, by distinguishing between employer-required and voluntary respirator use in the final rule, it will be easier for employers to determine the extent to which the standard will apply to their specific workplaces.

Other rulemaking participants (Exs. 54–208, 177, Tr. 782, Tr. 1722) were of the opinion that voluntary respirator use should not be distinguished from employer-required use in determining how the standard should apply, or reported that some employers already implement a program for voluntary use. The AIHA, in support of full coverage of the standard for voluntary respirator use, stated in written comment:

> The position of AIHA is that all use of respiratory protection should be covered by an employer's respiratory protection program. That includes both voluntary use as well as required use. Both groups should participate in all elements of the respiratory protection program. An individual desiring to wear a respirator to obtain some level of comfort or to further reduce their exposure to

a chemical in the workplace should receive the full benefits of an established program: training to convey proper knowledge in equipment selection, maintenance, and use; medical evaluation to confirm that its use will not present a risk to the individual; and fit testing to confirm that the equipment fits properly and workplace surveillance to confirm that the equipment being utilized is suitable for the exposure level. (Ex. 54–208)

At the public hearing, Larry Janssen of the AIHA elaborated that ''* * * there should be some kind of a minimum framework to prevent the misuse of respirators in those voluntary use situations, that you don't do harm by allowing a respirator to be used where it's not really needed'' (Tr. 782). Similarly, in a post-hearing comment, the Industrial Safety Equipment Association (ISEA) stated that it was important to cover voluntary use in the standard since ''* * * [r]espirators that are not used properly could present a hazard'' (Ex. 177). This practice is already being implemented in some workplaces; Richard Holmes of Union Carbide, representing the Chemical Manufacturers Association (CMA) at the hearings (Tr. 1722), testified that ''* * * [w]e treat the voluntary user just like a mandatory user so they're in the program just as though they were required to wear the respirator and the * * * medical surveillance is all handled the same * * * [as is the training].''

As discussed above, OSHA agrees that some voluntary respirator use (e.g., that involving tight-fitting negative-pressure respirators) may present a health hazard to employees if the respirator is not properly selected, maintained, and used. Therefore, OSHA has revised the final rule to ensure that employers who permit voluntary use of such respirators in their workplaces implement those portions of the standard necessary to protect employees from any health risks associated with respirator use. The position taken in the final rule also reflects OSHA's long-standing enforcement policy with the previous respiratory protection standard, as stated in the FIRM and in several letters of interpretation issued by the Agency (See letters dated 10/2/87 from Thomas J. Shepich, 4/11/91 from Patricia K. Clark, 3/19/91 from Patricia K. Clark, 3/4/93 from Roger A. Clark (2 letters), and 3/15/95 from Ruth McCully). For example, in the letter of March 4, 1993 from Roger A. Clark, OSHA stated its policy regarding the application of 29 CFR 1910.134 to the voluntary use of respirators:

OSHA's policy is that if the respirator itself could present an adverse health condition if a specific requirement of the respiratory protection standard is not observed, then the requirement applies. Examples may include a dirty respirator that is causing dermatitis, a worker's health being jeopardized by wearing a respirator due to an inadequately evaluated medical condition, or a significant ingestion hazard created by an improperly cleaned respirator. This is so regardless of whether the employee purchased the respirator or the employer provides it.

OSHA also has determined that complete training is not required for employees using respirators voluntarily. Instead, paragraph (k) of the final rule requires employers to provide the information contained in Appendix D to ensure that employees are informed of proper respirator use and the limitations of respirators.

Paragraphs (c)(1)(i) through (c)(1)(ix) list the elements of the respirator program required by this standard. Paragraph (c)(1)(i) requires the program to contain procedures for the selection of respirators appropriate to protect employees from the respiratory hazards present in the particular workplace. This provision is unchanged from the corresponding provision in the proposal and is also similar to paragraph (b)(2) of OSHA's previous standard. Paragraph (c)(1)(ii) addresses the medical evaluation of employees required to wear respirators and is unchanged from the parallel requirement in the proposal. The AIHA (Ex. 54–208) recommended that paragraph (c)(1)(ii), which requires employers to develop procedures addressing ''medical evaluations of employees required to wear respirators,'' be changed to specify that these procedures need only cover employees who are ''authorized by the employer to wear respirators''; the AIHA wanted this word change to ensure that employers understood that these procedures must cover both voluntary and required use. However, as explained above, OSHA has decided to require medical evaluation of employees who use respirators voluntarily only when such use may present a health hazard to employees, e.g., in the case of tight-fitting negative pressure respirators. Therefore, OSHA has not included the language suggested by the AIHA in the final rule.

Paragraph (c)(1)(iii) covers the fit test element of the program and has been modified since the proposal to respond to comments. The proposal would have required the program to contain fit testing procedures ''for air-purifying respirators and tight-fitting positive pressure respirators.'' The Service Employees International Union (Ex. 54–455) commented that this provision only needed to address ''tight-fitting respirators'' because this language adequately describes the respiratory equipment to be covered. Since OSHA has revised the fit testing requirements in paragraph (f) to cover all tight-fitting respirators, the language in paragraph (c)(1)(iii) has been revised accordingly.

Paragraph (c)(1)(iv) states that employers shall include ''Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations.'' In the NPRM, this requirement was addressed under paragraph (g)(1), but it has been moved into paragraph (c)(1) of the final rule to ensure that employers are aware that written workplace-specific procedures must address both routine and non-routine respirator usage, including that in reasonably foreseeable emergency situations. OSHA received no comments on this provision.

Paragraph (c)(1)(v) requires the workplace-specific procedures to cover ''procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators.'' This provision is unchanged from that proposed. The American Iron and Steel Institute (AISI) urged OSHA to remove the word ''schedules'' from paragraph (c)(1)(iv) and to substitute the word ''frequencies'' instead. AISI stated that the term ''schedules'' connotes a requirement for extensive recordkeeping and paperwork. OSHA does not agree. Since OSHA requires the respirator program to be written, as required under the prior standard and as proposed and supported by comments in this rulemaking, it is OSHA's conclusion that including the employer's schedule for cleaning, disinfecting, or otherwise maintaining respirators is not unduly burdensome. A schedule is needed to inform employees when they are to have their respirators fit tested, cleaned, and maintained. Therefore, OSHA is retaining the word ''schedule.'' Representatives of the Service Employees International Union [(SEIU) Ex. 54–455)] strongly supported the requirement for maintenance schedules as proposed under paragraph (c)(1)(v) of the NPRM for the same reason.

Paragraph (c)(1)(vi) is essentially unchanged from the proposal and requires ''Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators.'' Representatives from SEIU (Ex. 54–455) supported OSHA's addition of ''quantity and flow'' to paragraph (c)(1)(vi) in the NPRM. Proper air quality and quantity are crucial to the use of supplied air respirators to protect worker health. The revised provision has been slightly modified from the provision in the NPRM that

read ''* * * ensure proper air quality, quantity, and flow * * *'' for atmosphere-supplying respirators. The addition of the words ''* * * for breathing air * * *'' is to clarify that under no circumstances should air for atmosphere-supplying respirators be of less than Grade D breathing air quality.

Paragraph (c)(1)(vii), as proposed, would have required employers to include ''[t]raining of employees in the respiratory and health hazards of the hazardous chemicals to which they are potentially exposed as required under the Hazard Communication standard (29 CFR 1910.1200).'' Several commenters questioned the need to cross-reference an existing OSHA standard in the respirator standard, and recommended that this provision be deleted (Exs. 54–154, 54–271, 54–278, 54–295, 54–307). OSHA agrees that the cross-reference is unnecessary, and the reference to the Hazard Communication standard has been removed from the final standard. However, the requirement that employers develop procedures that address the ''Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations'' remains, because there are respiratory hazards, such as biological hazards and radioactive particles, that are not covered by the Hazard Communication standard.

Paragraph (c)(1)(viii) requires employers to develop procedures for the training of employees in the proper use of respirators, including putting on and removing them, the limitations of these devices, and maintenance procedures for respirators. OSHA received no comments on this provision, which has been revised slightly since the proposal for clarity.

Paragraph (c)(1)(ix) states that the program should include ''Procedures for regularly evaluating the effectiveness of the program.'' This provision is basically the same as in the NPRM except that the word ''periodically'' has been deleted to avoid the suggestion that OSHA has a fixed interval in mind. This provision notifies employers that their written workplace procedures must include routine evaluation of the program to ensure that it is effective, up-to-date, and includes all necessary provisions. In workplaces where worksite-specific conditions are relatively stable, such as a manufacturing site, program evaluation may be conducted on a fixed schedule. In other workplaces where worksite conditions are less stable, employers must develop schedules for evaluating the program that make sense in that context.

In a general comment, the United States Enrichment Corporation (Ex. 54–283) stated that the final rule's requirements for work procedures in paragraphs (c)(1)(i) through (c)(1)(ix) implied that OSHA intended separate documents to be developed to meet each of the requirements, and asked OSHA to clarify this. It has always been OSHA's intention that the employer can address the required program elements and the development of worksite-specific procedures in a single document, the written respiratory protection program. OSHA believes that reorganizing the elements of this program to track the order of the standard will facilitate the inclusion of all worksite-specific procedures into one document.

In another general comment, Peter Hernandez of the American Iron and Steel Institute (AISI) (Ex. 54–307) urged OSHA to revise paragraph (c) and other paragraphs of the final rule to remove the term ''ensure,'' which he interpreted as imposing an impossible burden on employers. OSHA disagrees with this interpretation, however. OSHA standards use the word ''ensure'' because they impose a mandatory requirement to comply on employers and because the OSH Act and subsequent case law have made it clear that it is the employer's responsibility to compel compliance. The reasoning behind this body of case law is that it is the employer, and not the employee, who controls the conditions of work at a given workplace. OSHA believes that the word ''ensure'' is appropriate because it indicates that the employer must manage, lead by example, train, direct, and, if necessary, set up a disciplinary system so that employees understand that they must follow safe and healthful practices on the job. However, case law also makes it clear that employers are not the ''insurers'' of their employees' behavior. In other words, if an employer establishes, implements, trains employees in, and enforces safe operating procedures, and does so in a consistent manner, the employer will not be liable for an employee's unforeseeable violation of its safety rule.

Paragraph (c)(3) of the final rule requires employers to designate a person as program administrator and to ensure that this person is qualified to perform the responsibilities of this position. The person can be qualified either by appropriate training or experience or both. The administrator is also the person responsible for evaluating the program, as stated in paragraph (c)(3). This requirement is essentially unchanged from the proposal, although its language has been clarified. The ANSI Z88.2–1992 respiratory protection standard (Ex. 81) also contains a description of the responsibilities of the program administrator and a requirement that the respirator program be ''periodically audited to ensure that (a) the program procedures reflect the requirements of current applicable regulations and industry accepted standards and (b) the program as implemented reflects the written procedures'' (See clause 5.3). The ANSI standard recommends that the audit be conducted by a knowledgeable person not directly associated with the program, rather than by the program administrator. OSHA has not adopted the ANSI recommendation that periodic audits be performed by knowledgeable outside persons because the OSHA standard requires the administrator to be qualified to perform this task; thus, an additional requirement for audits to be performed by an outside party is unnecessary and may prove unduly burdensome for some employers.

The training requirements and experience level necessary for the program administrator were the subject of substantial comment. OSHA proposed that the program supervisor be a person ''qualified by appropriate training and/or experience'' to be responsible for the respirator program. Many commenters supported this performance-based requirement (Exs. 54–68, 54–80, 54–91, 54–175, 54–187, 54–208, 54–219, 54–220, 54–222, 54–252, 54–319, 54–352, 54–361, 54–435, 54–455). For example, the Service Employees International Union (Ex. 54–455) supported the proposed ''performance-oriented qualifications for the designated person (program administrator).'' Allied Signal (Ex. 54–175) stated that ''there should be no specific minimum training for program administrators. We believe the level of training for the respirator program administrator must be adequate to deal with the complexity of the program.'' Motorola (Ex. 54–187) commented that ''Training requirements for those individuals designated by the employer to administer the program should be commensurate with the type of respirator program needed at the workplace.''

Several commenters urged OSHA to add a phrase to this requirement in the final rule to require that the level of program supervisor training must be adequate to deal with the complexity of the program because the level of training appropriate for a workplace with extensive respirator use is substantially different from one with limited respirator use (Exs. 54–175, 54–

187, 54–200, 54–206, 54–214, 54–219, 54–222, 54–245, 54–265, 54–266, 54–275, 54–361). As Monsanto (Ex. 54–219) stated:

> An employer's respirator usage may be limited to dust respirators or may have a wide variety of types covering both air-purifying and atmosphere-supplying respirators. Program administrator training/qualifications would need to cover a wider range of topics in the latter case than in the former case.

However, some commenters, e.g., the Sparks Nevada Fire Department (Ex. 54–129), wanted to avoid imposing overly stringent requirements on choosing a program administrator, while others, e.g., the Grain Elevator and Processing Society (Ex. 54–226), urged OSHA to delete the phrase ''qualified by training and/or experience'' on the grounds that there are no widely accepted criteria for determining such a program administrator's qualifications. A few commenters acknowledged that since the program administrator's tasks often vary by type of workplace, it would be difficult for OSHA to establish a required minimum level of training that would be appropriate for all program supervisors in all workplaces. Michael Rehfield, Safety Officer for the Westminster, Maryland Fire Department (Ex. 54–68) stated:

> I am in total agreement that the person fulfilling this role and the ''qualifications'' should be ''performance oriented''. That language should appear in this section. It is imperative that the emergency response community be represented by performance oriented standards or regulations since the associated tasks are so diverse.

A working group from the State Universities of New York (Ex. 54–357) felt that the performance language regarding program supervisors was too vague, and suggested that a nonmandatory appendix be added to identify the types of qualifications a program supervisor would need. The United Automobile, Aerospace & Agricultural Implement Workers of America (UAW) (Ex. 54–387) wanted OSHA to define a body of knowledge necessary to carry out the duties of a qualified program administrator.

OSHA discussed these qualifications in the preamble to the NPRM at 59 FR 58898–58899. That proposal discussion reiterated many of the points that are described above: that the level of training appropriate for a workplace with limited respirator use would be quite different from another with extensive use of different respirator types, and that the program administrator can work with a workplace respirator committee, or assign responsibility for portions of the program to industrial hygienists, safety professionals, or other respirator experts while retaining overall responsibility for the program. In other words, the level of training of the program administrator must be adequate to deal with the complexity of the respirator program.

The AFL–CIO (Exs. 54–428, 255) urged OSHA to add a new definition to paragraph (b) for qualified person as follows:

> *Qualified Person:* This should be defined as, someone who is capable of identifying existing and predictable respiratory hazards in the workplace and who maintains a common knowledge of the respirator standard. This individual should possess the authority to take prompt corrective action to eliminate hazards including the measures required in subsection (c). The qualified person shall be certified by the manufacturer(s) for their ability to select and maintain the type(s) of respirator(s) that is/are used on the job site or possess the experience and knowledge needed to properly select respirators for the employees and job situation.

Instead of adopting the AFL–CIO definition for ''qualified person,'' OSHA has relied on the type of wording used in the ANSI standard, which is more performance oriented. Specifying in detail the type and extent of training required for program administrators depends upon the type of workplace and is best left to the employer, in OSHA's opinion. For example, the level of training that would be appropriate for a workplace with limited respirator use would be quite different from that required at another workplace with extensive respirator use for IDLH atmospheres, highly toxic chemicals, or other complex respirator use operations. Therefore, OSHA has adopted a definition of training and experience that uses performance language and is similar to the ANSI Z88.2–1992 standard's requirement. However, OSHA does require employers to ensure that the level of training for the respirator program administrator is adequate to deal with the complexity of the workplace.

In keeping with this approach, OSHA has not established any one training program, such as the NIOSH respirator course, as the level of training program administrators must achieve. OSHA believes that NIOSH's course is excellent, and therefore more than sufficient in most cases. However, OSHA acknowledges commenters' concerns that a general respirator training course covers a broad range of many different respirator types and uses, and provides information that is not tailored to any one particular workplace (Exs. 54–220, 54–265, 54–342, 54–435). Typical of these comments is one by the United Parcel Service (Ex. 54–220), which stated: ''An attempt to fashion uniform standards for all administrators of all respiratory programs could result in inadequate training for administrators of particularly sophisticated or specialized programs and irrelevant training for administrators of relatively simple programs.'' The North American Insulation Manufacturers Association agreed, stating (Ex. 54–342) ''A requirement that supervisors undergo a rigid minimum training regimen, which would require instruction on many issues irrelevant to the supervisor's own situation, would be excessive and beyond the rule's intended objective.'' For example, extensive training on certain types of respirators such as SCBAs would be inappropriate for program administrators with simple programs that don't use SCBAs. In other cases, respirator program administrators with highly complex respirator programs may need an even more comprehensive course than that provided by a general respirator training course. Based on the above discussion, OSHA has retained a performance-based program approach. OSHA anticipates that larger establishments will develop training requirements for respirator program administrators that fit the needs of a workplace-specific respirator program.

OSHA has prepared a Small Entity Compliance Guide setting forth how a small business owner, manager or an employee of the small business can be qualified to be a program administrator. It also sets forth a sample respirator program to guide small businesses. If the employees of a small business are only exposed to nuisance dusts and relatively non-toxic chemicals and use only a few types of relatively simple respirators, knowledge of the guide and materials supplied by the respirator manufacturer may be sufficient for the small business owner or an employee to become qualified as a program administrator. If more dangerous chemicals or high exposures are present, or sophisticated respirators are used, the program administrator must have more knowledge or experience. In these circumstances, it may be necessary for the administrator to seek out the expertise needed or to obtain appropriate training.

The need for a specific individual to be in charge of the respirator program was discussed by several commenters. One commenter argued that requiring that a specific person be selected as program administrator requires the equivalent of a full-time person to

manage the program and conduct periodic reviews of its performance (Ex. 54–160). Motorola (Ex. 54–187) stated that one overall program administrator would be a problem for decentralized workplaces. Motorola recommended that OSHA permit a committee or multiple employees to be responsible for the respirator program, thus allowing the employer to tailor the program to meet the needs of each particular workplace. Dow (Ex. 54–278) also supported the use of a committee or team with joint responsibility for the respirator program at large sites. Duke Power (Ex. 54–326) stated that at large facilities, such as nuclear stations, it is often necessary to designate more than one program administrator to address radiological and non-radiological use of respirators. The Public Service Electric and Gas Company (Ex. 54–196) said it may be more effective to have a program administrator for each ''business unit'' in a decentralized, diversified company, particularly where each unit's respiratory protection needs are different (Ex. 54–196). The AFL–CIO (Ex. 54–428) wanted to have one qualified person responsible for the program, with a ''site person'' at each work site, who would be responsible for the program at that site, but who would report to the qualified person. The Department of Defense (Ex. 54–443), specifically the Navy, urged OSHA to add language to require that each ''activity'' designate a person responsible for the respiratory protection program because a single program administrator would be a potential problem for a large, multi-tiered employer with activities throughout the world, such as the Navy.

The final standard continues to require that a person qualified by training or experience be designated to be responsible for the overall management and administration of the program to ensure that the integrity of the respiratory protection program is maintained through the continuous oversight of one responsible individual. The program administrator may serve largely in an oversight and coordination role between the various subunits or departments that perform duties in support of the respiratory program. Regardless of the number of subunits, each employer must ensure that all subunits report to one overall program administrator for coordination of the program. The program administrator can use the assistance of industrial hygienists, safety professionals, or other respirator experts to help run the respirator program. The program administrator can work with a committee or assign responsibility for portions of the program to other personnel, but the overall responsibility for the operation of the program must remain with the designated program administrator. This approach promotes coordination of all facets of the program. For large companies or multiple worksites, the program administrator can delegate to a qualified person the responsibility for the day-to-day operation of the program at a specific site or for a specific activity. However, coordination between different worksites is an important aspect of the operation of a good program; therefore, ensuring implementation of the overall respirator program remains the duty and responsibility of the program administrator. For small and moderate sized employers, OSHA believes that the duties of a program administrator will require only a small part of one employee's time.

Paragraph (c)(4) of the final rule requires employers to provide respirators at no cost to the employee. This was included in the proposal in paragraph (d)(1) and has been moved to paragraph (c) of this final standard. This provision reflects OSHA's strong orientation that the costs of complying with safety and health requirements must be borne by the employer. OSHA has a long-standing policy that employers are obligated to provide and pay for necessary personal protective equipment (PPE) such as respirators used by employees on the job. A compliance memorandum of October 18, 1994, titled ''Employer Obligation to Pay for Personal Protective Equipment'' provides detailed guidance on this issue. It is available online on the Internet on OSHA's home page at http://www.OSHA.gov. The inclusion of this provision is consistent with recent OSHA standards, e.g., Cadmium, 29 CFR § 1910.1027; 1,3-Butadiene, 29 CFR 1910.1051; and Methylene Chloride, 29 CFR 1910.1052.

OSHA is aware that the Occupational Safety and Health Review Commission has not always agreed with the Agency that standards requiring an employer to ''provide'' safety or health equipment also require the employer to pay for that equipment. See, e.g., *Union Tank Car Co.*, OSHRC No. 96–0563 (October 16, 1997). OSHA believes the Commission is wrong about this issue. OSHA intends the language ''at no cost to the employee'' in paragraph (c)(4) to make the employer's obligation to pay for the respiratory protection required by this standard crystal clear.

The requirement that the employer bear the costs of employee training and medical evaluations has also been moved to paragraph (c)(4) of the final rule, in order to consolidate all similar provisions of the standard that clarify that, for these provisions, there is no cost to the employee. Section 6(b)(7) of the OSH Act requires that employers provide medical exams and evaluations at no cost to employees.

Paragraph (d)—Selection of Respirators

Overview

Paragraph (d) of the final rule contains respirator selection criteria and requirements. OSHA has included these provisions in the final rule because the record contains many examples of workers using respirators that are inappropriate for the type of respiratory hazards present (e.g., wearing paper dust masks where the exposure is to a gas or vapor contaminant (UAW, Ex. 54–387); using half facepiece respirators in acrylonitrile IDLH atmospheres of 20 ppm (International Chemical Workers Union (ICWU), Ex. 54–427)). In addition, OSHA's long enforcement experience has shown that employers often lack the information necessary to make informed choices about respirator selection. OSHA stated in the proposal (59 FR 58899) that a major deficiency of the previous standard is that it did not contain selection criteria; instead, it merely referred employers to the ANSI Z88.2–1969 standard.

No participant in this rulemaking disagreed with OSHA's decision that the final standard should include mandatory selection criteria. The record does show, however, that there are differences of opinion about how restrictive and comprehensive the required criteria should be, and how much flexibility should be left to employers in the selection process. For example, the Association of American Railroads (Ex. 54–286) stated that the details of respirator selection should be left to the regulated community and that OSHA should only specify the outcome desired, while the Service Employees International Union (SEIU) (Ex. 54–455) commented that OSHA should ''strengthen the wording to make it clear employers must obtain and account for all of the factors listed.'' OSHA believes that those employers who employ on-site occupational health professionals generally have the expertise to select respirators that are appropriate for their workers. The record contains a number of examples of well-thought-out selection programs (e.g., Exs. 142, 155, 163). These examples show that the current practice of many employers already conforms to the selection requirements of paragraph (d). For other employers, however, clearly stated

respirator selection rules and guidance are required.

OSHA notes that advice on the selection of respirators is available from many sources. NIOSH has developed a respirator decision logic, widely available and used since 1987, which provides a schematic selection guide covering all critical areas of respirator selection (Ex. 9). The selection guide for the ANSI Z88.2–1969 respirator standard was incorporated by reference into the previous OSHA standard, and the 1992 Z88.2 ANSI standard contains updated and comprehensive recommendations on respirator selection. OSHA believes that employers will find useful information in each of these guides on various technical problems that this standard may not cover explicitly. In addition, information is provided by respirator manufacturers who publish selection guides relating to their models (See, e.g., Mine Safety Appliances Company (MSA) Respirator Selection Guide, Ex. 150; and ISEA's Respirator Buyers Guide and Safety Video Resource List, referenced in Ex. 147). Manufacturers also provide selection advice through telephone help lines, sales staff, verbal communications or distribution of company product information, and on-site evaluations of product use (See, e.g., Tr. at 1438–1439). Chemical manufacturers also provide information about respirator selection to help the purchasers of their products (See CMA, Tr. 1726–7; Union Carbide Corporation, Ex. 54–255).

Because of the variety and detail of selection information available, OSHA believes it is necessary in the final rule to specify broad performance criteria, in addition to a few specific rules relating to highly hazardous operations (i.e., IDLH situations). The final rule sets forth general rules for selecting respirators for routine operations, prescribes specific kinds of respirators for identified highly hazardous atmospheres and emergency situations, and specifies when air-purifying respirators can reliably be used. OSHA chose not to specify in the regulatory text all the situations and respirator-related factors that an employer should consider but instead to state performance objectives. Only for workplace situations widely accepted as highly hazardous, such as those associated with IDLH atmospheres, does the standard require maximally protective respirators.

Because paragraph (d) does not address in detail all the relevant factors that may affect employers' selection of particular respirators, employers should rely on other information sources to ensure that the respirators they select are appropriate for conditions in their specific workplaces. Respirator manufacturers are the source of much useful information, and the record of this rulemaking indicates that much of this information is both helpful and reliable. Indeed, market mechanisms work to encourage the dissemination of accurate information. OSHA expects that smaller employers will thus generally be able to rely on the technical assistance provided by manufacturers on respirator selection and that doing so will mean that they will usually be in compliance with this standard. For these reasons, paragraph (d) concentrates on the minimum selection criteria that the record shows must be adhered to by all employers when selecting respirators for their employees' use.

In the following provision-by-provision summary and explanation, OSHA explains the changes reflected in the final rule, both from the provisions proposed and those in the Agency's previous respiratory protection standard (§ 1910.134).

Paragraph (d)(1)—General Requirements

Paragraph (d)(1) prescribes general rules that apply to the selection of all respirators. Paragraph (d)(1)(i) requires the employer to select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is or will be exposed and on the workplace and user factors that have the potential to affect respirator performance and reliability. This provision continues a requirement from the previous standard: (''respirators shall be selected on the basis of hazards to which the worker is exposed'' (§ 1910.134(b)(2)) and clarifies that the hazard must be viewed in the context of the workplace and worker conditions that may reduce or impair the effectiveness of a respirator otherwise appropriate for the hazard. There is general agreement that taking working conditions into account is crucial to proper respirator selection: a respirator that is protective under some conditions of wear will fail under others, while a respirator that is appropriate for a given hazard may not be workable in a particular workplace (e.g., an air supplied respirator in a tightly configured space). For example, a worker wearing SCBA who is required to perform extremely heavy work may deplete the air supply of the respirator well before its calculated service life is reached. This means that the employer must evaluate the employee's level of exertion in order to determine whether to choose a supplied-air respirator rather than a SCBA. The recent ANSI standard also states that the purpose of respirator selection is to determine which respirator type or class will offer ''adequate protection'' (ANSI Z88.2–1992).

Final paragraph (d)(1)(i) also requires employers to consider workplace and user factors that may affect the respirator's performance and reliability when making a respirator selection. Although other paragraphs of the standard address the major factors affecting respirator performance, i.e., fit, faceseal leakage, and maintenance and cleaning, factors specific to the job, user, or worksite often play an important role in respirator performance. OSHA noted in the proposal (59 FR 58900) that work activities and factors such as temperature and humidity ''also affect the stress level associated with wearing a respirator as well as the effectiveness of respirator filters and cartridges; employees using respirators for longer periods of time [under such stressful conditions] may need different types of respirators for more comfortable wear.''

Similarly, where the respirator-wearing employee must communicate with other workers, perhaps to warn them about the presence of workplace hazards, the respirator must allow the employee to perform this vital function. OSHA thus agrees with ANSI that ''it is important to ensure that respirator wearers can comfortably communicate when necessary, because a worker who is speaking very loudly or yelling may cause a facepiece seal leak, and the worker may be tempted to temporarily dislodge the device to communicate'' (ANSI Z88.2–1992, clause A.13). Therefore, for example, the employer must ensure that speaking will not interfere with the fit of the negative-pressure elastomeric respirator selected. If the employees are using PAPRs or SCBA, amplification devices, including speaking diaphragms and microphones, that can be worn with the respirators are available.

The proposal (59 FR 58900) noted another example in the proposal of worksite conditions that could affect respirator selection: ''* * * airline respirators should not be used by mobile employees around moving machinery unless entanglement of airlines in equipment is easily avoided.'' Employers have always been required by OSHA to consider such factors as these, because paragraph (a)(2) of the previous respirator standard required employers to select respirators that are ''applicable and suitable for the purpose intended.''

Paragraph (d)(1)(i) applies whenever employers provide respirators to their

employees and require their use, whether or not an OSHA standard mandates respirator use in the particular environment. The preamble discussion relating to paragraph (c)(1) discusses employer-required respirator use in more detail and explains OSHA's reasons for reaching this conclusion.

Paragraph (d)(1)(ii) requires the employer to select a NIOSH-certified respirator and to use the respirator only in ways that comply with the conditions of its certification. There was little controversy about this requirement, and there is no disagreement that respirators must be tested and found to be effective before they can be marketed. NIOSH has performed this function in the past and has begun to revise its certification requirements to ensure that its procedures continue to define the performance capabilities of acceptable respirator models, and to identify unacceptable models. The ISEA (Ex. 65–363), the trade association that represents most major respirator manufacturers, urged OSHA to require that only NIOSH-certified respirators be used to comply with this standard, and other commenters agreed (Exs. 54–187, 54–213, 54–387, 54–428).

The wording of this provision of the final rule differs slightly from that of the proposed provision. The proposal would have required that only NIOSH ''approved and certified'' respirators be selected. For clarity, the reference to NIOSH-approved respirators has been replaced in the final rule by a requirement that respirators be used only in accordance with the conditions of their certification. NIOSH approves respirators by certifying them; however, some certifications contain conditions limiting the situations in which the respirator may be used. This is sometimes described as NIOSH ''approval'' of the respirator for a particular use.

Increasingly, however, NIOSH does not certify respirators for specific uses. For example, NIOSH does not currently certify respirators for use against biological hazards. Where NIOSH has not specifically certified any respirator for use against the particular contaminant present in the workplace, the employer must select a NIOSH-certified respirator that has no limitation prohibiting its use against that contaminant. The respirator must be appropriate for the contaminant's physical form and chemical state and the conditions under which it will be used. All respirators must be chosen and used according to the limitations of the NIOSH certification, which appears on the NIOSH certification label.

The requirement for NIOSH certification is unconditional in the final standard, as it was in the proposal. However, because OSHA stated in the proposed preamble that this requirement would apply only when such respirators ''exist'' (59 FR 58901), some commenters urged OSHA to state in the regulatory text that the requirement for NIOSH certification applied only to existing certifications (See, e.g., Ex. 54–434). For example, the Department of the Army (Ex. 54–443) urged OSHA to permit the use of respirators not approved by NIOSH in situations where another authority has jurisdiction and the documentation to attest to the adequacy of the respirator's effectiveness against the contaminant of concern. The Army (Ex. 54–443D) stated that its employees and contractors may be exposed to certain ''military unique contaminants'' for which no NIOSH-approved respirator exists but for which military respirators, e.g., gas masks, have specifically been developed and tested and are being used by civilian and contractor personnel in operations subject to OSHA's jurisdiction. The Army urged OSHA to include in the standard ''approval authority of the Secretary of the Army for military respirators * * * for which no NIOSH approved respirator exists'' (Ex. 54–443D).

OSHA recognizes that there are unique contaminant situations, such as those involving chemical warfare agents, that involve primarily military exposure and that may require specialized respiratory protection equipment. NIOSH certification for respiratory protection specific to such hazards does not exist and is not likely to be forthcoming. OSHA also notes, however, that, although the Department of the Army argued strongly for OSHA recognition of Army authority to test and approve respirators, the Department of the Air Force commented that it uses only NIOSH-certified respirators, and requested no exception (Ex. 54–443A). OSHA will examine on a case-by-case basis those situations involving civilian contractors whose employees wear non-NIOSH tested respirators that they believe protect employees adequately and that have been tested and approved by other Federal agencies for use against unique contaminants.

A similar comment was raised by DOE regarding radioactive hazards (Ex. 54–215). DOE stated that, in the nuclear industry, no NIOSH-certified respirator exists for tritium applications and workers therefore must wear non-approved supplied-air suits; this equipment has been tested by Los Alamos National Laboratory, and the suits have been successfully used for many years. The DOE administers its own job-by-job approval system for these suits. OSHA's authority to enforce the Agency's safety and health standards at gaseous diffusion plants owned by DOE and leased to the United States Enrichment Corporation was established legislatively in 1992, and OSHA has recently completed a memorandum of understanding with DOE on this issue (60 FR 9949, Jan. 31, 1995). OSHA is currently evaluating an application from one of these facilities for a variance relating to these suits. The criteria set out in Section 6(d) of the OSH Act will govern this determination. OSHA is not determining the acceptability of supplied-air suits as part of this rulemaking proceeding, because the Agency believes the variance proceeding, which can focus closer attention on the strengths and limitations of these suits for the particular use situations, is the appropriate forum to decide this issue.

OSHA notes that NIOSH certification is a minimum qualification. The employer must still assess whether the respirator meets all other selection criteria in this standard before it can be chosen for a particular application. For example, as pointed out by an exchange with Richard Duffy of the International Association of Fire Fighters (IAFF), NIOSH representatives acknowledged that the employer must evaluate whether NIOSH-certified equipment will withstand the specific environmental conditions for firefighting because NIOSH flow rate requirements do not consider the stresses involved in firefighting, nor does NIOSH currently evaluate respirators for their ability to withstand those stresses (Tr. 364–365).

In his testimony at the OSHA hearings, Richard Duffy of the IAFF recommended that OSHA require that SCBAs used in firefighting meet the requirements of the National Fire Protection Association's NFPA–1981 Standard on Open Circuit Breathing Apparatus (Tr. 455). This NFPA standard establishes more stringent performance criteria for SCBAs used in firefighting than those currently used by NIOSH. NIOSH recognizes that its current 42 CFR 84 respirator certification standards may not be protective enough for respirators used in firefighting. In an October 7, 1997 letter to all manufacturers and interested parties, NIOSH announced its intent to develop new technical modules to update 42 CFR 84. One of the proposed technical modules to which NIOSH intends to give priority treatment will address SCBAs, including the

incorporation of NFPA performance requirements for SCBAs. NIOSH also intends to propose an Administrative/Quality Assurance module on the use of independent testing laboratories in the certification program, another issue raised by commenters in this proceeding. OSHA believes that NIOSH will resolve any deficiencies in its current respirator certification standards through these new 42 CFR 84 rulemaking modules. OSHA simply is not equipped to take on the respirator approval and certification process currently performed by NIOSH. Therefore, the final OSHA respirator standard continues to require the use of NIOSH-certified respirators and does not incorporate the NFPA performance requirements for SCBAs.

OSHA believes that carving out even limited exceptions to NIOSH control of respirator certification authority would confuse the regulated community and would not resolve the needs of the vast majority of respirator users. Comments by respirator users and worker representatives support OSHA's final decision (See, e.g., Exs. 54–265, 54–118, 54–213, 54–387, 54–455). The final rule, in paragraph (h), also requires that when respirator parts are replaced or changed, the replacement parts must be NIOSH certified.

In the proposal (59 FR 58901), OSHA stated that developing an OSHA respirator approval mechanism to fill in the gaps in NIOSH certification would not be an efficient use of government resources. Nonetheless, the Agency asked for comment on this issue. There was no consensus among the participants who commented on this point. Some commenters supported an OSHA role in approval on a temporary basis, while an employer waits for NIOSH approval, or an alternative governmental approval process (Exs. 54–213, 54–346, 54–443). Still others opposed OSHA's involvement in an approval process (Exs. 54–278, 54–265, 54–118, 54–213, 54–387, 54–455). The final rule is therefore similar to the proposal, which also discussed limited alternatives to NIOSH certification and concluded that ''it is inappropriate for OSHA to try to correct problems with present NIOSH/MSHA regulations in the revised respirator standard'' (59 FR 58891).

OSHA believes that NIOSH has focused on closing any gaps in its certification program. NIOSH's ability and experience in this area are unparalleled, and OSHA believes that NIOSH can best resolve any concerns through its own proceedings. Further, as stated in the proposal, OSHA lacks the resources to perform respirator testing. OSHA will, however, continue to evaluate, on a case-by-case basis, whether variance or compliance interpretations are appropriate in cases where employers claim that there are no NIOSH-certified respirators for use in a particular situation.

Paragraph (d)(1)(iii) of the final rule requires the employer to identify and evaluate the respiratory hazard(s) in the workplace. To perform this evaluation, the employer must make a ''reasonable estimate'' of the employee exposures anticipated to occur as a result of those hazards, including those likely to be encountered in reasonably foreseeable emergency situations, and must also identify the physical state and chemical form of such contaminant(s). Where conditions are such that the employer cannot carry out such an evaluation, e.g., where exposure monitoring or other means of estimation cannot be used, paragraph (d)(1)(iii) requires the employer to treat the atmosphere as IDLH. Many of the components of paragraph (d)(1)(iii) of the final standard have been required practice since 1971 because they were included in the selection provisions of the 1969 ANSI standard incorporated by reference into OSHA's previous respiratory protection standard. Paragraph (d)(1)(iii) of the new standard makes these provisions clearer by stating them explicitly in the regulatory text.

Identifying and evaluating the hazards a respirator is to provide protection against clearly play a pivotal role in respirator selection. For example, according to ANSI, ''Respirator selection involves reviewing each operation to * * * determine what hazards may be present (hazard determination)'' (ANSI Z88.2–1992, clause 7.2.2; See also AISI, Tr. 639). Many other commenters emphasized the important role of hazard identification in respirator selection (Exs. 54–168, 54–181, 54–186, 54–208, 54–234, 54–273, 54–307, 54–327, 54–346, 54–426, 54–428). Once an employer identifies the nature of the respiratory hazard or hazards present, the employer must evaluate the magnitude of the hazard to determine the potential exposure of each employee and the extent to which respirators of various types can reduce the harm caused by that exposure.

There was extensive comment on the selection process outlined in the proposed paragraph dealing with hazard evaluation (Exs. 54–154, 54–168, 54–181, 54–202, 54–219, 54–245, 54–278, 54–428). Commenters representing workers generally supported the detailed approach taken in the proposal toward hazard evaluation. For example, the Service Employees International Union ''support[ed] the detailed list of factors to be considered in respirator selection * * * [which] successfully incorporates the important framework from the NIOSH decision logic criteria in an easy-to-understand form'' (Ex. 54–428).

Some commenters, however (Exs. 54–154, 54–168, 54–181, 54–219, 54–245, 54–278), stated that the scope and depth of the hazard evaluation and the items to be covered should be left to the discretion of the employer. For example, the Eastman Chemical Company (Ex. 54–245) and the Dow Chemical Company (Ex. 54–278) requested that OSHA make the requirement ''performance oriented'' and ''flexible''; the Department of the Navy, Portsmouth Naval Shipyard (Ex. 54–154), noted that detailed analysis for each work situation is not necessary for shipbuilding, and that the timing and content of an appropriate evaluation vary.

In response to these comments, OSHA has revised paragraph (d)(1)(iii) to be more performance oriented; this provision of the final standard no longer specifies precisely how employers are to conduct the required evaluation. The proposal (at paragraph (d)(3)) would have required employers to ''obtain and evaluate'' information on eleven specific factors for each work situation. These proposed factors were the nature of the hazard; its physical and chemical properties; its adverse health effects; the occupational exposure level; the results of workplace sampling; the work operation; the time period of respirator wear; the work activities and stresses on the wearer; fit test results; warning properties; and the capabilities and limitations of respirator types. Although OSHA continues to believe that each of these factors is relevant to respirator selection under some circumstances, a review of the record has convinced OSHA that each factor is not crucial in every respirator selection process and that the proposed requirement would have led to needless duplication of effort and unnecessarily detailed evaluations.

The Oil, Chemical and Atomic Workers International Union (OCAW) (Ex. 54–202) urged OSHA to require a written hazard assessment each time that a respirator was selected. Paragraph (d)(1)(iii) of the final rule does not require a written assessment; this was not proposed, and OSHA believes that employers should be free to adopt the best approach for justifying their respirator selections, based on the hazard assessment. The final rule requires the employer to identify and evaluate the respiratory hazards present, determine their physical state and

chemical form (e.g., whether they are present in the form of a gas or vapor; what their valence state or condition is, where relevant), and assess the magnitude of the hazard they present to workers under normal conditions of use and in reasonably foreseeable emergency conditions.

OSHA finds that it is essential for employers to characterize the nature and magnitude of employee exposures to respiratory hazards before selecting respiratory protection equipment. The language contained in paragraph (d)(1)(iii) of the final rule does not specify how the employer is to make reasonable estimates of employee exposures for the purposes of selecting respirators, nor does the standard require the employer to measure worker exposures to airborne hazards. OSHA has always considered personal exposure monitoring the ''gold standard'' for determining employee exposures because this is the most reliable approach for assessing how much and what type of respiratory protection is required in a given circumstance. This general view is also shared by the industrial hygiene community. All of OSHA's comprehensive substance-specific health standards have required employee exposure monitoring to determine both the effectiveness of existing control measures and the type of respiratory protection needed.

OSHA continues to hold this view with regard to assessing employee exposure in connection with this respiratory protection standard. However, OSHA recognizes that there are many instances in which it may not be possible or necessary to take personal exposure measurements to determine whether respiratory protection is needed. Although sampling and analytical methods exist for the vast majority of substances for which OSHA has a PEL (29 CFR 1910.1000), there are numerous other substances for which there are no readily available methods for personal sampling. In other cases, the nature of the materials and products being used in the workplace, and the way in which they are used, make it highly unlikely that an employee working with them would be exposed in a manner that would make respiratory protection necessary. In these kinds of situations, the final rule permits employers to use other approaches for estimating worker exposures to respiratory hazards.

For example, employers may rely on information and data that indicate that use or handling of a product or material cannot, under worst-case conditions, release concentrations of a respiratory hazard above a level that would trigger the need for respirator use or require use of a more protective respirator. This approach is similar to that used in several OSHA substance-specific health standards, which permit employers to use objective data in lieu of exposure monitoring to demonstrate that their employees cannot be exposed above an action level (See, for example, 29 CFR 1910.1027, Cadmium; 1910.1048, Formaldehyde; 1910.1047, Ethylene Oxide; 1910.1028, Benzene). Objective data can be obtained from an industry study or from laboratory test results conducted by manufacturers of products or materials being used in the workplace. To generalize from data in an industry-wide survey to conditions in a specific workplace, the survey must have obtained data under conditions closely resembling the processes, types of materials, control methods, work practices, and environmental conditions in the workplace to which it will be generalized, i.e., the employer's operation.

Data from industry-wide surveys by trade associations for use by their members, as well as from stewardship programs operated by manufacturers for their customers, are often useful in assisting employers, particularly small-business owners, to obtain information on employee exposures in their workplaces. For example, representatives of the North American Insulation Manufacturer's Association (NAIMA) testified (Tr. 597) that * * * ''[w]e have conducted numerous surveys on end use customers, conducted research with Johns Hopkins University, for example to provide estimates of routine exposures and * * * those data, when collected appropriately and with organized labor and with other industry groups, * * * can assure that the right respirator is selected.'' NAIMA stated (Tr. 616, 618), ''it is ultimately the employer's responsibility'' to evaluate whether data provided by suppliers or others relate to their workplace conditions and operations. However, it is clear that such programs can often assist employers to estimate workplace exposures reliably enough to make correct respirator choices without the need for employee monitoring.

Another approach that can be used by employers to estimate employee exposures involves using mathematical approaches and obtainable information. Employers can use data on the physical and chemical properties of air contaminants, combined with information on room dimensions, air exchange rates, contaminant release rates, and other pertinent data, including exposure patterns and work practices, to estimate the maximum exposure that could be anticipated in the workplace. Methods that utilize this approach are readily available in several textbook sources; for example, the ACGIH Industrial Ventilation Manual contains calculations that can be applied to certain situations to estimate worker exposures. Relying on such an approach to estimate exposures requires the use of safety factors to account for uneven dispersion of the contaminant in the air and the proximity of the worker to the emission source. Usually, this approach works best in situations where employees use small amounts of a chemical product intermittently, or where contaminant releases are fairly constant and predictable. This approach must be used continuously, and the data obtained should therefore be interpreted conservatively (i.e., should err on the side of worker protection).

In workplaces involving many complex factors, the use of estimation techniques to characterize worker exposure is associated with a high degree of uncertainty. In these instances, OSHA recommends that employers conduct exposure monitoring instead of relying on estimation techniques because they will then be able to have confidence that the appropriate respiratory protection device has been selected and that they are in compliance with the standard. Furthermore, OSHA believes that in workplaces where many complex factors add uncertainty to exposure estimates obtained through modeling, employers will find it easier and less costly to conduct personal exposure monitoring to evaluate the need for respiratory protection.

Many commenters urged OSHA not to specifically require monitoring in the standard because other means of assessing potential exposures are available (Exs. 54–153, 54–208, 54–219, 54–237, 54–273, 54–307, 54–327, 54–443). These participants asked the Agency instead to adopt the approach taken in the ANSI standard Z88.2–1992, clause 7.2.2.1(e), which allows employers to estimate, as well as measure, exposures in the workplace. One commenter questioned the utility of exposure monitoring data for respirator selection because exposure sampling provides only a ''snapshot'' of hazards on any given day (Ex. 54–178). Other commenters disagreed, however. For example, Scott Schneider (Tr. 1520) of the AFL–CIO stated, ''In most workplaces that I've been in there really is very, very little exposure data to know how much a person is exposed to * * * exposures are quite variable from

day to day. And from worker to worker.'' (See comments to same effect by OCAW, Ex. 54–202.) Some participants specifically asked OSHA to make workplace sampling of airborne concentrations of contaminants explicit (Tr. 1009 and Ex. 54–428; Ex. 54–427).

That some exposure monitoring results may be inadequate begs the question of whether adequate monitoring should be conducted. OSHA's experience in enforcing permissible exposure limits in the Air Contaminant standard, 29 CFR 1910.1000, and for substance-specific standards, confirms that, unless operations are highly repetitive, conditions are constant, and estimates based on ''historical'' and ''objective data'' are made by experienced industrial hygiene professionals, most employers need exposure monitoring results to estimate employee exposure levels reliably. OSHA enforcement experience also demonstrates that, where exposures are highly variable, fragmentary monitoring results may mislead employees and employers, unless they are based on competent sampling strategies. The frequency and duration of monitoring, the representativeness of the employees and operations sampled, and the skill with which sampling and analysis are performed all influence the reliability of monitoring results. In making reasonable estimates of employee exposures to satisfy the requirements contained in paragraph (d)(1)(iii), OSHA expects employers to account for potential variation in exposure and to rely on data or information that reflect such variation. This is accomplished by using exposure data collected with a strategy that recognizes exposure variability, or by using worst-case assumptions and estimation techniques to evaluate the highest foreseeable levels to which employees may be exposed. The hazard assessment requirements in final paragraph (d)(1)(iii) carry over from the requirement of the previous standard, which incorporates by reference the ANSI Z88.2–1969 (clause 6.2) statement that ''[a]ny erring in the selection of respirators shall be on the safe side.''

Paragraph (d)(1)(iii) also requires an employer to consider the environment IDLH if employee exposures cannot be estimated reasonably. This provision is intended to address those limited situations where neither exposure monitoring, professional judgment, nor estimation techniques can be relied on to reliably select adequate respiratory protection equipment. This provision reflects a similar one in the 1992 ANSI standard, which requires atmospheres to be considered IDLH if it is not possible ''to determine what potentially hazardous contaminants may be present * * * or if no exposure limit or guideline is available, and estimates of toxicity cannot be made'' (ANSI Z88.2–1992, clause 7.2.2.2 (b)(c)).

Several commenters (Exs. 54–381, 54–352, 54–267) objected to OSHA's proposed requirement that atmospheres be considered IDLH ''where the concentration of the hazardous chemical is unknown'' (59 FR 58939), and stated that it would be neither practical nor necessary to wear positive pressure respirators in all such situations (Ex. 54–352). One commenter believed that requiring the most protective respirators for ''every unknown hazardous chemical atmosphere'' would result in 95 percent of the workforce being required to use them (Ex. 54–267). OSHA did not intend the absence of workplace-specific exposure measurements automatically to trigger selection of the most protective respirator; instead, the Agency intends employers to use such equipment when they do not have confidence that a less protective respirator is sufficient. An example of the kind of situation that should trigger the use of the most protective respirator was provided by a representative of CMA, who testified (Tr. at 1707) that, when a maintenance person opens a closed cycle manufacturing process to work on it for the first time, ''we don't know what the air concentration is so we put people in supplied-air respiratory protection under those circumstances.'' That is, the company in this case assumes that exposures will be extremely high and selects a respirator accordingly. OSHA believes that the language used in paragraph (d)(1)(iii) of the final rule makes OSHA's intent clear, i.e., that when reliable data or reasonable estimates of exposure are not available, the atmosphere must be considered IDLH.

Finally, a few participants suggested that exposure estimates should only be made by credentialed individuals (See, e.g., Ex. 54–327). OSHA agrees that persons trained and experienced in evaluating the respiratory hazards posed by workplace atmospheres are the most competent to evaluate exposure levels, especially in the absence of current exposure measurements. ANSI defines an ''occupational health professional'' as ''(a)n individual whom, by experience and education, is competent at recognizing, evaluating, and controlling health hazards in the workplace'' (ANSI Z88.2–1992, clause 3.39). This is the person who is responsible for performing expert evaluations under ANSI's recommended standard. OSHA believes that this definition has merit, and that employers whose workplaces have highly toxic respiratory hazards, or many different hazardous chemicals or mixtures, as well as other employers with the resources to do so, should utilize such professionals wherever possible. However, OSHA is not specifically including this requirement in the final rule because reasonable estimations can be conducted in many workplaces by persons with the qualifications required in the final rule for the respiratory protection program administrator.

Paragraph (d)(1)(iv) requires that the employer choose respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to and correctly fits the wearer. The 1992 ANSI standard includes a similar requirement aimed at achieving satisfactory fit and wearer acceptance (Z88.2–1992, clause 9.3.1. and 9.3.2.). This provision of the final standard revises the corresponding proposed provision, which would have required employers to provide for fit testing an array of three sizes and two brands of respirators with elastomeric facepieces. The dual intent of this provision was to assure that wearer acceptability plays a role in respirator selection, and that the respirators chosen maintain their fit over the period of use.

OSHA continues to believe that these goals for respirator selection are appropriate. However, OSHA was persuaded by this record that specifying the number of sizes, models and brands that an employer must provide is unnecessary. Therefore, the final provision deletes the specification language for the number of sizes, models and brands that must constitute the selection pool. Since this provision of the final standard applies to all respirators, the proposal's application only to ''elastomeric'' facepieces has been dropped.

Most participants (Exs. 54–1, 54–5, 54–75, 54–80, 54–91, 54–161, 54–208, 54–214, 54–237, 54–238, 54–246, 54–263, 54–273, 54–280, 54–291, 54–287, 54–350, 54–363, 54–389) endorsed the inclusion in the final rule of a performance-based provision addressing the selection of comfortably fitting respirators. Thus, most comment on this issue recognized that a sufficient assortment of respirators must be provided so that employees will obtain acceptable fits, but that more flexibility should be provided in the final rule. Commenters also stated that, in some cases, a single manufacturer has a variety of respirator models sufficient to