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## 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,<sup>TM</sup> 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 reasons. 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)(v) 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 Sec. 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 (Sec. 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" (Sec. 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 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 provide acceptable fit for their employees (Exs. 54-389, 54-150, 54-161), although others provided only one or two sizes of a particular model (Exs. 54-139, 54-38, 54-22, 54-163, 54-196). Some rulemaking commenters stated that mandating that respirators from two manufacturers be available would be costly and burdensome for small employers (Exs. 54-161, 54-295), would not provide any tangible improvement in the respirator program (Ex. 54-154), and would complicate training and inventory functions (Ex. 54-156).

In the case of SCBAs, participants pointed out that buying and storing two brands for fitting would be extremely costly, would create congested storage areas, and would pose the risk that parts could inadvertently be interchanged (Exs. 54-208, 54-209, 54-214, 54-250, 54-300, 54-233, 54-331, 54-348, 54-45, 54-458). Even the AFL-CIO, which generally supported the requirement that employers have respirators from different manufacturers available, stated that requiring a multi-manufacturer assortment was not feasible for SCBAs (Ex. 54-428).

OSHA concludes that providing a wide selection of sizes and models of respirators will improve both fit and acceptability, and most commenters agreed. In light of the comments, however, OSHA is making the final rule's provision more performance-oriented, and is not requiring a specific number of types and sizes. As ANSI noted, larger employers are more likely to need a larger variety of respirators to fit their employee population (Tr. 1426). Concomitantly, this change will reduce the burden on smaller employers who will not need to maintain such a wide array of respirator choices. OSHA believes therefore that employers are in the best position to determine whether their employee population is so diverse as to require the availability of respirators from more than one manufacturer. OSHA encourages employers to offer employees as wide a choice as practical when performing fit tests.

In addition to the general requirement of assuring that employers consider employee acceptability, some commenters requested that OSHA require employers to offer PAPRs to employees "who wear respirators for long periods of time." These commenters stated that PAPRs are cooler, more comfortable, and offer less breathing resistance than negative pressure respirators (Exs. 54-387, 54-23). OSHA has included such provisions in various substance-specific standards based on evidence in those records that proper respirator use is likely to be increased if more comfortable respirators are available (See, e.g., Ex. 330 in Docket H-033C, Asbestos in Construction standard, discussed at 51 FR 22719, June 20, 1986). For example, OSHA stated in the preamble to the Lead standard (43 FR at 52933, Nov. 14, 1978) that "PAPRs provide greater protection to individuals, especially those who cannot obtain a good face fit on a negative pressure respirator, and will provide greater comfort when a respirator needs to be worn for long periods of time. OSHA believes employees will have a greater incentive to wear respirators if discomfort is minimized."

OSHA continues to believe that under some circumstances PAPRs provide superior acceptability. These include situations where employees wear respirators for full shifts, where employees frequently readjust their negative pressure respirators to achieve what they consider a more comfortable or tighter fit, and where the air flow provided by a PAPR reduces the employee's psychological and physiological discomfort. However, where ambient temperatures are extremely high or low, PAPRs are often unacceptable because of the temperature of the airstream in the facepiece (See preamble to Coke Oven standard, 41 FR at 46774).

OSHA's experience in enforcing standards that contain a provision requiring PAPRs to be supplied is that the provision is rarely invoked by employees, and even less rarely cited. The Agency continues to believe that it is good industrial hygiene practice to provide a respirator that the employee considers acceptable. Fit testing protocols require that employees have an opportunity to reject respirator facepieces that they

consider unacceptable (See Appendix A).

However, this record does not provide a sufficient basis for the Agency to require PAPRs upon employee request in all situations where the standard applies. For example, Popendorf et al. (Ex. 64-513) reported results from a survey of respirator users in indoor swine production, poultry production, and grain handling facilities. "Acceptability among four classes of respirators (disposable, quarter-mask, half-mask and powered air-purifying helmets), varied among the three user groups. \* \* \* Powered helmets were rated best for breathing ease, communication ease, skin comfort and in-mask temperature and humidity, while disposables were rated best for weight and convenience." OSHA emphasizes, however, that if the medical evaluation required by this standard finds that an employee's health may be impaired by using a negative pressure respirator, the employer must provide a PAPR (See paragraph (e)(6)(ii)).

#### Paragraph (d)(2) -- Respirators for IDLH Atmospheres

Paragraph (d)(2) covers respirators for use in atmospheres that are immediately dangerous to life or health (IDLH). The comparable provision in the proposal was paragraph (d)(10), which several commenters stated was not clearly written (Exs. 54-38, 54-167, 54-213, 54-280, 54-297, 54-309, 54-455). OSHA has rewritten and reorganized the provision so that paragraph (d)(2) of the final rule covers all IDLH atmospheres, and paragraph (d)(3) covers all non-IDLH atmospheres.

The standard requires that the most protective and reliable respirators be used for IDLH atmospheres: either a full facepiece pressure demand SCBA certified for a minimum service life of thirty minutes, or a combination full facepiece pressure demand supplied-air respirator with an auxiliary self-contained air supply (paragraph (d)(2)(i)). The proposal would have imposed the same requirement, except for the addition of the requirement for a minimum service life in the final rule.

OSHA has determined, as have most respirator authorities, that IDLH atmospheres require the highest level of respiratory protection and reliability. These atmospheres, by definition, are the most dangerous environments in which respirators may be used. As OSHA explains in the summary and explanation for the definition of "IDLH," the term includes atmospheres that pose an immediate threat to life or health, would cause irreversible adverse health effects, or would impair an employee's ability to escape. In these atmospheres there is no tolerance for respirator failure. This record supported OSHA's preamble statement that IDLH atmospheres "require the most protective types of respirators for workers" (59 FR 58896). Commenters and authorities, including NIOSH, ANSI, and both labor and management, agree that, for these atmospheres, the most highly protective respirators, with escape capability, should be required (See the NIOSH Respirator Decision Logic, pg. 10; ANSI Z88.2-1992, clause 7.3.2; Ex. 54-38).

Paragraph (d)(2)(ii) requires employers to select respirators that are to be used exclusively for escape from IDLH atmospheres from those certified by NIOSH for escape from the atmosphere in which they will be used. This provision addresses the selection of escape-only respirators from IDLH atmospheres involving different substances and situations. For example, under current 29 CFR 1910.1050, the standard covering exposure to methylenedianiline (MDA), escape respirators may be any full facepiece air-purifying respirator equipped with HEPA cartridges, or any positive pressure or continuous flow self-contained breathing apparatus with full facepiece or hood; for formaldehyde exposure, escape respirators may be a full facepiece with chin style, front, or back-mounted industrial canister approved against formaldehyde (29 CFR 1910.1048).

Paragraph (d)(2)(iii) requires employers to consider all oxygen-deficient atmospheres to be IDLH atmospheres. An oxygen-deficient atmosphere is defined in paragraph (b) of the standard as one that

contains less than 19.5 percent oxygen. Below this level, employers are required to use the same respirators as are required for IDLH atmospheres, i.e., a full facepiece pressure-demand supplied-air respirator with auxiliary SCBA or pressure-demand SCBA. This paragraph contains an exception to permit employers to use any supplied-air respirator, provided that the employer demonstrates that oxygen levels in the work area can be maintained within the ranges specified in Table II of the final rule, i.e., between 19.5 percent and a lower value that corresponds to an altitude-adjusted oxygen partial pressure equivalent to 16 percent oxygen by volume at sea level. The language of paragraph (d)(2)(iii), along with the exception, reflects the same requirement as that proposed, but avoids the potential confusion associated with having separate definitions and requirements for oxygen-deficient, and oxygen-deficient IDLH, atmospheres, as originally proposed. The language used in the final rule also reinforces OSHA's belief that all atmospheres containing less than 19.5 oxygen must be considered IDLH unless the employer has good information that oxygen levels cannot fall to dangerously low levels; in atmospheres below this level but falling within the ranges shown in Table II, a SAR must be provided.

In the preamble discussion for paragraph (b), OSHA provided several reasons for the selection of the 19.5 percent cutoff to define oxygen deficiency. First, OSHA believes that consistency with the Agency's confined space standard is essential because most oxygen-deficient atmospheres will be associated with work in confined spaces. In the preamble to the permit-required confined space standard, 29 CFR 1910.146(b), OSHA used the term "asphyxiating atmosphere" when referring to an atmosphere containing less than 19.5 percent oxygen (58 FR 4466, January 14, 1993). In the confined space standard itself, OSHA included "atmospheric oxygen concentrations [of] less than 19.5 percent" within the standard's definition of "hazardous atmosphere." Using the same 19.5 percent cutoff point for defining an IDLH oxygen-deficient atmosphere in this respiratory protection standard will reduce the potential for confusion. In addition, OSHA's use of a 19.5 percent cutoff is consistent with the requirement that Grade D breathing air contain a minimum of 19.5 percent oxygen (See paragraph (i)).

OSHA believes that employers will only rarely have occasion to avail themselves of the exception in paragraph (d)(2)(iii), which allows the use of any supplied-air respirator (SAR) if oxygen levels can be maintained within the ranges shown in Table II. Except for confined spaces, there were no examples in the record of work operations being routinely conducted in well-controlled atmospheres where oxygen levels are below 19.5 percent. Most atmospheres with oxygen content between 16 and 19.5 percent are not well-controlled, and a drop in oxygen content could have severe consequences. OSHA's review of enforcement data also confirms that, except for confined spaces, such atmospheres are uncommon, although they occasionally occur when work is conducted in basements, open pits, and other enclosed spaces. If an employer can meet the difficult evidentiary burden of showing that the oxygen content can be controlled reliably enough to remain within the ranges specified in Table II, the atmosphere is not considered IDLH under this standard, and the employer may provide any SAR.

The low end of the ranges of oxygen concentrations in Table II are the same as those used to define oxygen-deficient IDLH atmospheres in the proposal: 16 percent oxygen by volume for altitudes from sea level to 3,000, and 19.5% oxygen content for altitudes above 8,001 feet. For altitudes from 3,001 to 8,000 feet, the listed oxygen concentrations correspond to an oxygen partial pressure of 100 mm mercury (Hg). OSHA explained in the proposal (59 FR at 58906) that these values are consistent with those in ANSI's Z88.2-1980 standard and with ANSI's definition of "oxygen deficiency -- immediately dangerous to life or health" as a partial pressure of 100 mm Hg at sea level.

ANSI's more recent 1992 standard permits lower oxygen concentrations before classifying an atmosphere as IDLH, provided that the employer has determined that the source of the oxygen reduction is understood

and controlled. OSHA noted in the proposal that IDLH oxygen deficiency is now defined by ANSI as an oxygen content at sea level that is equivalent to less than 12.5% oxygen (i.e., an atmosphere with an oxygen partial pressure of 95 mm Hg or less). However, there is general agreement that employees could be seriously and rapidly debilitated if their supplied-air respirators should fail in a 12.5% oxygen atmosphere. OSHA stated in the proposal that that level represents the "bare minimum safety factor." By choosing such a low oxygen partial pressure as the "floor" for oxygen-deficient IDLH atmospheres, the ANSI standard effectively removes any safety margin (59 FR 58905). ANSI representatives (Tr. 1289) agreed with OSHA during the hearing that OSHA's proposal offered a greater safety buffer than the 1992 ANSI standard. In addition, ANSI itself acknowledged in Table A-1 of its Z88.2-1992 standard (pg. 22, Ex. 54-50) that an oxygen level of 12.5% at sea level would produce effects such as "Very poor judgment and coordination \* \* \* impaired respiration that may cause permanent heart damage \* \* \* nausea and vomiting." OSHA considers these effects unacceptable and intends this standard to prevent their occurrence. The ANSI table also states that a 16% oxygen level would produce effects such as "Increased pulse and breathing rates \* \* \* impaired thinking and attention \* \* \* reduced coordination," and at an oxygen level of 14% effects would include "Abnormal fatigue upon exertion \* \* \* emotional upset \* \* \* faulty coordination \* \* \* poor judgment." All of these effects are potentially incompatible with the safe performance of duties.

The ANSI table shows that the adverse health effects of oxygen deficiency become significant at the 16% oxygen level, and that these effects increase in severity as the oxygen level decreases. ANSI chose the 12.5% level because that level represents the point below which significant reductions in blood oxygen levels occur. As ANSI stated in clause A.5.2 of the Z88.2-1992 standard "[t]his rapid rate of change then can present an unforgiving situation to an unprotected worker where debilitating physiological symptoms can appear suddenly, without warning, after only relatively small changes in ambient oxygen levels."

The ANSI standard anticipates that all atmospheres with reduced oxygen levels would be treated as IDLH unless the source of the oxygen reduction is understood and controlled (Clause 7.3.1 ANSI Z88.2-1992). OSHA found that situations with controlled reduced-oxygen atmospheres (below 16% oxygen by volume) are rare and are already treated as an IDLH atmosphere by employers. Outside of confined spaces, such as in a pit or a basement, a reduced-oxygen atmosphere is rarely stable. Reduced-oxygen atmosphere situations may result as a byproduct of dynamic processes such as oxygen-consuming operations caused by the combustion of fuels or the digestion of organic matter. OSHA considers all confined spaces with atmospheric concentrations of less than 19.5% oxygen hazardous, and does not permit an oxygen level below 19.5% for occupied confined spaces (See 29 CFR 1910.146(b)), because it is difficult to ensure that, in a confined space, oxygen levels will not drop precipitously with little or no warning. The work being performed can itself reduce the oxygen levels, due to displacement of air by asphyxiants or through consumption of oxygen by work processes or by employees performing the work. Such sources of variability in oxygen content, even in workplaces where employers are attempting to stabilize the atmospheric oxygen content, can cause oxygen levels to drop to a lower level, placing workers at risk. Furthermore, the accurate monitoring of oxygen levels can be difficult, since sampling instruments test a limited number of areas, and pockets of lower oxygen content can exist inside a confined space or in a basement that can cause a worker to be overcome. Thus, OSHA has chosen an oxygen level of 16% by volume as the level at which SCBA or an airline respirator with auxiliary air supply must be used because that is the level below which severe symptoms from oxygen deprivation first appear, because maintenance of oxygen levels below 16% is difficult, and because employees who are not protected risk their lives if an employer mistakenly believes oxygen content can be controlled.

OSHA's determination that, at altitudes of up to 3,000 feet, atmospheres containing less than 16% oxygen

must be considered IDLH was based on evidence that NIOSH submitted to the preproposal docket (See 59 FR at 58905). NIOSH showed that in an oxygen concentration of less than 16% at sea level, employees may experience impaired attention, thinking and coordination. The American Thoracic Society (Ex. 54-92) questioned whether allowing work to be performed in an atmosphere with as little as 16% oxygen, with no supplemental oxygen supply, at altitudes below 3000 feet is sufficiently protective and suggested that mandatory medical examinations might be necessary in such circumstances to avoid pulmonary or cardiac disease complications. OSHA believes that this comment reflects some of the confusion among rulemaking participants concerning the proposed language covering oxygen deficiency. OSHA wishes to make clear that, in both the proposed and the final rules, employees are not permitted to work in atmospheres containing less than 19.5 percent oxygen without the use of a supplied- air respirator. In the majority of these cases, employers will be obligated to provide highly protective respirators that can be used in IDLH conditions. In a few cases, employers may be able to justify use of any supplied-air respirator. In either case, employees will be provided a supplemental source of breathing air when working in oxygen- deficient atmospheres.

OSHA has not adopted NIOSH's recommendations that the IDLH concentration of oxygen be increased to a concentration above 19.5% for work above 8,001 feet. OSHA's experience confirms the record evidence that most work at higher altitudes is performed by fully acclimated workers (Exs. 54-6, 54-208). These provisions will allow acclimated workers to continue to perform their work without oxygen-supplying respirators, at any altitude up to 14,000 feet altitude, as long as the ambient oxygen content remains above 19.5% and the employee has no medical condition that would require the use of supplemental oxygen.

As noted above, oxygen deficiency frequently occurs in atmospheres that are not well controlled, and OSHA's decision to consider all oxygen-deficient atmospheres as IDLH except under certain strict conditions is appropriate for work conducted in such dangerous conditions. The requirement to use the most protective and reliable respirators for IDLH atmospheres is proper to protect workers from the dire consequences of exposure to these atmospheres.

#### Paragraph(d)(3) -- Respirators for Atmospheres That Are Not IDLH

Paragraph (d)(3) sets out criteria and requirements for choosing respirators for all non-IDLH atmospheres. These provisions supplement the general requirements in paragraph (d)(1). This paragraph has been reordered from the parallel paragraph of the proposed standard.

Paragraph (d)(3)(i) requires the employer to provide a respirator that is adequate to reduce the exposure of the respirator wearer under all conditions of use, including in reasonably foreseeable emergencies. Employers must also provide respirators that will ensure compliance with all other statutory and regulatory requirements, such as the permissible exposure limits (PELs) for substances in 29 CFR 1910.1000, substance-specific standards, and other OSHA standards. For example, 29 CFR 1910.120 (g)(2) of OSHA's Hazardous Waste Operations and Emergency Response standard has additional exposure limits that apply to hazardous waste sites and emergency response operations. In addition, the general duty clause (Sec. 5(a)(1)) of the OSH Act may require employers to protect their employees from substances that are not regulated but that are known to be hazardous at the exposure levels encountered in the workplace. However, as was discussed at length in the "Definitions" section of this summary and explanation, the final standard does not use the term "hazardous exposure levels," in part because the proposal was widely misunderstood to require compliance with ACGIH's TLVs or NIOSH's RELs in the absence of an OSHA standard. Moreover, as also noted above, this rulemaking does not address the hierarchy of exposure controls in paragraph (a)(1). Thus, employers may not rely on respirators to control

exposures when feasible engineering controls are available and are sufficient to reduce exposures.

As explained earlier, OSHA intends to address the issue of assigned protection factors (APFs) and their impact on respirator selection in a subsequent phase of this rulemaking. OSHA noted in the proposal (59 FR 58901) that APFs are "a recognition of the fact that different types of equipment provide different degrees of protection, and equipment limitations must be considered in selecting respirators." A respirator with a higher APF will provide more protection than a respirator with a lower APF. Considerable information on APFs has developed since OSHA adopted its existing standard in 1971. OSHA intends to promulgate APF provisions in the future. Accordingly, paragraphs (d)(3)(i) (A) and (B) are reserved at this time and will be addressed in the next phase of this rulemaking. 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. In addition, where OSHA has specific compliance interpretations for certain respirators, e.g., respirators used for abrasive blasting (such as for lead), these should be followed.

Based on the Agency's enforcement experience with the previous standard, OSHA does not believe that differences in the APFs set by NIOSH and ANSI will have a serious impact on respirator selection, because the major differences in NIOSH and ANSI APFs occur with respirators having APFs of 25 or greater, and most overexposures involve exposures at relatively small multiples of the PELs. An analysis of OSHA's Integrated Management Information System (IMIS) data showed that only 2 percent of the measurements taken by OSHA exceeded the PEL by more than 10 times.

Paragraph (d)(3)(ii) of the final standard provides that the respirators selected must protect employees against the physical state and chemical form of the particular contaminant or contaminants present in the workplace. For air-purifying respirator selection, the form of the contaminant is a critical factor. Different types of air filtration respirators are needed for dusts and gases, for example, and, among gases, different types are needed for acid gases and for carbon monoxide. If the respirator is not equipped with a filter suitable for the form of the contaminant to which a worker is exposed, then the worker has no protection against that contaminant. No commenter opposed this requirement. ANSI's standard acknowledges that this information is critical to appropriate respirator selection (ANSI Z 88.2-1992, clause 4.5.4.(b)).

Paragraph (d)(3)(iii) covers respirator selection for protection against gases and vapors. OSHA's primary intent in this paragraph is to ensure that air-purifying respirators are not used in situations where a chemical cartridge or canister becomes saturated such that the gas or vapor contaminant can "break through" the filter's sorbent element and enter the respirator and the worker's breathing zone. If this happens, even correctly fitting, well-maintained respirators provide no protection to their users. This breakthrough problem is avoided entirely by the use of atmosphere-supplying respirators. Such respirators do not rely on filter sorbents and instead deliver clean outside air to the wearer's respirator.

This paragraph establishes the requirements for selecting respirators for protection against gas and vapor contaminants. Paragraph (d)(3)(iii)(A) allows the use of atmosphere-supplying respirators against any gas or vapor, and paragraph (d)(3)(iii)(B) specifies the conditions under which air-purifying respirators may be used. These conditions protect users against the gas or vapor contaminant breaking through the canister/cartridge filter. Thus, this paragraph allows an air-purifying respirator to be used if it is equipped with a NIOSH-approved end-of-service life indicator (ESLI) (paragraph (d)(3)(iii)(B)(1)) or if the employer enforces a sorbent change schedule based on reliable information and data on the service life of cartridges and canisters used by the employer (paragraph (d)(3)(iii)(B)(2)).

These provisions differ significantly from those in the proposal. In proposed paragraphs (d)(8) and (d)(9), OSHA would have allowed air-purifying respirator use for gases and vapors with "adequate warning properties," such as odor or irritation, and would not have imposed additional conditions on their use. A substance would have been considered to have adequate warning properties if the threshold for detection was no higher than three times the hazardous exposure level. For contaminants having poor warning properties, the standard as proposed would have required employers to use an ESLI or develop a cartridge/canister change schedule that would ensure replacement of the sorbent element before 80 percent of its useful service life had expired.

Commenters expressed significant dissatisfaction with the proposed provisions, and some asked OSHA to reevaluate them in major respects (Exs. 54-414, 54-249, 54-374). Many rulemaking participants urged OSHA to rely much more heavily on end-of-service-life indicators (ESLIs) or appropriate cartridge or canister change schedules for air-purifying respirators, and some suggested that OSHA require NIOSH-certified ESLIs on these respirators (Exs. 54-387, 54-443). Other commenters opposed limiting the use of air-purifying respirators equipped with ESLIs or reliable change out schedules to situations where the odor/irritation threshold was less than three times the PEL. However, the Occidental Chemical Corporation (Ex. 54-346) stated that adopting this restriction would prohibit the use of air-purifying respirators for benzene exposures in excess of 3 ppm unnecessarily, and "counter 10 years of effective employee protection that industry has provided."

Many other participants criticized the proposal's reliance on sensory thresholds such as odor and irritation to indicate when a respirator's filtering capacity is exhausted, stating that there is too much variation between individuals, that there is no good screening mechanism to identify persons with sensory receptor problems, and that the proposal would have allowed employees to be overexposed to hazardous air contaminants (Exs. 54-151, 54-153, 54-165, 54-202, 54-206, 54-214, 54-414, 54-280, 54-386, 54-410, 54-427). Still other commenters suggested that the kind of respirator required should depend on the severity of the harm resulting from overexposure, with exposure to more serious hazards requiring supplied-air respirators (Exs. 54-202, 54-212, 54-347). Finally, some commenters interpreted the proposed provision as prohibiting the use of air-purifying respirators against particulates "without adequate warning properties" (Ex. 54-309). This, according to the Associated Builders and Contractors (Ex. 54-309), would require, for example, a "pipefitter who is torch cutting metal with a galvanized coating to use an air-supplied respirator or SCBA -- even when working outdoors \* \* \* [and] could add one more item to the array of electrical power cords, pneumatic lines, and fall-protection devices already attached to or trailing many construction workers."

ORC testified (Tr. 2164-65) that in general, the experience of most of its member companies is that most toxic substances do not have appropriate sensory warning properties. Indeed, in the preamble to its proposed Glycol Ethers standard, OSHA noted that reported values for the odor threshold of any substance vary widely, both because of differences between individuals' ability to perceive a particular odor and because of the methodology employed in conducting the odor threshold determination (58 FR 15526).

NIOSH's "Guide to Industrial Respiratory Protection -- Appendix C" reports that on average, 95% of a population will have a personal odor threshold that lies within the range from about one-sixteenth to sixteen times the reported mean odor threshold for a substance. As stated by Amoore and Hautala(1983):

[t]he interpretation of these data \* \* \* will depend markedly on the individual circumstances. The threshold data \* \* \* are based on averages for samples of the population, presumably in good health. Individuals can differ quite markedly from the population average in their smell sensitivity, due to any of a variety of innate, chronic, or acute physiological conditions \* \* \*

\* Continuing exposure to an odor usually results in a gradual diminution or even disappearance of the smell sensation. This

phenomenon is known as olfactory adaption or smell fatigue. If the adaption has not been too severe or too prolonged, sensitivity can often be restored by stepping aside for a few moments to an uncontaminated atmosphere, if available. Unfortunately, workers chronically exposed to a strong odor can develop a desensitization which persists up to two weeks or more after their departure from the contaminated atmosphere \* \* \* Hydrogen sulfide and perhaps other dangerous gases can very quickly lose their characteristic odor at high concentrations \* \* \* Certain commercial diffusible odor masking or suppressing agents may reduce the perceptibility of odors, without removing the chemical source.

Other commenters agreed that odor threshold levels are so variable that it is "virtually impossible" to set general rules for uniform application (Moldex-Metric, Ex. 54-153; See also Phillips Petroleum, Ex. 54-165 and Ex. 54-151). OSHA notes that NIOSH, in its 1987 Respirator Decision Logic (Ex. 9 at pg. 3) stated that "[w]hen warning properties must be relied on as part of a respiratory protection program, the employer should accurately, validly, and reliably screen each prospective wearer for the ability to detect the warning properties of the hazardous substance(s) at exposure levels that are less than the exposure limits for the substance(s)."

In light of this evidence, OSHA has reconsidered the conditions under which air-purifying respirators may be used. The final standard requires the use of ESLIs where they are available and appropriate for the employer's workplace, whether or not warning properties exist for a contaminant. If there is no ESLI available, the employer is required to develop a cartridge/canister change schedule based on available information and data that describe the service life of the sorbent elements against the contaminant present in the employer's workplace and that will ensure that sorbent elements are replaced before they are exhausted. Reliance on odor thresholds and other warning properties is no longer explicitly permitted in the final rule as the sole basis for determining that an air-purifying respirator will afford adequate protection against exposure to gas and vapor contaminants.

To date, only five contaminant-specific ESLIs have been granted the NIOSH approval necessary to allow them to be used. To the extent that NIOSH certified end-of-service life indicators are available, OSHA finds that there are considerable benefits to their use. As a representative of the Mine Safety Appliances Company (MSA) testified (Tr. 821), "ESLIs \* \* \* simplify administration of the respirator program. The idea of trying to administer control on the change out schedule for these cartridges leads to human error or could lead to human error. Where the end-of-service-life indicator is a more active indicator for the actual respirator user that his cartridge needs replacement, it takes the guesswork out of the respirator program and change out schedule."

NIOSH has established rigorous testing criteria for end-of-service life indicators. An applicant must supply NIOSH with data "demonstrating that the ESLI is a reliable indicator of sorbent depletion (equal to or less than 90% of service life). These shall include a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are representative of actual workplace conditions where a given respirator will be used \* \* \*. Additional data concerning desorption of impregnating agents used in the indicator, on the effects of industrial interferences commonly found, on reaction products, and which predict the storage life of the indicator" are also required (NIOSH 1987, Ex. 9 at 45-46). Other criteria cover the durability of an ESLI, and whether it interferes with respirator performance or otherwise constitutes a health or safety hazard to the wearer.

OSHA finds that these rigorous testing requirements will ensure that employers who can rely on ESLIs can be confident that their employees are adequately protected while using air-purifying respirators against gas and vapor contaminants, and is therefore requiring their use in the final rule. One commenter pointed out that the use of cartridges with moisture-dependent end-of-service life indicators will allow dangerously high exposures in dry atmospheres (Ex. 54-455). However, the final rule requires the use of cartridges and

canisters equipped with an ESLI only if its use is appropriate for the conditions of the employer's workplace. Thus, employers would not be required to rely on an ESLI if the employer could demonstrate that its use presents a hazard to employees.

There was much agreement in the record that it would not be possible or feasible to require replacement of cartridges and canisters before 80 percent of the useful service life of the sorbent element had expired, primarily due to the lack of data available to employers to make this determination (Exs. 54-6, 54-48, 54-165, 54-178, 54-181, 54-226, 54-231, 54-289, 54-374). To implement this requirement as it was proposed, the employer would need quantitative information that describes how long a cartridge or canister would last when challenged with a specific concentration of a gas or vapor. Such studies are called "breakthrough studies" and require the use of elaborate instrumentation and rigid test protocols. Several published breakthrough studies of a few dozen commonly used industrial chemicals are available in the literature (See, for example, Exs. 21-5, 21-7, 21-8, 21-10, 38-13, 38-14, 38-15). OSHA recently used breakthrough data to develop a general cartridge and canister change schedule for air-purifying respirators used against 1,3-butadiene (61 FR 56817). Under Section 5 of the Toxic Substances Control Act (TSCA), EPA's Office of Pollution Prevention and Toxics (OPPT) requires manufacturers and importers of new chemicals to conduct breakthrough studies and develop cartridge/canister change schedules based on this service life testing.

As described above, however, comments to the record indicate that breakthrough test data are not likely to be available for many hazardous gases or vapors encountered in American workplaces. For example, one commenter agreed that, although there is a need to protect employees against contaminant breakthrough, it disagreed with relying on employer-devised schedules because there has not been enough breakthrough testing (Laidlaw Environmental Services, Ex. 54-178). The American Electric Power Service Corporation asked OSHA to provide needed guidance on how to assess the useful life of gas and vapor cartridges under widely varying conditions (Ex. 54-181).

The record shows clearly that respirator manufacturers, chemical manufacturers, and even NIOSH must provide more information about how long respirator cartridges and canisters can be expected to provide protection for employees, as well as additional tools to assess whether the cartridges are still functioning. NIOSH's certification process does not require respirator manufacturers to provide information on the maximum or expected life span for gas and vapor cartridges. Nor do chemical manufacturers' written specifications routinely include this information. The certification process tests only for minimum service life, which for most cartridges is 25 to 50 minutes, and for most canisters is 12 minutes (42 CFR part 84, Tables 6, 11). Also, as stated by Cohen and Garrison of the University of Michigan (Ex. 64-207, at 486), "(c)urrent certification by NIOSH involves testing respirator cartridges containing activated carbon against carbon tetrachloride in the presence of water vapor. Testing cartridges with carbon tetrachloride cannot predict how other organic vapors will be adsorbed."

Alternatives to OSHA's proposal that were suggested by rulemaking participants included adopting the ANSI requirement to develop and implement a cartridge change schedule based on cartridge service data (which would require the use of breakthrough test data) and information on expected exposure and respirator use patterns (Ex. 54-273), or following manufacturers' recommendations for cartridge and canister use (Ex. 54-6). Therefore, in the final rule, OSHA is not retaining the proposed requirement for employers to ensure that chemical cartridges and canisters be replaced before 80 percent of their useful life. Instead, OSHA is requiring that employers develop cartridge/canister change schedules based on available data or information that can be relied upon to ensure that cartridges and canisters are changed before the end of their useful service life. Such information may include either information based on

breakthrough test data or reliable use recommendations from the employer's respirator and/or chemical suppliers.

Unlike the proposal, the requirement in the final rule would not require the employer to search for and analyze breakthrough test data, but instead permits the employer to obtain information from other sources who have the expertise and knowledge to be able to assist the employer to develop change schedules. OSHA has revised the final rule from the proposal in this manner to recognize that there may be instances in which specific breakthrough test data are not available for a particular contaminant, but manufacturers and suppliers may nevertheless still be able to provide guidance to an employer to develop an adequate change schedule. If the employer is unable to obtain such data, information, or recommendations to support the use of air-purifying respirators against the gases or vapors encountered in the employer's workplace, the final rule requires the employer to rely on atmosphere-supplied respirators because the employer can have no assurance that air-purifying respirators will provide adequate protection.

Ideally, change schedules should be based on tests of cartridge/ canister breakthrough that were conducted under worst-case conditions of contaminant concentration, humidity, temperature and air flow rate through the filter element. One such protocol is described in the EPA Interim Recommendations for Determining Organic Vapor Cartridge Service Life for NIOSH Approved Respirators (dated May 1, 1991), as revised in May 1994. This protocol requires breakthrough testing at three different concentrations at 80 and 20 percent relative humidity. Additional testing is required if it is determined that the substance may be used in workplaces where there are elevated temperatures, or where breakthrough is evident at lower humidity. The protocol also requires manufacturers to develop change schedules that incorporate a safety factor of 60 percent of the measured service life.

OSHA emphasizes that a conservative approach is recommended when evaluating service life testing data. Temperature, humidity, air flow through the filter, the work rate, and the presence of other potential interfering chemicals in the workplace all can have a serious effect on the service life of an air-purifying cartridge or canister. High temperature and humidity directly impact the performance of the activated carbon in air-purifying filters. OSHA believes that, in establishing a schedule for filter replacement, it is important to base the schedule on worst-case conditions found in the workplace, since this will provide the greatest margin for safety in using air-purifying respirators with gases and vapors. Thus, to the extent that change schedules are based on test data that were not obtained under similar worst-case conditions, OSHA recommends that employers provide an additional margin of safety to ensure that breakthrough is not likely to occur during respirator use. OSHA encourages respirator and chemical manufacturers to perform their own tests to provide appropriate breakthrough test data to employers, particularly to small companies with limited resources, for those situations where the data are not already publicly available.

If breakthrough data are not available, the employer may seek other information on which to base a reliable cartridge/canister change schedule. OSHA believes that the most readily available alternative is for employers to rely on recommendations of their respirator and/or chemical suppliers. To be reliable, such recommendations should consider workplace-specific factors that are likely to affect cartridge/canister service life, such as concentrations of contaminants in the workplace air, patterns of respirator use (i.e., whether use is intermittent or continuous throughout the shift), and environmental factors including temperature and humidity. Such recommendations must be viewed by the employer in light of the employer's own past experience with respirator use. For example, reports by employees that they can detect the odor of vapors while respirators are being used suggest that cartridges or canisters should be changed more frequently.

Another potential approach involves the use of mathematical models that have been developed to describe the physical and chemical interactions between the contaminant and sorbent material. Theoretical modeling has been conducted to determine the effect of contaminant concentration on breakthrough time and other similar relationships. It is generally agreed, however, that the relationships between contaminant concentrations, exposure durations, breathing rates, and breakthrough times are complex and heavily dependent upon assumptions concerning several factors, including environmental conditions (See references 1-8 in Ex. 64-331). As a result, predictive models are probably not likely to present an acceptable alternative for most employers, and their use would require that a considerable margin of safety be incorporated into any change schedule developed from such estimation techniques.

Research is also underway to develop a field method for evaluating the service lives of organic vapor cartridges using a small carbon-filled tube to sample air from the work environment. The principal investigator for this research stated in 1991 that "(a) field evaluation of the method is currently underway. It is expected to be the final step in evaluating and validating the method for predicting the service lives of organic vapor respirator cartridges in workplace environments" (Ex. 64-208 at 42). Although OSHA cannot at this time evaluate the utility of this method because results of the field testing of this device have not been reported, the development of such tools to assist employers to better estimate cartridge/canister service times is encouraged, and their use would be permitted under the standard providing that the reliability of such a method had been appropriately demonstrated.

Representatives of CMA testified in favor of requiring the employer to provide some written documentation for determining service life or a change out schedule (Tr. 1736-1737). OSHA agrees that it is important for the employer to document the basis for establishing the change schedule and has included in paragraph (d)(3)(iii)(B)(2) a requirement for the employer to do so as part of his or her written respiratory protection program. The written respirator program is the proper place for employers to document change schedules, since the written program is the place where employers give specific directions on workplace-related operations and procedures for their employees to follow. The written program also documents the exposure measurements or reasonable estimates that were made, which form the basis of the calculations used to make the filter change schedules. Developing a filter change schedule involves a number of decisions. The employer must evaluate the hazardous exposure level, the performance capacity of the filters being used, and the duration of employee use of the respirator, which impact on the service life calculations. OSHA believes that including the basis for the change schedule in the written program will cause employers to better evaluate the quality and reliability of the underlying information, and will prompt the employer to obtain additional information, ask additional questions of their suppliers, or seek competent professional help to develop a change schedule that will ensure adequate performance of cartridges and canisters used in the employer's workplace.

OSHA proposed in paragraph (d)(3)(ii) that, as part of the required selection evaluation, the employer evaluate the physical properties of the relevant contaminant and, in the preamble, listed "the particle size for dusts" as a factor affecting respirator selection (59 FR 58900). ANSI recommended in its 1992 standard particle size/filter selection criteria as follows: if the contaminant is an aerosol, with an unknown particle size or a size less than 2  $\mu\text{m}$ , use a high efficiency filter; if the contaminant is a fume, use a filter approved for fumes or a high efficiency filter; and if the contaminant is an aerosol, with a particle size greater than 2  $\mu\text{m}$ , use any filter type (ANSI Z88.2-1992, clause 7.2.2.2.j, k, and l).

NIOSH agreed with ANSI's recommendations insofar as particulate filtering respirators certified under former 30 CFR 11 are concerned. However, NIOSH expressed particular concern about very small particles: "Laboratory research beginning in the early 1970s, and continuing into the 1990s, demonstrated

that some, but not all, members of the Dust Mist (DM) and Dust Fume Mist (DFM) filter classes allow significant penetration of submicron-sized particles. Additionally submicron particulates present special medical concerns because they can diffuse throughout the respiratory system \* \* \*" In NIOSH's new 42 CFR part 84, classes of particulate filters now certified as filter series N, R, and P may be used against any size particulate in the workplace (Ex. 54-437).

Based on this evidence, OSHA has determined that where employees are exposed to submicron particles of a respiratory hazard, OSHA will enforce paragraph (d)(3)(iv) as limiting the use of DM and DFM filters certified under former 30 CFR 11 to employers who can demonstrate that exposure in their workplace is limited to particulates that have a mass median aerodynamic diameter of 2 µm or larger. OSHA notes that employers have alternative choices to using HEPA filters where the sizes of particles are unknown or are less than 2 µm. The new filter media certified by NIOSH under new 42 CFR part 84 as series N, R and P, may be used for any size particulate; however, where another OSHA standard requires the use of HEPA-filtered respirators, the employer may only use HEPA filters defined under 30 CFR 11 or N100, R100, or P100 filters defined under 42 CFR part 84.

### ***Paragraph (e) -- Medical Evaluation***

Medical evaluation to determine whether an employee is able to use a given respirator is an important element of an effective respiratory protection program and is necessary to prevent injuries, illnesses, and even, in rare cases, death from the physiological burden imposed by respirator use. The previous standard stated, at 29 CFR 1910.134(b)(10), that employees should not be assigned to tasks requiring the use of respirators unless it has been determined that they are physically able to perform the work while using the respiratory equipment. That standard also provided that "the local physician shall determine what health and physical conditions are pertinent," but listed no specific medical or workplace conditions to consider when making such a determination. The previous standard also stated that regular reviews of the medical status of respirator users should be undertaken, and suggested that a once yearly evaluation would be appropriate. Employers are thus aware of the need for medical evaluations of respirator users and have been conducting such evaluations as part of their respiratory protection programs for years.

OSHA believes that, to ensure employee protection, medical evaluations for respirator use must be conducted before initial respirator use, and that such evaluations must consist of effective procedures and methods. Accordingly, the final standard's medical evaluation requirements for respirator use identify who is to be evaluated, and address the frequency and content of these evaluations. It authorizes licensed health care professionals, both physicians and nonphysicians, to evaluate employees for respirator use to the extent authorized by the scope of their state licensure, and to conduct follow-up medical evaluations based on specific indicators of need.

In the proposal, OSHA described three alternative approaches to medical evaluation for respirator users. The first proposed alternative in the regulatory text would have required employers annually to obtain a physician's written opinion for every employee using a respirator for more than five hours in any work week. The physician's opinion was to inform the employer whether or not a medical examination of the employee was necessary and, if so, was to specify the content of the medical examination.

The second proposed alternative required a mandatory medical history and examination, using questions and procedures similar to those contained in the ANSI standard on physical qualifications for respirator use, ANSI Z88.6-1984 (Ex. 38-4). This alternative would have applied only to employees using a respirator for more than five hours during any work week. Medical evaluation was to be performed annually and whenever an employee experienced breathing difficulty while being fitted for, or using, a

respirator. The medical evaluation was to be conducted by a physician or a health care professional supervised by a physician, who, in arriving at a decision regarding the employee's medical ability for respirator use, was to consider a number of respirator and workplace conditions (e.g., type of respirator used, duration and frequency of respirator use, substances to which the employee is exposed, work effort and type of work, need for protective clothing, and special environmental conditions (e.g., heat, confined spaces)) that could affect the health and safety of respirator users. The resulting medical opinion, which was to be written by a physician, was to recommend any medical limitation on respirator use, and was to be provided to both the employer and employee. This proposed alternative contained an exemption for employees who had received a comparable medical history and examination within the previous year for the same respirator and conditions of respirator use. OSHA proposed a nonmandatory Appendix C with this alternative that specified the elements of the medical evaluation.

The third proposed alternative would have required that a medical questionnaire be administered to every respirator user, regardless of the duration of respirator use. The medical questionnaires could be administered by health professionals or other personnel who had been trained in medical administration by a physician. If the answers to the medical questionnaire showed that a medical examination was needed, the employee had to be provided such an examination (see 59 FR 58911). Medical examinations were to be mandatory for employees who would be required to use SCBAs when assigned to emergency or rescue operations. Medical examinations were to be conducted by physicians or physician-supervised health care professionals. The medical opinion was to be written by a physician; consider the same respirator and workplace conditions specified for the second alternative; specify any medical limitations on respirator use; and be provided to both the employer and employee.

In addition to proposing three medical evaluation alternatives, the proposal requested comments on medical removal protection, including the need to provide alternative respirators or job assignments to employees found to be medically unable to use the required respirator.

### Overview of the Final Rule's Provisions

The provisions of paragraph (e) in the final Respiratory Protection standard are based on an extensive review of the comments received on the proposal, especially comments regarding the three proposed medical evaluation alternatives. Final paragraph (e)(1) specifies that every employee must be medically evaluated prior to fit testing and initial use of a respirator. Paragraph (e)(2) states that employers must select a physician or other licensed health care professional (PLHCP) to conduct the medical evaluation, which must consist either of the administration of a medical questionnaire or an initial medical examination. Mandatory Appendix C contains the medical questionnaire to be administered to employees if the medical questionnaire approach is taken.

Paragraph (e)(3) requires the employer to provide a follow-up medical examination to an employee who answers "yes" to any question among questions 1 through 8 in Section 2, Part A of the medical questionnaire in Appendix C. The follow-up medical examination is to consist of any tests, consultations, or diagnostic procedures that the PLHCP deems necessary.

Paragraph (e)(4) specifies that the medical questionnaire and examinations shall be administered confidentially and at a time and place, during working hours, that is convenient to the employee, and that the employee understands the content of the questionnaire.

Paragraph (e)(5) requires the employer to provide the PLHCP with specific information needed to make an informed decision about whether the employee is able to use a respirator. The information includes

descriptions of the respirator to be used and workplace conditions that may impose physiological burdens on respirator users, or that may interact with an existing medical condition to increase the risk that respirator use will adversely affect the employee's health.

Final paragraph (e)(6) requires the employer to obtain a written recommendation from the PLHCP on whether or not the employee is medically able to use a respirator. The recommendation must identify any limitations on the employee's use of the respirator, as well as the need for follow-up medical evaluations to assist the PLHCP in determining the effects of respirator use on the employee's health. The employee must receive a copy of the PLHCP's written recommendation. The last provision of paragraph (e)(6) requires that a powered air- purifying respirator (PAPR) be provided to an employee when information from the medical evaluation shows that the employee can use a PAPR but not a negative pressure respirator. If the PLHCP determines at a subsequent time that the employee is able to use a negative pressure respirator, the employer is no longer required to provide a PAPR to that employee.

Paragraph (e)(7) specifies circumstances that require the employer to provide additional medical evaluations to respirator users. Medical reevaluations must be provided under the following conditions: when the employee reports signs or symptoms that are relevant to the employee's ability to use a respirator; when a PLHCP, supervisor, or respirator program administrator informs the employer that an employee needs to be reevaluated; when information from the respirator program, including observations made during fit testing or program evaluation, indicates a need for employee reevaluation; or if a change in workplace conditions occurs that may result in a substantial increase in the physiological burden that respirator use places on the employee. The following paragraphs describe the comments received in connection with each medical evaluation requirement, and discuss OSHA's reasons for including each requirement in the final rule.

## Introduction

OSHA is including an introduction to the regulatory text that provides a brief rationale for requiring employers to implement a medical evaluation program as part of their overall respiratory protection program. The introduction is provided for informational purposes, and does not impose regulatory obligations on employers.

The purpose of a medical evaluation program is to ensure that any employee required to use a respirator can tolerate the physiological burden associated with such use, including the burden imposed by the respirator itself (e.g., its weight and breathing resistance during both normal operation and under conditions of filter, canister, or cartridge overload); musculoskeletal stress (e.g., when the respirator to be worn is an SCBA); limitations on auditory, visual, and odor sensations; and isolation from the workplace environment (Exs. 113, 22- 1, 64-427). Certain job and workplace conditions in which a respirator is used can also impose a physiological load on the user; factors to be considered include the duration and frequency of respirator use, the level of physical work effort, the use of protective clothing, and the presence of temperature extremes or high humidity. Job- and workplace- related stressors may interact with respirator characteristics to increase the physiological stress experienced by employees (Exs. 113, 64-363). For example, being required to wear protective clothing while performing work that imposes a heavy workload can be highly stressful.

Specific medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee at increased risk of illness, injury, and even death (Exs. 64-363, 64-427). These medical conditions include cardiovascular and respiratory diseases (e.g., a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic

bronchitis, emphysema), reduced pulmonary function caused by other factors (e.g., smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (e.g., ringing in the ears, epilepsy, lower back pain), and impaired sensory function (e.g., a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease (Ex. 22-14). One commenter (Ex. 54-429) emphasized the importance of evaluating claustrophobia and severe anxiety, noting that these conditions are often detected during respirator training.

The introduction states that the medical evaluation requirements in paragraph (e) of the final rule are minimal requirements that OSHA believes are necessary to protect the health of respirator users.

#### Paragraph (e)(1) -- General

This paragraph requires that employees required to wear a respirator, or those voluntarily wearing a negative pressure air purifying respirator, be medically evaluated, and that a determination be made that they are able to use the respirators selected by the employer. A medical evaluation must be performed on every employee required to use a respirator, regardless of the duration and frequency of respirator use. In addition, as discussed above in connection with paragraph (c)(2), employers must provide a medical evaluation to any employee who elects to use a respirator that may place a physiological burden on the user, e.g., a negative pressure air-purifying respirator. By medically evaluating employees prior to respirator use, employers will avoid exposing employees to the physiological stresses associated with such use. Paragraph (e)(1) is similar to a provision in the American National Standards Institute (ANSI) consensus standard Z88.2- 1992 ("American National Standard for Respiratory Protection) that states: "any medical conditions [of an employee] that would preclude the use of respirators shall be determined."

Commenters (Exs. 54-21, 54-307, 54-361, 54-419, 54-420, 54-421, 54- 441) generally agreed that medical evaluation should precede initial respirator use, i.e., should take place before fit testing and first time use of the respirator in the workplace. For example, the International Brotherhood of Electrical Workers (Ex. 54-441) stated, "The physical fitness of respirator users must be known prior to them donning a respirator, not after they become injured." Three other commenters (Exs. 54-419, 54-420, 54-421) agreed, without elaboration, that medical evaluations should be performed before respirator use. One commenter (Ex. 54-21) recommended that employees receive medical evaluations after fit testing but before actual use so that difficulties with respirator use during fit testing could be reported to the PLHCP, and two other commenters (Exs. 54-307, 54-361) also suggested that the medical evaluation be conducted prior to fit testing.

OSHA believes that the initial medical evaluation must be conducted prior to fit testing to identify those employees who have medical conditions that contraindicate even the limited amount of respirator use associated with fit testing. If medical problems are observed during fit testing, the employee must be medically reevaluated (see final paragraph (e)(7)).

Final paragraph (e)(1) requires the medical evaluation of employees who use respirators, regardless of duration of use. This final requirement differs from proposed alternatives 1 and 2, which would have exempted from medical evaluation those employees who used a respirator for five or fewer hours during any work week. The overwhelming majority of commenters stated that the exemption should be eliminated entirely or be limited only to those employees who are exposed to minimal physiological stresses or workplace hazards. These comments can be grouped, and are summarized, as follows:

- (1) If the five-hours-per-week threshold were used, employers would avoid the proposed medical evaluation requirement by rotating employees who use respirators into jobs not requiring respirators just short of the five-hour limit (Exs. 54-5, 54-165, 54-178, 54-419);
- (2) Employees who use respirators frequently for periods of less than five hours per work week, or who use respirators for more than five hours per work week but do so infrequently, are still at risk of the adverse health effects potentially associated with respirator use and, therefore, they should also be medically evaluated (Exs. 54-163, 54-178, 54-308, 54-345);
- (3) The five-hour exemption should not apply to respirator use that is known to be physiologically burdensome (e.g., use of SCBAs by emergency responders) or to use under the job or working conditions (including hazardous exposures) that impose a significant physiological burden on employees (Exs. 54-5, 54-68, 54-92, 54-107, 54-137, 54-153, 54-158, 54-159, 54-187, 54-194, 54-195, 54-206, 54-208, 54-213, 54-224, 54-247, 54-264, 54-265, 54-275, 54-283, 54-290, 54-327, 54-342, 54-348, 54-363, 54-395, 54-415, 54-427, 54-429, 54-453);
- (4) The five-hour exemption would be too difficult for OSHA to enforce or could not be administered effectively and efficiently by employers (Exs. 54-70, 54-136, 54-167, 54-196, 54-244, 54-250, 54-267, 54-327, 54-348, 54-443);
- (5) The health of employees with preexisting medical problems would be endangered because these problems may go undetected until the five-hour limit is reached (and, in some cases, may never be detected if employees "self-select" into jobs with little respirator use because of their medical problems) (Exs. 54-92, 54-159, 54-247, 54-415, 54-441, 54-455); and
- (6) The five-hour exemption is not appropriate because every employee who uses a respirator should have a medical evaluation (Exs. 54-6, 54-46, 54-79, 54-196, 54-202, 54-208, 54-214, 54-218, 54-233, 54-272, 54-275, 54-287, 54-289, 54-295, 54-357, 54-394, 54-420, 54-424, 54-430, 54-434, 54-453), or the exemption is arbitrary, has no scientific basis, or would increase an employer's risk of liability (Exs. 54-188, 54-434).

Several commenters recommended that medical evaluation not be required for SCBA users (Exs. 54-68, 54-320, 54-331, 54-353); that medical evaluations for emergency responders be contingent on respirator use exceeding five hours per year (Ex. 54-429); or that emergency responders be exempted from medical evaluation requirements that are unique to employees who use airline respirators or SCBAs (Ex. 54-420).

Some commenters recommended adopting the five hours per week exemption (Exs. 54-14, 54-80, 54-91, 54-182, 54-220, 54-223, 54-224, 54-252, 54-283, 54-319) to achieve cost savings and improve the efficiency of the respiratory protection program. Two commenters (Exs. 54-177, 54-402) stated that the five-hour limit represented the point at which the effects of job-related physical stress should be medically evaluated. Although generally endorsing the provision, several commenters (Exs. 54-168, 54-206, 54-209, 54-295, 54-357, 54-366) found the phrase "during any work week" to be vague, confusing, or in need of being defined.

Several commenters wanted the five hours per week limit revised upwards. One commenter (Ex. 54-300) recommended that the limit be raised to 10 hours per week, while another commenter (Ex. 54-249) endorsed a limit of 30 days per year. A third commenter (Ex. 54-116) stated that the limit could be increased, without danger, to 10 hours per week for firefighters who use SCBAs, but presented no data to support this position, while three other commenters (Exs. 54-209, 54-254, 54-454) stated that a 10 or

15-hour per week limit could be tolerated without stress by most employees who use respirators. One commenter (Ex. 54-435) believed that the exemption should be broadened to cover seasonal employees because medical evaluations are too difficult to administer to these employees. Another commenter (Ex. 54-263) opposed any requirement for the medical evaluation of employees who use respirators.

One commenter recommended that medical evaluations not be required for employees who use disposable half-mask or dust mask respirators, regardless of workplace exposure conditions (Ex. 54-329). A number of commenters suggested eliminating medical evaluations if employers choose to provide respirators to their employees (i.e., if they are not required by OSHA to provide such respirators) (Exs. 54-69, 54-91, 54-265, 54-287, 54-295, 54-320, 54-327, 54-339, 54-346, 54-421); two of these commenters (Exs. 54-69, 54-339) expressed the concern that employers may stop offering respirators to their employees if medical evaluation is required in these cases.

The final standard, as noted above, provides an exception from the requirement that employees who use dust masks on a voluntary-use basis, as defined in paragraph (c), must be medically evaluated. OSHA based the decision to require medical evaluation for all employees required to use respirators, and for those employees voluntarily using negative pressure respirators, on a number of scientific studies, discussed below, which demonstrated that adverse health effects can result, in some cases, even from short duration use of respirators. Several experimental studies in the record show that even healthy individuals using what is generally believed to be a "low risk" respirator for short periods can experience adverse physiological and psychomotor effects. In one experiment (Ex. 64-388), 12 individuals using low resistance, disposable half-mask respirators under heavy workloads (using a treadmill apparatus) for only five minutes experienced statistically significant elevations in heart and respiratory rates, systolic and diastolic blood pressure, and body temperatures compared with these measures in the same individuals under control (i.e., no respirator use) conditions. Some of these effects were observed while the study participants were working at light and moderate workloads. For two of these individuals, the study's author classified blood pressure changes at heavy workload levels as "clinically important." These results suggest that in an individual with cardiac insufficiency, such physiological stress could cause fatal arrhythmia.

In another study (Ex. 64-444), 15 individuals used a full facepiece respirator while performing light, moderate, and heavy workloads on a bicycle ergometer for 15 minutes. Immediately following the 15 minute exercise period, the ability of the individuals to maintain their equilibrium (i.e., postural stability) was assessed using a special platform designed for this purpose. Under every workload condition, respirator use resulted in significantly increased heart rates and impaired equilibrium compared to conditions when the individuals did not use respirators.

A third study (Ex. 64-490) involved 12 individuals, each of whom exercised for 30 minutes on a bicycle ergometer at a light-to-moderate workload while using one of three types of respirators, i.e., disposable half-mask, negative pressure half-mask, and full facepiece airline respirators. After taking a 10 minute rest, the study participants repeated the procedure until each respirator type had been tested. Compared to the control condition in which the subjects exercised without respirators, the individuals were found to consume more oxygen while exercising with the negative pressure half-mask and full facepiece airline respirators, and to have higher systolic and diastolic blood pressures while using the full facepiece airline respirator. Under the test conditions of this study, therefore, negative pressure half-mask and full facepiece airline respirators imposed significant physiological stress on the respirator users.

Louhevaara (Ex. 164, Attachment D), after reviewing the available research literature on respirator physiology, concluded that the major physiological effects of negative pressure respirators and

supplied-air respirators, as well as SCBAs, are "alterations in breathing patterns, hypoventilation, retention of carbon dioxide, and [an] increase in the work of breathing," and that these effects are worse under conditions of increased filter resistance, poor respirator maintenance, and heavy physical work. Sulotto et al. (Ex. 164, Attachment D) found that negative pressure respirators resulted in higher breathing resistances as physical workload on a bicycle ergometer increased, leading to substantially reduced breathing frequency, ventilation rate, oxygen uptake, and carbon dioxide production.

One study (Ex. 164, Attachment D, Beckett) that reviewed the scientific literature on the medical effects of respirator-imposed breathing resistance among healthy young men noted that "[t]hese and other studies indicate no clinically significant impairment of normal respiratory function at submaximal workloads with the loads imposed by currently approved, properly maintained, negative pressure respiratory protective devices." This reviewer stated further, however, that "[r]elatively less is known about the use of respirators by those with abnormal physiology (for example, obstructive or restrictive pulmonary diseases) and about the use of respirators whose resistance characteristics are altered by excessively long use, such that inspiratory resistance is increased by the deposition of matter within the filter or absorptive elements of the canister."

The Agency finds that these studies demonstrate the potential for adverse health effects resulting from respirator use, even for healthy employees using respirators designed for low breathing resistance and used for short durations. The Agency believes, therefore, that respirator use would impose a substantial risk of material impairment to the health of employees who have preexisting respiratory and cardiovascular impairments. As the earlier discussion of final paragraph (e)(1) indicates, the record contains overwhelming support for requiring medical evaluation of respirator users; many employers who provided comments to the record have established medical evaluation programs for all employees who use respirators (see, e.g., comments by Organization Resources Counselors, Inc., Ex. 54-424). Consequently, OSHA finds, consistent with the results of these studies and the entire record, that the use of any respirator requires a prior medical evaluation to determine fitness.

Other considerations that have caused OSHA to make this decision are the potential impairment of health that may occur among employees with preexisting medical problems if these problems are not detected before respirator use; the need to identify medical problems that can arise even from short term use of respirators of the types known to impose severe physical stress on employees (e.g., SCBAs); and the administrative difficulties and inefficiencies that employers would experience if OSHA adopted a provision that required medical evaluations only of some respirator users, i.e., those using certain types of respirators or those using them for a specified number of hours per week.

OSHA specifically disagrees with those commenters who stated that no medical evaluations are needed for employees who only occasionally use SCBAs. SCBAs create the highest cardiovascular stress of any type of respirator because of their weight, and they are often used in high physical stress situations, such as fires and other emergencies. This combination of stressors makes medical evaluation necessary to avoid myocardial infarction in susceptible individuals; at least 40 million people in the United States have some form of heart disease (Levy, in 54 FR 2541).

One commenter (Ex. 54-284) recommended that the required medical evaluations should be discontinued after an employee stops using respirators. OSHA agrees with this recommendation, and has revised final paragraph (e)(1) accordingly.

Paragraph(e)(2) -- Medical Evaluation Procedures

**Paragraph (e)(2)(i).** This final paragraph requires the employer to identify a physician or other licensed health care professional (PLHCP) to perform medical evaluations using a medical questionnaire or medical examination. Two major issues were raised in the rulemaking record: (1) What must be done to evaluate employees, and (2) who must perform the evaluation. Proposed paragraphs (e)(1) and (e)(3) would have required physician involvement in the medical evaluation process, with nonphysician health care professionals permitted to review the employee's medical status only under the supervision of a licensed physician. The final rule allows the evaluation to be performed either by a physician or other licensed health care professional (e.g., nurse practitioners, physician assistants, occupational health nurses), provided that their license permits them to perform such evaluations.

Many commenters, representing labor, management, occupational nurses, nurse practitioners, and physician assistants, recommended that OSHA permit the use of nonphysician health care professionals (usually nurse practitioners, physician assistants, occupational health nurses, or registered nurses) to take medical histories, conduct physical examinations (including pulmonary function tests), and administer and review employee responses to medical questionnaires, provided that they do so under the supervision of a licensed physician (Exs. 54-6, 54-7, 54-21, 54-134, 54-153, 54-157, 54-171, 54-176, 54-185, 54-187, 54-205, 54-239, 54-240, 54-244, 54-245, 54-251, 54-267, 54-273, 54-304, 54-357, 54-363, 54-381, 54-387, 54-389, 54-396, 54-424, 54-432, 54-443, 54-453). Some commenters stated that nonphysician health care professionals are competent to conduct medical assessments, while physician supervision or involvement would guarantee that quality control was maintained over the assessment process (Exs. 54-273, 54-363, 54-381, 54-443, 54-453). Two of these commenters (Exs. 54-278, 54-430) noted that any health care professional could review medical questionnaires without physician supervision, but that physicians should conduct or supervise any medical examinations conducted on the basis of answers to the medical questionnaires.

Many other commenters, representing labor, management, and physicians, preferred that only physicians be involved in medical evaluation programs (Exs. 54-14, 54-46, 54-70, 54-101, 54-107, 54-150, 54-151, 54-165, 54-175, 54-180, 54-186, 54-189, 54-199, 54-217, 54-219, 54-220, 54-249, 54-271, 54-295, 54-313, 54-352, 54-455). This preference was usually based on the prior or current practices of these commenters. For example, the American College of Occupational and Environmental Medicine (ACOEM) (Ex. 54-453) stated that the health status of employees in a respiratory protection program should be reviewed by physicians with specific training and experience in occupational medicine because these medical specialists have knowledge of the physical demands of respirator use needed to make valid decisions regarding an employee's medical ability for the program. A similar recommendation was made by the Service Employees International Union (Ex. 54-455).

Some commenters recommended that the employee's medical ability to use a respirator be evaluated solely by nonphysician health care professionals (Exs. 54-16, 54-19, 54-25, 54-32, 54-79, 54-159, 54-184, 54-213, 54-222, 54-226, 54-253, 54-265, 54-272, 54-278, 54-397). Most of these commenters cited their favorable experiences with nonphysician health care professionals, and pointed to the cost savings of using nonphysicians (Exs. 54-19, 54-79, 54-184, 54-226, 54-253). Several of these commenters provided additional justifications. For example, one commenter (Ex. 54-184) stated that "physician assistants, by education, training, and state regulation, are well qualified and legally able to perform all aspects of a medical evaluation," and argued that the scope of practice with regard to medical evaluations should remain the prerogative of state licensing boards.

Another commenter (Ex. 54-213) noted that "many physicians are not familiar with occupational health risks as they relate to respiratory exposures, types of respiratory protection available, and work

requirements." This commenter stated further that "nurse[s] or other qualified health care professional[s], operating within their licensed scope of practice, [have] clinical expertise and knowledge of the work environment and can best evaluate the physical requirements placed on the user of respiratory protective equipment" and that "[u]se of qualified health care professionals other than physicians is cost- beneficial to employers, particularly [in] small business settings" (Ex. 54-213).

The American Thoracic Society (Ex. 54-92), which recommended the use of medical questionnaires rather than medical examinations, stated that "there is no demonstration that [physician-based] examinations actually predict who will develop difficulties with respirator use" because "[v]ery few physicians have in-depth knowledge of respiratory protection and workplace hazards sufficient to render a fully reasoned view."

None of the commenters, including those who used nonphysician health care professionals to conduct medical evaluations as part of their respiratory protection programs, cited any data or experience showing that the type of PLHCP qualification and licensure, or the manner in which PLHCPs are involved in the medical evaluation process, had compromised the medical evaluation process or had resulted in faulty medical evaluations.

After reviewing the entire record, OSHA decided to allow any PLHCP to evaluate an employee's medical ability to use a respirator, providing that the PLHCP is authorized to do so by his or her state license, certification, or registration. Although OSHA agrees that physicians with training and experience in occupational medicine are highly qualified to conduct medical evaluations for respirator use, an insufficient number (slightly more than 2,000 nationally) of these specialists are available for this purpose (personal communication, American Board of Medical Specialties, to Vanessa Holland, M.D., 5/29/ 97). In addition, in circumstances where questions arise as to the employee's physical condition and capability, OSHA believes that the PLHCP can be relied on to consult with an appropriate specialist or physician.

After a review of the licensing provisions of the 50 states and Puerto Rico, OSHA concludes that state licensing laws often require some physician involvement in conducting the medical evaluations required by the final standard. For example, the majority of states require that nurse practitioners perform their medical functions under a formal written agreement with a physician. Only six states (i.e., Montana, New Mexico, North Dakota, Oregon, Vermont, and Washington) and Puerto Rico allow licensed nurse practitioners to function independently of physician supervision. Even these jurisdictions, however, require licensed nurse practitioners to refer patients to a physician for further evaluation and treatment when a medical problem beyond the nurse practitioner's level of expertise arises. OSHA believes that the states are best suited to judge the medical competencies of those PLHCPs who practice within their jurisdictions, and to regulate the scope of practice of these individuals.

To summarize, the final rule allows any PLHCP to administer the medical questionnaire or to conduct the medical examination if doing so is within the scope of the PLHCP's license. The basis for this decision includes the following:

- (1) The record (Exs. 54-19, 54-79, 54-92, 54-184, 54-253) generally supports the position that properly qualified PLHCPs, regardless of the type of health care specialization, are competent to assess the medical ability of employees to use respirators using accepted medical questionnaires or medical examinations;
- (2) Evidence in the record that employers who operate respiratory protection programs have successfully used PLHCPs, including nonphysicians, to conduct medical evaluations and to make medical ability recommendations, shows that nonphysicians have done so safely and efficaciously (Exs. 54-213, 54-240,

54-389);

(3) Providing employers with ready access, at reasonable cost, to the basic medical assessment skills required to perform at least the initial phases of employee medical evaluation for respirator use contributes to the efficient and effective allocation health care resources; and

(4) The lack of record support for a requirement allowing medical evaluations to be performed only by physicians. The record (Exs. 54-6, 54-7, 54-21, 54-134, 54-153, 54-157, 54-171, 54-176, 54-185, 54-187, 54-205, 54-239, 54-240, 54-244, 54-245, 54-251, 54-267, 54-273, 54-304, 54-357, 54-363, 54-381, 54-387, 54-389, 54-396, 54-424, 54-432, 54-443, 54-453) indicates that medical evaluations performed independently by nonphysician health care professionals, as defined by this section, are effective for at least the initial phases of an employer's medical evaluation program (i.e., evaluating the medical questionnaire or conducting an initial medical examination), and protect employee health as well as medical evaluations conducted only by physicians or with physician oversight. Employers are free, however, to select any PLHCP they wish to satisfy this requirement, provided that the PLHCP is qualified by license to do so. In some cases, the medical condition of the employee or the conditions of respirator use may warrant physician involvement, and OSHA is confident that LHCPs faced with such situations will seek such medical advice.

**Paragraph (e)(2)(ii).** Paragraph (e)(2)(i) requires employers to identify a PLHCP to perform the medical evaluations required by the final rule. It also specifies that employers may choose to use the medical questionnaire in Appendix C to conduct the initial medical evaluation or provide a medical examination that obtains the same information as the medical questionnaire. Employers are free to provide respirator users with a medical examination in lieu of the medical questionnaire if they choose to do so, but they are not required by the standard to administer a medical examination unless the employee gives a positive response to any question among questions 1 through 8 in Section 2, Part A of Appendix C (see paragraph (e)(3)).

The approach taken in the final rule thus resembles the third alternative proposed by OSHA in the NPRM: reliance on a medical questionnaire (with medical examination follow-up if positive responses are given to selected questions on the medical questionnaire). Those commenters (Exs. 54-3, 54-14, 54-46, 54-67, 54-107, 54-151, 54-168, 54-175, 54-180, 54-218, 54-220, 54-224, 54-226, 54-227, 54-240, 54-244, 54-264, 54-292, 54-294, 54-295, 54-324, 54-326, 54-327, 54-339, 54-346, 54-352, 54-366, 54-370, 54-210, 54-432, 54-434, 54-443, 54-445, 54-453) who preferred the other alternatives (i.e., medical history and medical examination for all respirator users, or medical examination and written opinion) supported their views with a variety of opinions.

A number of the commenters who recommended the medical history and examination alternative (Exs. 54-153, 54-165, 54-218, 54-226, 54-227, 54-263, 54-264, 54-294, 54-326, 54-327, 54-363, 54-443) favored this approach only in those cases when employees would be using SCBAs, while others (Exs. 54-16, 54-220) stated that medical questionnaires should be used only for employees who use dust masks, and that other respirator users should receive a medical history and examination regardless of the duration of respirator use. Another commenter (Ex. 54-101) recommended that medical questionnaires be administered to employees who use dust masks for fewer than five hours per week, while other employees should receive a medical history and examination. One commenter favored medical questionnaires only for respirator users who perform "isolated operations," while recommending that respirator use in other employment settings require a medical history and/or examination (Ex. 54-46). Another commenter stated that employees using respirators under workplace exposure conditions exceeding an OSHA PEL should

receive a medical history and examination, while respirator users exposed to other workplace atmospheres should only be required to complete a medical questionnaire (Ex. 54-339).

Those commenters (Exs. 54-7, 54-16, 54-21, 54-25, 54-32, 54-69, 54-91, 54-92, 54-101, 54-134, 54-142, 54-153, 54-154, 54-157, 54-158, 54-165, 54-170, 54-171, 54-172, 54-173, 54-176, 54-187, 54-190, 54-192, 54-194, 54-197, 54-205, 54-206, 54-208, 54-209, 54-213, 54-214, 54-219, 54-222, 54-223, 54-234, 54-239, 54-241, 54-242, 54-245, 54-251, 54-252, 54-253, 54-254, 54-262, 54-263, 54-265, 54-267, 54-269, 54-272, 54-273, 54-275, 54-278, 54-284, 54-286, 54-289, 54-296, 54-304, 54-309, 54-319, 54-320, 54-325, 54-330, 54-332, 54-334, 54-342, 54-350, 54-357, 54-361, 54-363, 54-381, 54-389, 54-396, 54-401, 54-421, 54-424, 54-426, 54-428, 54-429, 54-430, 54-441, 54-453, 54-455) recommending medical questionnaires (proposed alternative 3) objected to the medical examination and written opinion approaches because, in their view, medical examinations and opinions are difficult to obtain, have poor predictive value, and are expensive, especially for workplaces that have high employee turnover. Regarding costs, the American Iron and Steel Institute (Ex. 175) stated that the medical opinion required by alternative 1 would cost their industry \$195 per employee, including \$150 for the medical examination and opinion, and \$45 in lost work time for the employee.

The record does not demonstrate that any of the three alternatives were superior in detecting medical conditions that could potentially limit employee use of respirators. Testimony at the hearing by the United Steel Workers of America (USWA) (Tr. 1059 and following) in support of alternative 2 (medical history and examination) provided information on the ability of different medical assessment procedures to detect disqualifying medical conditions. This information showed that, among 126 employees, 16 were disqualified for respirator use because of various medical conditions. Medical histories identified six of the employees with these conditions, while a medical examination conducted by a physician identified the remaining 10 employees. The USWA attributed the reduced effectiveness of the medical histories in this instance to the lack of awareness among employees of the medical conditions that could potentially limit such use.

The United Steel Worker's testimony (Tr. 1059 and following) also described a study in which physician-administered medical examinations were found to be about 95 percent accurate and medical questionnaires were found to be 60 to 70 percent accurate in identifying specific medical problems. The final rule is designed to overcome this problem to some extent by requiring that employees be trained to recognize the medical signs and symptoms associated with the physiological burden imposed by respirator use; see paragraph (k)(1)(vi).

A number of commenters supported the medical questionnaire option on the grounds that this approach is more efficient and effective. The United States Air Force (Ex. 54-443G) stated, "After working under the provisions of [proposed] alternative 2 for several years and comparing the Air Force's occupational health and cost savings by reducing unnecessary medical evaluations and freeing physician time under [proposed] alternative 3, the Air Force supports [proposed] alternative 3." Similarly, the CITGO Petroleum Corporation (Ex. 54-251) endorsed medical questionnaires as more cost-effective than medical examinations. CITGO administered medical examinations to a sample of 1634 employees in 1994 to detect respiratory disorders, a major medical concern for respiratory protection programs, and identified only one abnormal case that was confirmed after referral for follow-up medical examination.

An additional study involving validation of medical questionnaires was described by Organization Resources Counselors, Inc. (ORC) (Ex. 54-424). One of ORC's member companies, a large, diversified manufacturing organization, recently reviewed approximately 700 records of employee respirator medical

examinations to determine the effectiveness of using a medical questionnaire as a screening tool. This company currently gives all respirator users a full medical examination in addition to having them fill out a medical questionnaire. The records review revealed that, out of 700 examinations, only 10 (less than 2%) required medical limitations on respirator use. These limitations were due to claustrophobia, asthma, and heavy smoking. All of these limitations would have been identified, in the company's view, by a medical questionnaire. The employees identified through the medical questionnaire could then have been given a complete medical examination. By using the medical questionnaire as a screening tool, this company believes it could have eliminated unnecessary examinations for 98% of its worker population.

A private physician and three management groups (Exs. 54-32, 54-424, 55-29, 155) submitted medical questionnaires to the record and expressed satisfaction with these medical questionnaires, in terms of both the medical conditions that were detected and the administrative efficiency of the process; these commenters, however, recommended that physicians be involved in reviewing the medical questionnaires. Several commenters (Exs. 54-70, 54-159, 54-215) endorsed the medical evaluation procedures specified in the American National Standard Institute's (ANSI) consensus standard Z88.6-1984, titled "American National Standard for Respiratory Protection -- Respirator Use -- Physical Qualifications for Personnel." This ANSI standard recommends that a medical history questionnaire be administered to employees who are enrolled in respiratory protection programs, and that a physician review each employee's responses to the medical questionnaire to determine if additional medical examinations are required.

OSHA concludes that information in the record supports the use of medical questionnaires for detecting medical conditions that may disqualify employees from, or limit employee participation in, respiratory protection programs. OSHA believes that the ORC study (Ex. 54-424) provides support for the conclusion that medical questionnaires are an efficient and effective means of screening employees for subsequent medical examination. OSHA also believes that the training required by paragraph (k)(1) of the final rule, which requires that employees understand the limitations of respirator use and recognize the signs and symptoms of medical problems associated with respirator use, will increase employee awareness and overcome the problems that the USWA (Tr. 1059 and following) noted in its testimony. A number of commenters (Exs. 54-107, 54-151, 54-153, 54-165, 54-190, 54-218, 54-251, 54-253, 54-272, 54-339, 54-361, 54-401) stated that medical questionnaires had several advantages over the other alternatives, including simplicity and efficiency of use, completeness and accuracy of the medical information obtained, and adaptability (i.e., easily revised to accommodate new or different medical problems, different employee groups, and changing job, workplace, and respirator conditions). An additional advantage of medical questionnaires is lower cost, most notably in terms of development, administration, and analysis.

Employers are free to use medical examinations instead of medical questionnaires, but are not required by the standard to do so (see paragraph (e)(2) of the final standard). OSHA also recognizes that medical examinations are necessary in some cases, e.g., where the employee's responses to the medical questionnaire indicate the presence of a medical condition that could increase the risk of adverse health effects if a respirator is used. Examples of such cases are employees who report a history of smoking, pulmonary or cardiovascular symptoms or problems, eye irritation, nose, throat, or skin problems, vision or hearing problems (for employees who use full facepiece respirators), and musculoskeletal problems (for employees who use SCBAs). In addition, certain workplace conditions or job requirements, such as SCBA use, being an emergency responder or a member of a HAZMAT team, working in an IDLH atmosphere, wearing heavy protective clothing, or performing heavy physical work, may warrant a medical examination. In the future, however, OSHA may, on a case-by-case basis, require medical examinations to detect respirator-related conditions in its substance-specific standards, depending on the particular

circumstances and physiological effects of the toxic substance being regulated.

The medical questionnaire in Appendix C of the final standard is based on the medical history questionnaire contained in ANSI Z88.6- 1984, as well as medical questionnaires submitted to the record by commenters (Exs. 54-32, 54-424, 55-29). The medical questionnaire is designed to identify general medical conditions that place employees who use respirators at risk of serious medical consequences, and includes questions addressing these conditions. These medical conditions include seizures, diabetes, respiratory disorders and chronic lung disease, and cardiovascular problems. As the discussion of the Introduction and paragraphs (e)(1) and (5) in this Summary and Explanation demonstrate, these conditions have been found to increase the risk of material impairment among employees who use respirators. A question asking about fear of tight or enclosed spaces was included in the medical questionnaire because claustrophobia and anxiety associated with such spaces were mentioned by a commenter as the most frequent medical problem detected during respirator training (Ex. 54-429); additionally, research submitted to the record (Ex. 164, Attachment D, Morgan) indicates that more than 10 per cent of "normal" young men experience dizziness, claustrophobia, or anxiety attacks while exercising during respirator use.

Questions 10 through 15 of the medical questionnaire in Appendix C must be answered only by employees who use a full facepiece respirator or SCBA. These questions ask about hearing and vision impairments, as well as back and other musculoskeletal problems. Employees who use full facepiece respirators, for example, must be asked about eye and hearing problems because the configuration of these respirators (e.g., helmets, hoods) can add to the limitations associated with existing visual and auditory impairments, resulting in an elevated risk of injury to employees with such impairments, as well as to other employees who may rely on the impaired employee to warn them of emergencies (Ex. 164, Attachment D, Beckett). The heavy weight and range-of-motion limitations of SCBAs may prevent employees who have existing problems in the lower back or upper or lower extremities from using these respirators.

A physician (Ex. 54-16) commented that an employee's medical history should be considered by the PLHCP in making a recommendation about the employee's ability to use respirators. This commenter specified a number of prior medical conditions, including those involving cardiovascular and respiratory health, psychological variables, neurological and sensory organ status, endocrine function, and the use of medications that would be useful to PLHCPs in arriving at a medical ability recommendation. OSHA believes that these variables, especially cardiovascular and respiratory fitness, are important determinants of respiratory fitness, and, therefore, included items specific to these medical conditions in the medical questionnaire. OSHA concludes that the employee's answers to the medical questionnaire will provide an adequate medical history for the PLHCP.

Two commenters (Exs. 54-222, 54-251) requested that OSHA define medical evaluation procedures and provided sample definitions. OSHA believes that the regulatory text of the final rule, which has been clarified and simplified since the proposal, provides clear guidance and that these definitions are, therefore, not necessary. As used in the final rule, "medical evaluation" means the use of subjective (e.g., medical questionnaires) or objective methods (e.g., medical examinations), as well as other available medical, occupational, and respirator information, to make a determination or recommendation about an employee's medical ability to use respirators; "medical examination" means the use of objective methods (i.e., manipulative, physiological, biochemical, or psychological devices, techniques, or procedures) to directly assess the employee's physical and mental status for the purpose of making a recommendation regarding the employee's medical ability to use the respirator.

Paragraph (e)(3) -- Follow-up Medical Examination

Paragraph (e)(3) addresses follow-up medical examinations and states that the employer must provide such examinations to any employee who gives a positive response to any question among questions 1 through 8 in Section 2, part A in Appendix C. The PLHCP is free to include any medical tests, consultations, or diagnostic procedures that he or she determines to be necessary to assist him or her in making a final determination of the employee's ability to use a respirator. OSHA expects that the number of cases where PLHCPs will have to provide follow-up examinations will be small, because it is generally possible to recommend against respirator use, or determine the limitations to place on an employee's use of respirators, on the basis of responses to the medical questionnaire. However, where difficult medical issues are involved, such as the need to make a differential diagnosis or to assess an employee's ability to handle the physical stress imposed by an extra-hazardous job, a medical examination and involvement of a physician may be needed. Many commenters (Exs. 54-92, 54-101, 54-134, 54-171, 54-223, 54-278, 54-304, 54-363, 54-389) endorsed this requirement. Two commenters (Exs. 54-151, 54-189) stated that medical examinations should not be limited to answers on the medical questionnaire that indicate a need for medical examinations. A few commenters (Exs. 54-153, 54-176, 54-218) recommended that a mandatory medical examination requirement based on the employee's responses to the medical questionnaire is wasteful and unnecessary.

OSHA agrees that PLHCPs should be permitted to obtain any medical information they believe would be useful in arriving at a final medical recommendation, and they should not be limited to investigating problems associated only with answers on the medical questionnaire. Information from medical examinations may also be needed to validate an answer that a PLHCP believes is incorrect. Also, as recommended by ORC (Ex. 54-424), a PLHCP should be free to investigate through medical examination any medical conditions related to respirator use that may not have been addressed by the medical questionnaire or may not have been obtained from other sources.

#### Paragraph (e)(4) -- Administration of the Medical Questionnaire and Examinations

**Paragraph (e)(4)(i).** This paragraph sets out the procedures employers must follow when administering the medical questionnaire or examinations required by paragraph (e)(2). Paragraph (e)(4)(i) requires employers to administer the required medical questionnaire or examinations in a manner that protects the confidentiality of the employee being evaluated. In addition, the evaluation must be administered during normal work hours or at a time and place convenient to the employee, and in a manner that ensures that the employee understands the questions on the medical questionnaire. Although this requirement was not specifically proposed, it is consistent with OSHA policy and with Section 6(b)(7) of the Act. OSHA has included similar requirements in a number of substance-specific health standards (see, e.g., the Cadmium standard, 29 CFR 1910.1027, the Lead standard, 29 CFR 1910.1025, and the Benzene standard, 29 CFR 1910.1043). If an employee must travel off-site for medical evaluation, travel arrangements must be made, and costs incurred paid or reimbursed, by the employer.

The final standard differs from the proposal in that it does not specify who must supervise the administration of the medical questionnaire. Alternative 3 in the proposal would have required that the medical questionnaires be administered by "a health professional or a person trained in administering the questionnaire by a physician." (See 59 FR 58911.) Commenters (Exs. 54-25, 54-69, 54-153, 54-165, 54-190, 54-218, 54-251, 54-253, 54-272, 54-339, 54-361, 54-401) recommended that persons performing this function have various qualifications, e.g., be a trained designee of the employer, a safety or health professional, a physician, or a nonphysician health care professional operating under the supervision of a physician. Some commenters (Exs. 54-25, 54-101, 54-214, 54-389, 54-421) recommended that a PLHCP be present during administration of the medical questionnaire to ensure the accuracy and validity of the

employee's answers. Others (Exs. 54-69, 54-361) stated that the medical questionnaire should be designed so as to be easily comprehended by the employee and simple to administer, thereby requiring only minimal involvement by an employer. OSHA agrees with those commenters (Exs. 54-69, 54-361) who urged that the medical questionnaire be easy to understand, and has developed the medical questionnaire in Appendix C accordingly. OSHA does not believe that oversight is necessary because the standard requires that the medical questionnaire be understandable to the employee and that the employee be given an opportunity to ask questions of the PLHCP administering the questionnaire.

Although the OSHA medical questionnaire is designed to be easily comprehended by employees, paragraph (e)(4)(i) of the final standard specifically requires that employers ensure that employees understand the medical questionnaire. For employees who are not able to complete the medical questionnaire because of reading difficulty, or who speak a foreign language, OSHA requires that the employer take action to ensure that the employee understands the questions on the medical questionnaire. Language and comprehension deficits could invalidate the answers of such employees and result in inaccurate determinations. Under these circumstances, the PLHCP may assist the employee in completing the medical questionnaire (perhaps with the aid of an employer-supplied interpreter). The employer also may have the medical questionnaire translated into the employee's language or administer a physical examination that meets the requirements of paragraph (e)(2) of the final standard. In fulfilling this requirement, OSHA is not requiring employers to hire professional interpreters. Instead, employers may use an English-speaking employee who can translate the medical questionnaire into the questionnaire taker's native language, or other nonprofessional translators who can perform the same function (for example, a friend or family member of the test taker).

**Paragraph (e)(4)(ii).** This paragraph requires the employer to permit the employee to discuss the medical questionnaire results with a PLHCP. Employees who are uncertain of the significance of the questions asked will thus be able to obtain clarification. One commenter, Dr. Ross H. Ronish, Site Medical Director for the Hanford Environmental Health Foundation (Ex. 54-151), agreed that the opportunity for discussion between the PLHCP and the employee would improve the usefulness of the medical questionnaire. The standard does not require the employer to follow a specific procedure in providing employees with the opportunity to discuss the medical questionnaire with a PLHCP. Employers must, however, at least inform employees that a PLHCP is available to discuss the medical questionnaire with them and notify the employees how to contact the PLHCP. For example, the employer could post the PLHCP's name and telephone number in a conspicuous location, or include this information on a separate sheet with the medical questionnaire.

Paragraph (e)(5) -- Supplemental Information for the PLHCP

**Paragraph (e)(5)(i).** The first requirement in this paragraph requires employers to provide the PLHCP with specific information for use in making a recommendation regarding the employee's ability to use a respirator. OSHA had proposed a similar requirement, stating that "[i]n advance of the medical examination the employer shall provide the examining professional with [supplemental] information \* \* \*" OSHA received four comments (Exs. 54-181, 54-234, 54-330, 54-445) on this proposed requirement. These commenters stated that only supplemental information requested by the PLHCP should be provided because PLHCPs can best determine what information they need to make medical-ability recommendations; additionally, limiting the requirement to information requested by the PLHCP would lower the associated paperwork burden. The Boeing Company (Ex. 54-445), for example, stated, "The employer should not be required to provide additional information unless requested to do so by the examining physician." Another commenter (Ex. 54-434) stated that the proposed supplemental

information might not be meaningful to every PLHCP.

OSHA believes that the supplemental information specified is important to the PLHCP in making a recommendation regarding the employee's medical ability to use the respirator. However, as indicated in paragraph (e)(5)(ii) of the final standard, this information need only be provided once to the PLHCP unless the information differs from what was provided to the PLHCP previously, or a new PLHCP is conducting the medical evaluation.

With few exceptions, the supplemental information that must be provided by the employer to the PLHCP is the same information listed in the proposed regulatory language for alternative 3 (59 FR 58911, paragraphs (e)(vi) (A) to (G)). Three commenters (Exs. 54-160, 54-191, 54-287) endorsed the entire list of supplemental information items in the proposal. Most of the commenters who took exception to the proposed list disagreed with the item requiring that information be provided to the PLHCP on the substances to which the employee will be exposed (i.e., paragraph (e)(vi)(B) of proposed alternative 3); two commenters (Exs. 54-352, 54-453), however, believed it was important to specify these substances so that the PLHCP would be aware of the hazards in the workplace. One commenter (Ex. 54-339) stated that information on substance exposure would be useful to the program administrator for fit testing, but was not needed by the PLHCP. Another commenter (Ex. 54-208) stated that information about these substances was unnecessary because OSHA intended to propose a separate rule for medical surveillance, and one commenter (Ex. 54-273) wanted this item to be deleted and replaced by an item informing the PLHCP about the employee's use of impervious clothing because such clothing, if worn, may impose serious heat stress on the employee.

The record also contains an article by Dr. William S. Beckett advising occupational health professionals on medical evaluations for respirator use (Ex. 164, Attachment D). The article addressed the need to provide these professionals with exposure information: "An employer's inability to provide this basic information [regarding employee exposure levels] on which a respirator choice has been made should throw the adequacy of the respiratory protection program into serious doubt." Dr. Beckett explained that such information was necessary because preexisting lung impairments make some employees "more sensitive to the effects of some occupational agents and [these employees] may thus suffer further impairment at exposure concentrations that would not affect a normal worker." In explaining these effects, Dr. Beckett stated that employees who have become "sensitized immunologically to a workplace substance may not be able to attain protection factors using usual respirator precautions even though the same respirator might be adequate for individuals not sensitized to the substance." Dr. Beckett noted that "the worker sensitized to toluene di-isocyanate (TDI) \* \* \* will experience alterations in pulmonary function at an air concentration of 0.001 ppm TDI while normal individuals will not experience symptoms at 20 times this concentration."

In response to these comments, OSHA has modified the proposed requirement specifically requiring employers to inform PLHCPs of the substances to which employees may be exposed. Under paragraph (e)(5)(iii) of the final rule, employers must provide the PLHCP with a copy of the written respiratory protection program. As required by paragraph (c)(1)(i) of the final rule, the written program must specify the procedures for selecting respirators for use in the workplace; accordingly, these procedures must describe the workplace exposure conditions that require respirator use. OSHA believes these descriptions will provide the necessary information, while imposing little additional burden on employers.

These requirements are necessary, the Agency concludes, because employees can have medical conditions that predispose them to respond adversely to the workplace substances to which they are exposed, and the

resulting effects can impair an employee's ability to use some types of respirators. Consequently, providing PLHCPs with information about the workplace substances to which employees are exposed will assist the PLHCPs in determining if these substances may interact with preexisting medical conditions to impair an employee's ability to use the respirator. In addition, the Agency believes that knowledge about the substances to which employees are exposed will provide an indirect means of determining the effectiveness of the overall respiratory protection program. If employees experience signs and symptoms typically associated with exposure to the workplace substances documented in the written respiratory protection program, the PLHCP can alert the employer to these effects, and corrective action can be taken.

In response to the commenter who urged OSHA to include information on impervious clothing, OSHA notes that the final standard requires employers to provide information on other protective clothing and equipment to be worn by the employee. This item will provide information on impervious clothing, and, therefore, addresses the commenter's concerns regarding the heat stress imposed on employees by such clothing.

One commenter (Ex. 54-214) stated that descriptions of the type of work performed and physical work effort should be dropped from the list, while another commenter (Ex. 54-445) believed that information about the type of respirator would not be useful to the PLHCP. As noted in the discussion of final paragraph (e)(1) in this Summary and Explanation, cardiovascular and respiratory fitness are important variables in determining the ability of an employee to use a respirator. The physical work effort required by the employee's job, in combination with the characteristics of the respirator (e.g., weight, breathing resistance, interference with range of motion), are variables that must be considered by a PLHCP in making a recommendation regarding the employee's fitness to use the respirator.

A study conducted by NIOSH (Ex. 64-469) found that tolerance to work conditions, heart rate, and skin temperature were affected by three variables: the type of personal protective clothing worn, the weight of the respirator, and the level of physical work effort. In the NIOSH study, nine healthy young men who had prior experience with respirators and personal protective clothing (most of them were firefighters), exercised on a treadmill at low and high physical workloads under each of the following conditions: wearing light work clothing and using a low-resistance disposable half-mask respirator (LT condition); wearing light work clothing and using an SCBA (SCBA condition); wearing firefighter turnout gear and using an SCBA (FF condition); and wearing chemical protective clothing and using an SCBA (CBC condition). While exercising at low physical workloads under the LT, SCBA, FF, and CBC conditions, the study participants tolerated these work conditions for 167, 130, 26, and 73 minutes, respectively; at high physical workloads, the four protective clothing conditions were tolerated for 91, 23, 4, and 13 minutes. Heart rates and skin temperatures rose as tolerance diminished. At the high workload level, testing under the SCBA, FF, and CBC conditions had to be terminated early because the heart rates of the study participants reached critically high levels (i.e., 90% of the predicted maximal heart rate). At low physical workloads, heart rate rose progressively under the SCBA conditions (about 15 beats per minute) compared to the LT condition, then remained steady. Under high physical workloads, heart rates rose sharply and never reached a steady level until after the testing was terminated.

The authors of the NIOSH study noted that the work tolerance, heart rate, and skin temperature effects found in the study would be more severe among individuals who were not as healthy or experienced as the study participants. They attributed these effects both to the weight of the respirator and to the poor evaporative cooling properties of the personal protective clothing (i.e., the capacity to remove body heat under the humid conditions generated inside the protective clothing as a result of physical work). Based on these findings, the authors concluded that "[the study participants] wearing protective clothing and

respirators during exercise exhibited a significant degree of cardiorespiratory and thermoregulatory stress

\* \* \*

The conclusion reached by the NIOSH study is supported by other researchers who have tested the physiological effects of personal protective clothing combined with SCBA use among healthy men performing exercise or simulated work tasks under light to moderate levels of physical exertion. (See Ex. 164, Attachment D, Smolander et al. (1984), and Smolander et al. (1985).) These researchers found that personal protective clothing substantially increased oxygen consumption and carbon dioxide production, and recommended careful evaluation of the cardiovascular health and heat tolerance of workers who must wear personal protective clothing.

In another study (Ex. 64-445), healthy young men (average age: 29 years), older men (average age: 47 years), and women (average age: 29 years) used air-purifying respirators while performing the following simulated, low physical workload, mining task: lifting a shovel weighing 3.1 lbs. (6.8 kg.) from the floor to the top of a table (a distance of 3 feet (90 cm)), releasing the shovel's grip, then lifting the shovel from the table back to the floor and releasing the grip again. The task was performed at a rate of 10 cycles per minute for 20 minutes at temperatures of 73 deg. F (23 deg. C) and 104 deg. F (40 deg. C). The study participants wore appropriate mining clothing (i.e., pants, heavy shirt, gloves, leather apron, and safety helmet) while performing the task. The results showed that respirator use and heat combined to raise the heart rate substantially more than either variable alone, and that this effect was especially pronounced for the women.

This study, and the NIOSH study described earlier, demonstrated that information regarding such physiological stressors as physical work effort, respirator type and weight, personal protective clothing, and temperature and humidity conditions must be provided to PLHCPs who are responsible for medically evaluating employees for respirator use. The studies found that these stressors, especially respirator weight, impose physiological burdens that result in substantial impairment to functional capacity, even among healthy respirator users. OSHA believes, therefore, that information on respirator type and weight, personal protective clothing, and temperature and humidity must be provided to, and be considered by, PLHCPs to ensure that only employees who can endure these stressors without adverse medical consequences are recommended for the respiratory protection program; consequently, these items were included in paragraph (e)(5)(i) of the final standard.

The United Steelworkers (Tr. 1057) stated that "[PLHCPs should be] mandated to have knowledge of the workplace, and possibly to have visited it at some point in time." OSHA agrees that familiarity with the workplace is important, and believes that many employers will make such visits a requirement. OSHA believes, however, that making such visits a requirement is unnecessary because the information required to be given to the PLHCP by the standard will be sufficient for the PLHCP to make a valid recommendation regarding the employee's ability to use the respirator.

Other revisions made to the proposed paragraph include a requirement that the weight of the respirator be provided to the PLHCP, principally to inform the PLHCP of the physical stress that a heavy respirator may impose on an employee's cardiovascular and respiratory systems. This revision was made in response to the number of commenters (Exs. 54-153, 54-165, 54-218, 54-226, 54-227, 54-263, 54-264, 54-294, 54-326, 54-327, 54-363, 54-443) who recommended that employees using SCBAs and other heavy respirators be administered medical examinations, largely because of the additional workload associated with using these respirators. A physician (Tr. 398) testified that SCBAs in particular increased an employee's workload by 20 percent. The studies just discussed also demonstrate that respirator weight

plays a significant role in the increased burden that a respirator places on the user. In addition, scientific evidence obtained by Louhevaara et al. (Ex. 164, Attachment D) demonstrates that use of SCBAs by experienced firefighters performing light to moderate exercise on a treadmill substantially reduces tidal volume and increases heart rate, oxygen consumption, and ventilation rate. These physiological effects led Kilbom (Ex. 164, Attachment D) to recommend that no firefighter over the age of 50 be assigned tasks that require SCBA use.

In the NPRM, OSHA asked whether information on the duration and frequency of respirator use should be provided to the PLHCP. No comments were received on this subject. The research studies described earlier in this Summary and Explanation show that duration and frequency of respirator use interact with other respirator use conditions (e.g., respirator weight, protective clothing, temperature and humidity) in imposing pulmonary and cardiovascular stress on respirator users. OSHA believes that information about the duration and frequency of respirator use will be important to PLHCPs in making medical ability recommendations, and concludes that this information must be included in the information required to be provided to the PLHCP.

**Paragraph (e)(5)(ii).** As noted above, OSHA received recommendations from several commenters (Exs. 54-181, 54-234, 54-330, 54-445) to reduce the amount of information required to be submitted to the PLHCP. In responding to this recommendation, OSHA first reduced the number of items required. Second, OSHA revised the requirement so that employers only need to provide the supplemental information once to the PLHCP, unless the information differs from the information provided to the PLHCP previously or a new PLHCP is conducting the medical evaluations. Under the revised provision, therefore, the employer must ensure that: the PLHCP retains the supplemental information that is provided by the employer; the supplemental information is updated appropriately and in a timely fashion; and a new PLHCP is provided with the required supplemental information. The requirement to provide the new PLHCP with the appropriate information does not mean that the new PLHCP must medically reevaluate employees, only that the new PLHCP obtains the information required under this paragraph. The employer can meet this requirement by either providing the relevant documents to the new PLHCP or ensuring that the documents are transferred from the former PLHCP to the new PLHCP.

**Paragraph (e)(5)(iii).** OSHA believes that the requirement for employers to provide a copy of the final standard and a copy of the written respiratory program to the PLHCP, although not included in the proposed standard, is needed to assure that PLHCPs have a thorough understanding of their duties and responsibilities in the medical evaluation process, thereby enhancing their ability to make a sound medical recommendation on an employee's ability to use the respirator. The written program is site-specific, and will inform the PLHCP of the working conditions the employee will encounter during respirator use. This information is critical if the PLHCP is to make a thorough and accurate evaluation of the employee's ability to use the assigned respirator. The PLHCP's ability to conduct appropriate medical evaluation will also be aided by knowledge of the standard, which sets forth the requirements of the medical evaluation program, as well as other requirements that affect the employee's respirator use. Consequently, this requirement will help ensure that medical evaluations conducted by PLHCPs are thorough and accurate; recommendations regarding an employee's medical ability to use the respirator are valid; employees are informed of these recommendations; and the privacy and confidentiality of employees are maintained. OSHA believes that this requirement is necessary to ensure that the objectives and other requirements of final paragraph (e) are fulfilled.

As noted in the previous discussion of paragraph (e)(5)(ii), this information must be provided to the PLHCP only once for all employees who are involved in the employer's respiratory protection program.

This information does not have to be provided again to the same PLHCP unless the standard or the employer's respiratory protection program is substantially revised. For example, the information does not have to be provided again when only minor revisions have been made to either the standard or the respiratory protection program. When the employer hires a different PLHCP to conduct medical evaluations, the employer must ensure that the new PLHCP has this information, by either providing the new PLHCP with the appropriate documents or ensuring that the documents are transferred from the former PLHCP to the new PLHCP.

#### Paragraph (e)(6) -- Medical Determination

Paragraph (e)(1) of the NPRM proposed that the employer be responsible for making the final determination regarding the employee's ability to use the respirator. The proposed regulatory language required the physician (now a PLHCP) to deliver a medical opinion regarding the employee's medical ability to use the respirator, including any recommended limitations on this use, to the employer. OSHA proposed, consistent with its substance-specific standards, to make the employer responsible for the final determination regarding an employee's ability to use the respirator. This determination was to be based on all of the information available to the employer, including the physician's opinion and recommendations. The final standard follows this approach, although the final rule's requirements have been revised to reflect the record.

**Paragraph (e)(6)(i).** This provision states that the "employer shall obtain a written recommendation regarding the employee's ability to use the respirator from the PLHCP \* \* \* " Because the PLHCP's recommendation is an important element in the employer's determination as to whether it is hazardous for an employee to use a respirator, the recommendation needs to be clear and in writing.

Final paragraph (e)(6)(i) requires that the PLHCP's recommendation be restricted to the three elements listed in paragraphs (e)(6)(i)(A) through (C) (i.e., "[t]he recommendation shall provide only the following information") [emphasis added]. This requirement is similar to the proposed regulatory language for paragraph (e)(1) and paragraph (e)(1)(v) of proposed alternative 3. The purpose of this limitation is to protect employee privacy with regard to medical conditions not relevant to respirator use.

Several commenters (Exs. 54-92, 54-455) supported the need for privacy but recommended further that the basis of the PLHCP's medical recommendation not be disclosed to employers because such information could be used by an employer to remove an employee from the workforce. The AFL-CIO (Ex. 54-428) stated that "[medical] reports to employers should contain only a statement of approval or disapproval for employees who are tested." The Brotherhood of Maintenance of Way Employees (BMWE) (Ex. 122) supported limiting the medical information provided to the employer to whether or not the employee can perform the required work while using the respirator, and whether or not restrictions need to be applied to the employee's respirator use. The BMWE stated further that no information should be provided on the specific medical conditions detected during the medical evaluation.

OSHA believes that protection of employee privacy and confidentiality is important to obtain accurate and candid responses from employees about their medical conditions. OSHA has retained this requirement in the final standard and believes that, as worded, it strikes the proper balance between the need to provide sufficient information to the employer to make a decision on respirator use and the need to protect employee privacy.

Paragraph (e)(6)(i)(A) in the final standard also specifies the information the PLHCP is to include in the recommendation to the employer: "Any limitations on respirator use related to the medical condition of the

employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically eligible to use the respirator." OSHA's experience in enforcing standards with similarly worded provisions indicates that this language is appropriate; also, OSHA believes a statement regarding the employee's medical ability to use the respirator will assist both the employer and employee in determining the final medical disposition of the employee.

Paragraph (e)(6)(i)(B) of the final standard specifies that the PLHCP must state whether there is a need for follow-up medical evaluations. This provision was added to the final standard for several reasons. First, the initial medical evaluation may indicate that there is a possibility that the employee's health may change in a way which would reduce the employee's ability to use a respirator. In these circumstances, the PLHCP is required to specify appropriate follow-up medical evaluations. Second, the final standard does not provide for periodic (such as annual) evaluations, as most other OSHA health standards do. It is therefore important that the PLHCP specify whether an employee requires follow-up medical evaluation so that the employee's ability to use a respirator can be carefully monitored by the PLHCP. This requirement will ensure that employees are using respirators that will not adversely affect their health.

Paragraph (e)(6)(i)(C) requires that the employee be provided with a copy of the PLHCP's written recommendation. No comments were received by the Agency on this proposed requirement. OSHA believes that a copy of the PLHCP's written recommendation will provide employees with information necessary to ensure that they are using respirators that will not adversely affect their health.

The employer may either transmit the PLHCP's written recommendation to the employee or arrange for the PLHCP to do so. The employer shall allow the employee, consistent with paragraph (e)(4)(ii) of the final standard, to discuss the recommendation with the PLHCP. During the discussion, the PLHCP may inform the employee of the basis of the recommendation, as well as other medical conditions that are indicated by the results of the medical evaluation but that are not directly related to the employee's medical ability to use the respirator. OSHA believes that the additional information provided to the employee by the PLHCP should be determined by the legal, professional, and ethical standards that govern the PLHCP's practice and, therefore, should not be regulated by the final standard.

**Paragraph (e)(6)(ii).** If the PLHCP's medical evaluation finds that use of a negative pressure respirator would place the employee at increased risk of adverse health effects, but that the employee is able to use a powered air-purifying respirator (PAPR), this paragraph requires employers to provide the employee with a PAPR. The rationale for this provision was discussed in the proposal (59 FR 58906). Negative pressure respirators can result in sufficient cardiovascular and respiratory stress to make employees medically unable to use this class of respirators. The use of PAPRs involves lower cardiovascular and respiratory stress, and PAPRs can often be tolerated by employees when negative pressure respirators cannot. Consequently, OSHA believes that this requirement is consistent with the requirements of paragraph (a)(2) of the final standard, which states that "employers [must] provide the respirators which are applicable and suitable for the purpose intended."

Several commenters endorsed this provision (Exs. 54-101, 54-363, 54-455). ISEA (Ex. 54-363) recommended that "employers ensure that all alternative types [of respirators] be considered and made available" to employees found to be medically unable to use the respirator selected initially by the employer. The proposal was consistent with this recommendation in requiring that alternative respirators be selected from among existing positive pressure respirators, including supplied-air respirators. OSHA has determined, however, that supplied-air respirators should not be listed as alternative respirators in the final standard because, as noted earlier in this Summary and Explanation, these respirators impose many of

the same pulmonary and cardiovascular burdens on employees as negative pressure respirators. The Brotherhood of Maintenance and Way Employees (BMWE) (Ex. 126) found that PAPRs would be an effective substitute for negative pressure respirators, and endorsed issuing PAPRs to employees who were found to be medically unable to use negative pressure respirators. In making this endorsement, the BMWE estimated that less than 1 percent of its membership would require such an upgrade. Consequently, OSHA removed the requirement for supplied-air respirators from the final standard, and now requires only that employers provide PAPRs to employees who are medically unable to use negative pressure respirators but who are able to use PAPRs. In addition, paragraph (e)(6)(ii) of the final standard specifies that if a subsequent medical evaluation finds that the employee is able to use a negative pressure respirator, then the employer is no longer required to provide that employee with a PAPR.

#### Paragraph (e)(7) -- Additional Medical Evaluations

Paragraph (e)(7) of the standard requires the employer to provide additional medical evaluations whenever there is any indication that a reevaluation is appropriate. At a minimum, this would occur: if the employee reports any signs or symptoms that are related to the ability to use a respirator; if the PLHCP, program administrator or supervisor determines that a reevaluation is necessary; if information from the respiratory protection program indicates a need for reevaluation; or if a change in workplace conditions could affect the physiological burden placed on the employee. This is a significant change from the proposal, which in alternatives 2 and 3 would have required reevaluation on an annual basis of employees subject to medical evaluation. Although this would not necessarily have required a medical examination, proposed paragraph (e)(3) and alternative 3 would have required a written medical opinion. The provision in the final standard is similar to the requirement in several of OSHA's substance-specific standards that employees be medically reevaluated if they experience breathing difficulties during fit testing or under other respirator use conditions (see, e.g., the Cadmium standard at 29 CFR 1910.1027(l)(6)(iii)).

OSHA also made a specific request for comments on the appropriateness of requiring medical evaluations at the age-related intervals used by ANSI or NIOSH. ANSI and NIOSH recommend that older employees should be screened more frequently than younger employees because of the heightened risk of cardiovascular and respiratory disease associated with age. The ANSI Z88.6-1984 consensus standard recommends medical evaluations at the following age intervals: every five years below age 35, every two years for employees aged 35 to 45, and annually thereafter. NIOSH's Respirator Decision Logic (Ex. 9) calls for medical evaluations at similar intervals, except that employees over 45 years old should be evaluated every one to two years. One commenter (Ex. 54-394) stated that age-based medical evaluations are important because the American workforce is aging.

The proposed requirement that medical reevaluation be conducted annually resulted in numerous comments, most of which recommended that the requirement be revised. Eight commenters (Exs. 54-219, 54-224, 54-253, 54-264, 54-348, 54-421, 54-441, 54-455) endorsed the proposed requirement without revision. Three commenters (Exs. 54-70, 54-326, 54-357) stated that cost concerns and the administrative burden should limit annual medical evaluations to employees who use SCBAs. Other commenters (Exs. 54-70, 54-185, 54-206, 54-326, 54-357, 54-429) recommended that annual medical evaluations be administered to employees who use non-SCBA respirators only if such use is on a daily basis, for more than 50 per cent of the work week, or at least five hours per work week. A few commenters (Exs. 54-220, 54-244, 54-327, 54-424, 54-429) recommended annual medical evaluations if the evaluations consisted entirely of a medical questionnaire.

The Boeing Company (Ex. 54-445) was one of the commenters recommending that OSHA reconsider the

requirement for annual medical examinations. Boeing stated:

[Our] experience with annual review has been that approximately 1-2% of [our] employees reviewed per year are restricted from respirator use. Very rarely to never are these restrictions due to a medical condition that would make respirator use dangerous for an employee. Rather, the restrictions are related to other aspects of an employee's job or to administrative reasons, such as failure to undergo the review or employee preference.

The American Iron and Steel Institute (AISI) (Ex. 175) also provided limited evidence that regular (e.g., annual) medical examinations are ineffective. AISI cited an industry study in which 2,195 medical examinations were administered to 1,816 employees subsequent to their initial medical examination; the elapsed interval, however, was unspecified. The medical reevaluations found only two employees who had unknown (to the employees) medical conditions; one of the employees had claustrophobia, and the other employee had reduced pulmonary function and an abnormal chest x-ray. AISI recommended that the frequency of medical reevaluation be "determined by a licensed medical provider or to verify a suspected functional disability that might affect the ability to wear a respirator."

The statements and recommendations made by commenters who believed that the requirement should be revised or eliminated are summarized as follows:

- (1) An annual interval is arbitrary or unnecessary (Exs. 54-234, 54-263, 54-267);
- (2) A biannual interval should be used (Exs. 54-191, 54-278, 54- 326);
- (3) The intervals should be age-based, using either the ANSI or age intervals (Exs. 54-66, 54-172, 54-215, 54-245, 54-250, 54- 273, 54-318, 54-374, 54-381, 54-388, 54-426, 54-441, 54-450, 54-451, 54-452, 54-453), the age intervals recommended by the National Fire Protection Association (NFPA) under NFPA standard 1582 (Ex. 54-155), or unspecified age intervals (Exs. 54-67, 54-218, 54-240, 54-271, 54-326, 54-327, 54-342, 54-346, 54-361, 54-363, 54-429, 54-445, 54-454);
- (4) Medical reevaluation should be conducted only at the request of the PLHCP (Exs. 54-70, 54-150, 54-180, 54-217, 54-224, 54-313, 54-348, 54-350, 54-361, 54-432, 54-448, 54-449, 54-450, 54-451, 54-452), employers (Ex. 54-251), employees (Ex. 54-157), or employees trained to recognize respirator-induced medical effects (Exs. 54-181, 54-219, 54- 242);
- (5) Medical reevaluation should be event-driven, with the events specified as a combination of age, physical condition or medical symptoms (including breathing difficulty), job conditions, respirator type, frequency of respirator use, medical history, or type of exposure (Exs. 54-79, 54-187, 54-189, 54-217, 54-218, 54-219, 54-220, 54-242, 54-253, 54-265, 54-275, 54-278, 54-318, 54-319, 54-342, 54-357, 54-381, 54-395, 54-439), or when job conditions or the type of respirator used by the employee increase the risk of adverse effects on the employee's health (Exs. 54-151, 54-153).

Several commenters (Exs. 54-38, 54-191, 54-388) stated that medical reevaluation should not be conducted when employees experience breathing difficulties during respirator use because these effects usually occur as a result of canister or filter overloading rather than an employee's medical condition.

The commenters who endorsed the proposed requirement for an annual medical evaluation stated that annual medical evaluations would identify or prevent medical problems that may arise as a result of less frequent or event-driven medical evaluations. After carefully reviewing the entire record, OSHA decided to revise the proposed requirement and to make medical reevaluation contingent on specific events that may occur during respirator use, regardless of the duration of respirator use. OSHA also has determined that a rigid approach to medical reevaluation based on age may ignore serious medical conditions among

younger employees that could be aggravated by continued respirator use. As noted by Dr. Ross H. Ronish, Site Medical Director for the Hanford Environmental Health Foundation (Ex. 54-151), "[m]edical conditions which can affect the ability of an individual to use various types of respirator occur even in young people."

This approach is appropriate because medical problems requiring evaluation by a PLHCP can occur after any period of respirator use and in workers of any age, and the requirement for medical reevaluation must be sufficiently flexible to accommodate this variability. In addition, the employee, supervisor, and program administrator are in a position to note conditions, such as breathing difficulty, which would trigger the need for a medical reevaluation.

The events described in paragraph (e)(7) of the final standard include significant medical, occupational, and respirator use conditions that warrant medical reevaluation because these conditions are known to impose additional physiological stress on employees, or are recognized indicators of medical problems associated with respirator use. This paragraph, therefore, will provide for flexible and prompt detection of medical problems among employees who use respirators.

The specific events OSHA has listed in paragraphs (e)(7)(i), (ii), (iii) and (iv) that trigger medical reevaluation are based on OSHA's experience with substance-specific standards and the record of this rulemaking. OSHA believes that these events cover most situations in which employees are at risk of experiencing adverse health effects because of respirator use and in which the employee's underlying medical conditions or workplace conditions have changed sufficiently to make the initial medical evaluation obsolete. As noted earlier in the discussion of this paragraph, these variables were considered by many commenters to be important in determining the frequency with which employees should be medically reevaluated.

### Medical Removal Protection

The proposed rule did not include a provision for medical removal protection (MRP). Such a provision requires employers to provide employees who are unable to use respirators with alternative jobs at no loss of pay and other benefits. In the notice of proposed rulemaking (59 FR 58912), the Agency noted that MRP provisions had been included in some earlier substance-specific standards, but stated that insufficient information had been provided in response to the ANPR to include in the proposed rule an MRP provision that would be applicable to all workplaces in which respirators are used. To enable it to evaluate whether an MRP provision might be appropriate for this generic respirator standard, OSHA asked for comments and information about cases in which employees were found to be unable to use respirators in their jobs. The Agency specifically requested information about the frequency of cases in which employees were found to be unable to use respirators and the details of such cases, including how the determination of an employee's inability to use a respirator affected the worker's job responsibilities.

Numerous comments were received on this issue. Most of the commenters who addressed the issue (Exs. 54-92, 54-206, 54-220, 54-240, 54-250, 54-267, 54-273, 54-286, 54-295, 54-342, 54-381, 54-435, 54-443) suggested that a provision requiring employers to provide alternative jobs as a consequence of medical removal be excluded from the final standard, although some (Exs. 54-213, 54-387, 54-427, 54-428, 54-455) endorsed such a provision. The commenters who opposed the provision argued that: employees already receive adequate protection against medically related job displacement and unemployment through existing federal, state, and local law (e.g., the Americans with Disabilities Act and the Rehabilitation Act of 1973); the requirement exceeded OSHA's statutory authority; and OSHA failed to justify the provision adequately in the proposal. Commenters who favored MRP believed that such a provision was needed for

medical evaluation to be effective. They stated that employees will refuse necessary medical evaluation if they believe their jobs might be placed in jeopardy. The Brotherhood of Maintenance of Way Employees (BMWE) (Ex. 126) endorsed MRP, claiming that in most cases such protection is feasible on both a temporary and permanent basis for the railroad industry; infeasible or inconvenient cases could be resolved, according to this commenter, under their collective bargaining agreement. The BMWE also recommended that employees who have been determined by employers to be unable to use respirators be allowed to seek a second medical opinion (i.e., to have multiple physician review) "unencumbered by ulterior motives on the part of the employer."

As noted above, OSHA has included MRP in some of its existing substance-specific standards for employees who are unable to use respirators. In the Cotton Dust standard, for example, OSHA provided that if a physician determines that an employee is unable to use any type of respirator, the employee must be given the opportunity to transfer to an available position in which respirator use is not required, with no loss of wages or benefits (50 FR 51154-56). OSHA specifically found, based on the evidence in the Cotton Dust rulemaking record, that some employees would be reluctant to reveal information necessary for proper health care if the employee feared that the information might result in transfer to lower paying jobs. Similar MRP provisions for employees unable to use respirators have been included in OSHA's Asbestos and Cadmium standards. However, MRP provisions for workers unable to use respirators have not been included in most of OSHA's substance-specific standards, even though all such standards require that employees who use respirators undergo medical evaluation to determine their ability to do so (e.g., the 1,3-Butadiene, Formaldehyde, Ethylene Oxide, Acrylonitrile, Benzene, and Lead standards).

OSHA believes that a number of provisions of the final standard will effectively avoid any disincentive on the part of employees to cooperate with medical evaluation. Paragraph (e)(1) requires the employer to provide medical evaluation to an employee before the employee uses a respirator in the workplace. Therefore, employees cannot refuse to undergo medical evaluation and continue in a job that requires respirator use. All employees who use SCBAs, the type of respirator that imposes the greatest physiological burden on the user, must receive medical examinations, and the PLHCP who conducts the examination has discretion to determine the tests, consultations, and diagnostic procedures to be included in the examination. Given this discretion on the part of the PLHCP, and the PLHCP's awareness of the considerable physiological burden that SCBA use places on the user, OSHA believes that the PLHCP will be able to evaluate the employee's ability to use an SCBA even if the employee is reluctant to cooperate fully with the examination.

Moreover, paragraph (e)(7) requires the employer to medically reevaluate an employee when a PLHCP, supervisor, or program administrator observes that the employee is having a medical problem during respirator use and they inform the employer of their observation. Many of the jobs in which SCBA use is required are strenuous, and any undue physiological burden the respirator places on an employee will often be readily observable by the employer, PLHCP, supervisors, or program administrator. Paragraph (e)(7), therefore, will help ensure that an employee who is medically unable to use a respirator, whether a SCBA or another type of respirator, cannot avoid medical evaluation by refusing to cooperate.

The final standard also encourages cooperation in medical evaluation by employees who are assigned to use negative pressure respirators. Some employees will be unable to use negative pressure respirators because of breathing resistance caused by medical conditions such as asthma and bronchitis. The final standard provides these employees with a strong incentive to cooperate with medical evaluation by requiring the employer to provide them with a powered air-purifying respirator (PAPR) when the PLHCP who conducts the evaluation determines that the employees cannot use a negative pressure respirator but

can use a PAPR. OSHA believes that many workers who are medically unable to use a negative pressure respirator will be able to use a PAPR, which offers considerably less breathing resistance than a negative pressure respirator. Therefore, those employees who are concerned about their medical ability to use a respirator will have a strong incentive to cooperate fully with the medical evaluation because they are likely to be provided with a less physiologically burdensome respirator that will enable them to continue in their jobs.

### ***Paragraph (f) -- Fit Testing***

#### **Introduction**

The final rule requires that, before an employee is required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style and size of respirator that will be used. The ANSI Z88.2-1992 respiratory protection standard also recommends such testing before respirator use. Employers who allow employees to voluntarily use respirators need not provide fit testing for those employees, although OSHA encourages them to do so.

It is axiomatic that respirators must fit properly to provide protection. If a tight seal is not maintained between the facepiece and the employee's face, contaminated air will be drawn into the facepiece and be breathed by the employee. The fit testing requirement of paragraph (f) seeks to protect the employee against breathing contaminated ambient air and is one of the core provisions of the respirator program required by this standard.

In the years since OSHA adopted the previous respirator standard, a number of new fit testing protocols have been developed and tested (Exs. 2, 8, 24-2, 24-12, 24-20, 46, 49). During the same period manufacturers have developed multiple sizes and models of respirator facepieces in order to provide better fits for the variety of facial sizes and shapes found among respirator users. Incorporation of these advances into the standard is particularly important because facepiece leakage is a major source of in-mask contamination.

Studies show that lack of fit testing results in reduced protection. In a health hazard evaluation (HHE) conducted by NIOSH at a medical center (Ex. 64-56), NIOSH found that workers using disposable respirators were not getting adequate protection because the respirators had not been fit tested. Other HHEs conducted by NIOSH show that workers who used respirators where there was no fit testing suffered adverse health effects resulting from overexposure to airborne contaminants (See HETAs 81-283-1224 and 83-075-1559).

Based on the record evidence, OSHA concludes that poorly fitting facepieces expose workers to contaminants and that the use of an effective fit testing protocol is the best way of determining which respirator facepiece is most appropriate for each employee. Indeed, the need to include fit testing requirements in the standard, and to specify the proper method of accomplishing such testing, were among the major reasons OSHA proposed to revise the existing respirator standard.

Fit testing may be either qualitative or quantitative. Qualitative fit testing (QLFT) involves the introduction of a gas, vapor, or aerosol test agent into an area around the head of the respirator user. If the respirator user can detect the presence of the test agent through subjective means, such as odor, taste, or irritation, the respirator fit is inadequate. In a quantitative respirator fit test (QNFT), the adequacy of respirator fit is assessed by measuring the amount of leakage into the respirator, either by generating a test aerosol as a test atmosphere, using ambient aerosol as the test agent, or using controlled negative pressure

to measure the volumetric leak rate. Appropriate instrumentation is required to quantify respirator fit in QNFT.

OSHA's prior respirator standard required training that provided opportunities for each user to have the respirator "fitted properly" and to wear it in a test atmosphere. However, it did not specify the test protocols to be used. The previous standard also required that employees be trained to check the fit each time the respirator is put on, although without specifying how the fit check was to be performed or the types of fit checks that were acceptable. OSHA's own compliance experience, and the experience gained from respirator research over the past 25 years, demonstrates that the existing standard's limited fit testing requirements do not provide employers with adequate guidance to perform appropriate fit testing.

The substance-specific standards that have been issued over the past 20 years show the evolution of OSHA's recognition of the need for fit testing guidance. The early standards, such as the 1978 Acrylonitrile standard (29 CFR 1910.1045) and the 1978 Lead standard (29 CFR 1910.1025), required quantitative fit tests but did not provide specific protocols. Subsequently, in 1982, the lead standard was amended to allow qualitative fit testing for half mask negative pressure respirators, provided that one of three specified protocols was followed (47 FR 51110). These specified qualitative fit testing (QLFT) protocols use isoamyl acetate, irritant smoke, or saccharin as the test agents. They have been used in all subsequent standards (e.g., Cadmium, Sec. 1910.1027; 1-3 Butadiene, Sec. 1910.1051; Methylene Chloride, Sec. 1910.1052) with fit testing requirements.

One of the major changes from requirements in the previous standard made by this final standard is its requirement that fit testing be conducted according to specific protocols and at specific intervals or on the occurrence of defined triggering events. Paragraphs (f)(1) and (f)(2) of the standard require employers to ensure that each employee using a tight-fitting facepiece respirator passes an appropriate fit test before using such a respirator for the first time and whenever a different respirator facepiece is used, as well as at least annually thereafter. Paragraph (f)(3) requires the employer to provide an additional fit test whenever the employee reports, or the employer, PLHCP, supervisor, or program administrator observes, changes in the employee's physical condition that could affect respirator fit. Examples of conditions causing such changes could be the wearing of new dentures, cosmetic surgery, or major weight loss or gain. Paragraph (f)(4) specifies that if an employee who has passed a fit test subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee must be given a reasonable opportunity to select a different respirator facepiece and to be retested. Paragraph (f)(5) requires that the fit test be administered according to one of the protocols included in mandatory Appendix A.

Paragraph (f)(6) limits qualitative fit testing to situations where the user of a negative pressure air-purifying respirator must achieve a minimum fit factor of 100 or less. Paragraph (f)(7) explains that a quantitative fit test has been passed when the fit factor, as determined through an OSHA accepted protocol, is at least 100 for tight-fitting half masks or 500 for tight-fitting full facepiece respirators.

Paragraph (f)(8) requires that all QLFT or QNFT fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators be performed with respirators in the negative pressure mode, even if they are to be used in positive pressure mode in the workplace, and contains additional requirements for measuring fit testing results. It also requires that all facepieces modified to perform a fit test be restored to their NIOSH-approved configuration before being used in the workplace.

Detailed discussions of each of the paragraphs related to fit testing follow.

## Fit Testing -- Paragraph (f)(1)

Paragraph (f)(1) of the final standard requires that all tight-fitting respirators be fit tested in accordance with the requirements of the final standard. The ANSI Z88.2-1992 standard has a similar fit testing requirement, as did proposed paragraph (f)(3). The need to fit test "negative pressure" respirators was widely supported (Exs. 54-5, 54-38, 54-67, 54-153, 54-158, 54-167, 54-172, 54-173, 54-185, 54-208, 54-219, 54-263, 54-273, 54-278, 54-313, 54-330, 54-424). No comments opposing this requirement were received.

However, the record contains comments both supporting and opposing the need to require the same type and frequency of fit testing for "positive pressure" respirators, which are defined in the final standard as respirators "in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator." A number of commenters stated that positive pressure atmosphere-supplying respirator users should not be required to pass a fit test (Exs. 54-271, 54-280, 54-290, 54-297, 54-314, 54-324, 54-330, 54-339, 54-346, 54-350, 54-352, 54-361, 54-424). These commenters believed that fit testing of such respirators was not needed because the positive pressure inside the facepiece would prevent contaminated ambient air from leaking from the outside atmosphere to the area inside the facepiece.

For example, the Southern California Edison Company (Ex. 54-316) stated that there was no need to fit test tight-fitting positive pressure respirators because "[t]he chances of these type of respirators becoming negative pressure under normal use conditions are very slim and generally occur only when there has been a restriction or failure of the air supply system." The Alabama Power Company (Ex. 54-217) similarly stated that there was no need to fit test tight-fitting supplied air respirators (SARs) or powered air-purifying respirators (PAPRs) because the chance was slight that a negative pressure condition would occur during normal use. The Reynolds Metals Company (Ex. 54-222) stated that, with positive pressure respirators, gross leaks were unlikely to occur if the user was trained. Beaumont & Associates (Ex. 54-246) stated that a well trained user of pressure demand or continuous flow respirators would quickly be aware of any gross leakage. Eric Jaycock, CIH, (Ex. 54-419) questioned whether requiring the fit testing of positive pressure respirators would cause employers to choose other, less protective, respirators. The County of Rockland Fire Training Center (Ex. 54-155) stated that positive pressure SCBAs may, theoretically, leak around the seal, but that, in its experience, this was unlikely to happen in normal working situations. It recommended that positive pressure SCBAs be exempted from the fit test requirement if the user passes a negative pressure fit check upon donning to ensure an effective seal.

Other evidence in the record, however, demonstrates that, even with positive pressure respirators, facepiece leakage can occur when the high inhalation rates associated with increased workloads cause the facepiece pressure to become negative in relation to the outside atmosphere. An evaluation of the performance of powered air-purifying respirators equipped with tight-fitting half masks by the Lawrence Livermore National Laboratory (Ex. 64-94) demonstrated what its authors called the "Myth of Positive Pressure." The study found that, at the NIOSH-required flow rate of 4 cubic feet/minute (cfm), a half mask PAPR tested at an 80% work rate had a negative facepiece pressure during inhalation for all subjects. The authors concluded that the respirator protection that the device can provide is dependent in large part on the tightness of the seal to the face of the wearer.

Dahlback and Novak (Ex. 24-22) also found negative pressure inside the facepieces of pressure-demand respirators when workers engaged in heavy work and had inhalation peak flow rates of 300 liters a minute. Workers in this study who had not been fit tested developed negative pressure inside their masks much more frequently than those who had been fit tested.

Some commenters (Exs. 54-214, 54-217, 54-222, 54-232, 54-234, 54-245, 54-251, 54-278, 54-330, 54-424) stated that any negative pressure due to leaks on inhalation can be countered by the increased air flow of a positive pressure respirator. While increased air flow can reduce the number of negative pressure episodes (Ex. 64-94), OSHA does not believe that the realities of respirator usage allow exclusive reliance on this mechanism to substitute for fit testing. Moreover, the air pressure that positive pressure respirators provide inside the facepiece is intended to overcome the momentary leakage that may occur even with a properly fitting facepiece. This positive airflow alone is not an adequate substitute for a properly fitting facepiece, and cannot be relied upon to overcome the leakage that can occur into poorly fitting facepieces.

Requiring fit tests for positive pressure respirators is also necessary because the consequences of facepiece leakage into positive pressure respirators can be extremely serious. Positive pressure respirators are usually worn in more hazardous situations than those in which negative pressure respirators are worn. For example, only positive pressure respirators can be worn in IDLH atmospheres. By definition, there is little tolerance for facepiece leakage in such atmospheres. Positive pressure respirators also are used when the concentration of the toxic substance is many times greater than the permissible exposure limit. Even where positive pressure respirators are worn in lower risk situations, they are often selected because the hazardous gas or vapor in the atmosphere lacks adequate sensory warning properties, clearly a factor calling for the minimum amount of facepiece leakage. Employees also may believe that they can afford to use less care in using a respirator that appears to be highly protective; they may ignore seal checks and strap tensioning because they are relying on air flow to overcome any leaks. Fit testing demonstrates to employees that positive pressure respirators can leak, and offers an opportunity for the employee to see, via quantification, what actions (e.g., bending at the waist, jerking the head, talking) relating to fit will decrease protection.

Similarly, although a negative or positive pressure user seal check is important to ensure proper donning and adjustment of the respirator each time it is put on, it is not a substitute for the selection of an adequately fitting respirator through fit testing. Most respirator fit testing is preceded by a user seal check, but experience with respirator fit testing has shown that some individuals who pass this user seal check with what they think is an adequately fitting facepiece subsequently fail their fit test due to poor respirator fit. As John Hale of Respirator Support Services (Ex. 54-5) stated, "Yes, there is some information to be obtained about gross facepiece-to-face leakage by performing these checks. But, there are no performance criteria, there is no known correlation between the result of this check and respirator fit or performance \* \* \* ."

A number of experts and consensus organizations supported the proposal's requirement for fit testing of all tight-fitting respirators. The Washington State Department of Labor and Industries (Ex. 54-173), the Aluminum Company of America (Ex. 54-317) and the United Auto Workers (Ex. 54-387) endorsed fit testing for positive pressure respirators because these respirators do not always maintain positive pressure due to overbreathing or physical exertion. The Industrial Safety Equipment Association (ISEA)(Ex. 54-363) supported OSHA's proposal for fit testing of all tight-fitting respirators, stating that it was consistent with the ANSI Z88.2-1992 standard's requirements. Fit testing for all tight-fitting respirators is found in clause 9.1.2 of the ANSI Z88.2-1992 respirator standard (Ex. 81), which requires that positive pressure respirators with tight-fitting facepieces be qualitatively or quantitatively fit tested in the negative pressure mode. The National Fire Protection Association (NFPA) standards 1500 and 1404 also require that firefighters using SCBAs pass a fit test (Tr. 479). The American Industrial Hygiene Association (Ex. 54-208) also supported the fit testing of all tight-fitting respirators. Moreover, workplace protection factor studies conducted by respirator manufacturers, NIOSH, national laboratories and others always fit test subjects to reduce the effect of facepiece leakage that is unrelated to design and construction (See, e.g.,

Exs. 64-14, 64-36, 64-94).

This record has convinced OSHA that it is necessary to require the fit testing of both positive and negative pressure tight-fitting respirators. Even positive pressure respirators do not always maintain positive pressure inside the facepiece, particularly when facepiece fit is poor, strenuous work is being performed, and overbreathing of the respirator occurs (Exs. 64-94, 64-101). Leakage must be minimized so that users consistently achieve the high levels of protection they need. Most workplace use of positive pressure atmosphere-supplying respirators occurs in high hazard atmospheres (e.g., emergencies, spills, IDLH conditions, very high exposures, abrasive blasting), where a high degree of certainty is required that the respirator is maximally effective. Positive pressure respirators, like negative pressure respirators, come in a variety of sizes and models, each with its own unique fit characteristics. The only reliable way to choose an adequately fitting facepiece for an individual user from among the different sizes available is by fit testing. The problem of leakage due to poor facepiece fit can be minimized by choosing good fitting facepieces through fit testing for positive pressure respirator users. OSHA concludes that the requirement to fit test tight-fitting positive pressure respirators is appropriate to reduce leakage into facepieces, and to improve the protection that all kinds of tight-fitting respirators provide in the workplace.

#### Frequency of Fit Testing -- Paragraph (f)(2)

Final paragraph (f)(2), like the proposal, requires that fit testing be performed prior to an employee's initial use of a respirator in the workplace; whenever a different model, size, make, or style of respirator facepiece is used; and at least annually thereafter. Only the requirement to conduct fit testing annually was disputed in the rulemaking. Commenters generally agreed that some additional fit testing beyond an initial test was necessary, but opinions varied widely on the appropriate intervals at which such tests should be performed. A few participants, including the UAW (Ex. 54-387), urged that fit testing be required every six months, since changes in weight, facial hair and scarring, dental work, and cosmetic surgery may alter respirator fit. The UAW also stated that visual observation was not a reliable way to identify the presence of these changes.

A number of commenters suggested that longer intervals, generally two to three years, would be appropriate. For example, Allied Signal (Ex. 54-175) recommended "periodic" or "every two-years" as the fit testing interval. Public Service Electric and Gas Co. (Ex. 54-196) stated that a "two year time frame strikes a good balance between safety concerns and practicality." The Texas Chemical Council (Ex. 54-232) stated that, in its members' experience, "\* \* \* virtually no individuals fail fit tests a year after initial testing for a given chemical exposure using the same manufacturer's respirator." The Exxon Company (Ex. 183), in response to questions asked at the June hearings, reported that of the 230 employees at their Baton Rouge refinery given an annual QNFT in 1995, a year after their initial respirator selection in 1994, less than one percent (two employees) changed their respirator size because of failing the annual QNFT. Exxon stated that few employees change the size of their respirator from year to year, and that "the data suggest that annual quantitative fit-testing should not be necessary and such testing may be done on a less frequent basis than once per year." The Peco Energy Company (Ex. 54-292) stated that its experience showed that a three year interval is sufficient to ensure a proper fit, provided that mandatory refitting is conducted if there are changes in the respirator user's physical condition. The Eastman Chemical Co. (Ex. 54-245) recommended that the time limit be not less than two years. The International Paper Co. (Ex. 54-290) stated that "bi-annual (sic) [every two years] fit-testing with proper training should be adequate" and that proper training would require that employees report to the employer facial feature changes that have occurred or failure to get an adequate seal during the positive/negative pressure seal check.

Other participants believed that fit testing beyond initial fit testing should be required only when an employee switches to a different respirator, or when a significant change occurs in an employee's physical condition that may interfere with obtaining an adequate facepiece seal (Exs. 54-177, 54-187, 54-190, 54-193, 54-197, 54-214, 54-286, 54-297, 54-396, 54-397, 54-435, 54-323, 54-422, Ex. 123). The American Iron and Steel Institute (Ex. 54-307, Ex. 175) stated that annual fit testing was unnecessary, and that the steel industry experience shows that once a wearer has been fit tested and has an acceptable fit, subsequent fit tests demonstrate consistent fit factors. Mallinckrodt Chemical (Ex. 54-289) questioned the need for annual fit testing for those employees who may use a respirator infrequently, such as once or twice a year.

However, a large number of rulemaking participants supported OSHA's proposal to require the testing of respirator fit on an annual basis (Exs. 54-5, 54-6, 54-20, 54-153, 54-167, 54-172, 54-179, 54-219, 54-273, 54-289, 54-293, 54-309, 54-348, 54-363, 54-410, 54-428, 54-455, Ex. 177; Tr. 1573, 1610, 1653, 1674). The comments of these participants and other evidence in the rulemaking record convince OSHA that the annual testing requirement is appropriate to protect employee health.

Annual retesting of respirator fit detects those respirator users whose respirators no longer fit them properly. The Lord Corporation, which already performs annual fit tests, reported that of its 154 employees who wear respirators, one to three (2 percent or less) are identified each year as needing changes in model or size of mask (Ex. 54-156). Hoffman-LaRoche only performs fit tests at two-year intervals, and it reported a much higher incidence of fit test failures. Sixteen of the 233 people tested in a recent two year cycle of fit testing (6.86%) needed a change in their assigned respirators (Ex. 54-106).

The Lord experience (Ex. 54-156) indicates that annual retesting of facepiece fit detects poorly fitting facepieces, while the Hoffman- LaRoche evidence demonstrates that waiting two years for retesting can result in the discovery that quite a high percentage of workers have been relying on poorly fitting respirators. Extending the retest interval to more than one year would allow those individuals with poor fits that could have been detected by annual fit testing to wear their respirator for a second year before the poor fit is detected.

This evidence also supports OSHA's view that triggering the requirement to retest only by certain events, such as a change in the worker's condition, and not including a required retest interval, would allow poor fits to continue. Changes in a worker's physical condition, such as significant weight gain or loss, new dentures or other conditions, can cause alterations in facial structure and thus respirator fit. Physiological changes that affect facepiece fit can occur gradually over time and are easily overlooked by observers, and by the users themselves. Individuals with poorly fitting respirators were often detected only through fit testing, and not by other methods such as observation of changes in facepiece fit, failure to pass a user seal check, or an employee reporting problems with the fit of the respirator. Retesting facepiece fit solely on the basis of physical changes in individual respirator users would not be a reliable substitute for fit testing on an annual basis. These changes in an individual's physical condition do, however, indicate the need for retesting that individual's facepiece, and paragraph (f)(3) requires additional fit testing whenever any of these changes is detected.

Moreover, fit testing not only determines whether a facepiece seal is adequate; it also provides an opportunity to check that fit is acceptable, permits the employee to reduce unnecessary discomfort and irritation by selecting a more comfortable respirator, and reinforces respirator training by providing users with a hands-on review of the proper methods of donning and wearing the respirator. Therefore, as well as providing the opportunity to detect poorly fitting respirator facepieces, the annual fit testing requirement

complements OSHA's requirement for, and may partially fulfill, annual training under final paragraphs (k)(1), (k)(3) and (k)(5). For the reasons presented above, and based on a thorough review of the record, OSHA has included an annual fit test requirement in the final rule.

### Refitting Due to Facial Changes -- Paragraph (f)(3)

Paragraph (f)(7) in the proposal addressed the need to refit respirators when changes in the employee's physical condition occur. The proposal identified facial scarring, cosmetic surgery, or an obvious change in body weight as conditions requiring refitting. Some commenters (Exs. 54-280, 54-428, 54-455) suggested that dental work affecting facial shape should also trigger refitting. The International Chemical Workers Union (ICWU) suggested that a change of five percent in body weight or twenty pounds should be regarded as an obvious change in body weight that requires refitting (Ex. 54-427). One commenter opposed requiring the employer to determine whether an employee's physical change should trigger refitting, stating that the responsibility for reporting physical changes should rest with the employee (Ex. 54-357).

The language of the proposed paragraph has been revised in the final rule to provide greater clarity and to account for these comments. Because weight loss or gain affects the facial configuration of different individuals differently, OSHA does not believe it possible to stipulate a given weight change "trigger" for requiring a new fit test. The final standard thus retains the proposed language regarding an obvious change in body weight. In response to the comments that dental work can affect facial shape and respirator fit, the language in final paragraph (f)(3) has been revised to add dental changes as another item that can trigger a new fit test requirement. The provision has been modified to trigger retests based on employee reports of facial changes, in addition to changes observed by the employer, supervisor, program administrator, or PLHCP that may affect facepiece fit. Employer observations of potential problems with fit, along with self-reported problems with facepiece fit or changes in facial configuration, would trigger a respirator fit retest under final paragraph (f)(3).

Paragraph (f)(3) requires employers to conduct an additional fit test whenever an employee reports changes, or there are observations of changes, in the employee's physical condition that could affect respirator fit. This provision addresses the rare situation in which an employee's facial features change to the extent that a respirator that once fit properly may no longer fit. The conditions listed in the standard that may cause such changes in facial features -- facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight -- will generally be observable by the employer. If the employee reports facial changes that are not readily observable, the employer may require verification of the changes before offering an additional fit test.

### Retesting for Unacceptability -- Paragraph (f)(4)

Paragraph (f)(4) of the final standard requires retesting whenever the respirator becomes "unacceptable" to the employee. An employee who notifies the employer, the program administrator, supervisor, or the PLHCP that the fit of the respirator is unacceptable must be given a reasonable opportunity to be retested and to select a different respirator facepiece. This requirement was derived from paragraph (f)(8) in the proposal, which required refitting within the first two weeks of respirator use for masks that become "unacceptably uncomfortable."

Although some commenters wanted to delete this provision on the grounds that a properly fitted and trained worker should have no reason to exchange the respirator (Exs. 54-6, 54-20, 54-156, 54-209, 54-215), others urged that the employee be allowed to request a refit at any time a respirator becomes

unacceptable. These commenters saw no reason to limit this period to two weeks (Exs. 54-154, 54-165). The utility of the two week period was specifically questioned for situations where respirators are not routinely used for long periods of time (Ex. 54- 66), or are used only occasionally (Ex. 54-220). Exxon (Ex. 54-266) stated that the two week provision was too restrictive, and that employees should be allowed to select another respirator or facepiece as necessary . Dow (Ex. 54-278) also suggested dropping the two week limitation. The American Petroleum Institute (Ex. 54-330) recommended revised performance language for this provision. The Occidental Chemical Company (Ex. 54-346) saw no reason to specify a two week period, and stated that employees should be permitted to select a new respirator facepiece at any time because of unacceptable discomfort.

In the final rule, OSHA has deleted the two week limitation on the time in which an employee may have a respirator retested. In addition, the term "unacceptable" has been substituted for the term "uncomfortable," which was used in the proposal and was objected to by several commenters (Exs. 54-154, 54-266, 54-278, 54-330). A respirator may be unacceptable if it causes irritation or pain to an employee or if, because of discomfort, the employee is unable to wear the respirator for the time required.

#### Fit Testing Protocols -- Paragraph (f)(5)

Paragraph (f)(5) in the final standard, which is substantively the same as proposed paragraph (f)(3), requires that the employer use an OSHA-accepted QLFT or QNFT protocol for fit testing. These protocols are described in mandatory Appendix A. Appendix A also describes the methods OSHA will use to determine whether to approve additional fit test methods. The provisions in proposed paragraphs (f)(3), (f)(4), and (f)(5) that referenced alternative fit test procedures therefore have been removed from the final rule.

For qualitative fit testing (QLFT), Part I of Appendix A contains the OSHA-accepted qualitative fit testing protocols for the isoamyl acetate QLFT protocol; the saccharin QLFT protocol; and the irritant smoke QLFT protocol, which were first adopted in the Lead standard (29 CFR 1910.1025). In addition, Appendix A contains an OSHA-accepted protocol for the Bitrex™ (Denatonium benzoate) QLFT method, which was submitted to the rulemaking record and commented on during this rulemaking.

Appendix A also lists three protocols for the QNFT methods that are OSHA-accepted. The first is the traditional generated aerosol QNFT method in which a test atmosphere (corn oil, DEHS, or salt) is generated inside a test enclosure and the concentration inside and outside the mask is measured. The second method is the ambient aerosol QNFT method, commonly called the Portacount™ method, which uses a condensation nuclei counter to measure the ambient aerosol concentrations inside and outside the mask. The third method that has been added is the controlled negative pressure (CNP) QNFT method (Dynatech Nevada FitTester 3000™), which was the subject of comments during this rulemaking. These OSHA-accepted QLFT and QNFT methods are described further in the discussion of Appendix A that follows.

The only fit test method that generated any controversy during the rulemaking proceeding was the irritant smoke QLFT protocol. OSHA is continuing to accept the irritant smoke QLFT protocol for use under this standard because the method is valuable when used properly and is often used by small employers because it is relatively inexpensive. Moreover, it is also the only QLFT method where facepiece leakage elicits an involuntary response, which can eliminate the possibility that a wearer could pretend to pass the fit test in order to be eligible for a job requiring respirator use.

Nevertheless, OSHA is aware that high levels of irritant smoke can be produced during a fit test and that

these concentrations can be dangerous. Employees exposed to excessive concentrations of irritant smoke have suffered severe reactions (Ex. 54-437; Tr. 390). For this reason, it is particularly important that employers using the irritant smoke protocol ensure that test operators are well trained in this method and comply with all the steps in the OSHA protocol. To ensure that any leakage will be as minimal as possible, the test must not be performed until the employee has passed a user seal check. In performing the sensitivity check necessary to determine that the particular user is sensitive to irritant smoke, it is extremely important to assure that the employee is exposed to the least amount of irritant smoke necessary to trigger a response. Appendix A is a mandatory appendix, and failure to comply completely with its protocols will constitute a violation of this standard.

#### QLFT Limits -- Paragraph (f)(6)

Paragraph (f)(6) of the final standard limits qualitative fit testing to situations where the user of a negative pressure air-purifying respirators must achieve a minimum fit factor of 100 or less. A similar limitation was contained in the proposal (paragraph (f)(6)(i)(A)). This limitation is based on the fact that the existing evidence only validates the use of qualitative fit testing to identify users who pass the QLFT with a respirator that achieves a minimum fit factor of 100. Dividing the fit factor of 100 by a standard safety factor of 10 means that a negative pressure air-purifying respirator fit tested by QLFT cannot be relied upon to reduce exposures by more than a protection factor of 10. The safety factor of 10 is used because protection factors in the workplace tend to be much lower than the fit factors achieved during fit testing; the use of a safety factor is a standard practice supported by most experts to offset this limitation. For example, the ANSI Z88.2-1992 standard states, in clause 9.1.1, "If a quantitative fit test is used, a fit factor that is at least 10 times greater than the assigned protection factor (table 1) of a negative-pressure respirator shall be obtained before that respirator is assigned to an individual. If a qualitative test is used, only validated protocols are acceptable. The test shall be designed to assess fit factors 10 times greater than the assigned protection factor."

The only objection to this limitation was expressed by a few commenters (Exs. 54-153, 54-178) who noted that in the future, new QLFT protocols may be developed allowing the measurement of higher fit factors. If new methods are developed that permit QLFT use for higher fit factors, OSHA will, as part of the acceptance process for these new methods, adjust this requirement appropriately.

#### QNFT Minimum Fit Factors -- Paragraph (f)(7)

Paragraph (f)(7) of the final standard lists the minimum fit factors required to be achieved during quantitative fit testing. These minimum fit factors were listed in paragraphs (f)(6)(i)(B) and (f)(6)(ii)(B) of the proposal. Half masks are required to achieve a minimum fit factor of 100 during QNFT, and full facepiece respirators must achieve a minimum fit factor of 500. Paragraph (f)(7) in the final standard consolidates the minimum QNFT fit factors for half mask and full facepiece respirators into one provision. The safety factor of ten used for full facepiece respirators is the same as that for half masks.

The minimum fit factors in the final standard for QNFT are the same as those that were proposed, and are identical to the minimum fit factors required in OSHA substance-specific standards that require QNFT (See e.g., Asbestos, 29 CFR 1910.1001; Cadmium, 29 CFR 1910.1027; Benzene, 29 CFR 1910.1028; Formaldehyde, 29 CFR 1910.1048; 1,3- Butadiene, 29 CFR 1910.1051).

Most participants who commented on the issue agreed with these minimum fit factors. A few participants argued for higher minimum fit factors (Exs. 67, 54-405). For example, Robert da Roza, citing his study on the reproducibility of QNFT (Ex. 24-9), stated in his testimony at the OSHA hearings on minimum fit

factors that "What I feel confident in is that you do need something higher than a ten. It may be as high as 800. I'm suggesting that some statistician look at this a little more rigorously and come up with some better number." (Tr. 102)

TSI, Inc. (Ex. 54-405), in discussing the pass/fail levels for QNFT, recommended the following:

The proposed requirement that a successful QNFT achieve a fit factor of at least 100 for a half mask and 500 for a full-face mask should be raised. The proposed values allow employers to accept what in reality is a very poor fit compared to what can be achieved with proper employee training \* \* \* We feel that a fit factor of at least 1000 for half masks and at least 2000 for full face respirators is justifiable and readily achievable with minimal extra effort by the employer.

However, empirical data or statistical analyses that supported the need to increase the minimum fit factors proposed were not presented. Although fit factors substantially higher than the minimum values are frequently achieved, OSHA's experience enforcing the substance-specific standards that have similar requirements to the minimum fit factors contained in the final respiratory protection standard shows that these factors are adequate to distinguish well fitting respirators from those that fit poorly, which is the purpose of fit testing. Accordingly, OSHA is retaining the proposed fit factors in the final standard.

#### Testing Positive Pressure Respirators -- Paragraph (f)(8)

Paragraph (f)(6)(iii)(B) in the proposal required that fit testing of positive pressure respirators be conducted without any of the air- supplying equipment or attachments that produce a positive pressure inside the facepiece during respirator use. Thus, the proposal required positive pressure respirators to be tested under negative pressure. Final paragraph (f)(8) similarly requires that positive pressure tight- fitting respirators be fit tested in the negative pressure mode. Fit testing seeks to measure the tightness of the facepiece seal. If the air pressure inside the facepiece is higher than that outside, the pressure differential reduces the amount of ambient air leaking into the facepiece, and the measurements obtained during the fit test do not represent the tightness of the seal between the face and the facepiece. Many tight-fitting respirator facepieces are available in both air- purifying models and atmosphere-supplying units. For these, fit testing can be performed using an identical negative pressure air-purifying respirator facepiece, with the same sealing surfaces, as a surrogate for the atmosphere-supplying facepiece the employee will actually be using. Where an identical negative pressure facepiece is unavailable, the employer may convert the facepiece of the employee's unit to allow for qualitative or quantitative fit testing. Many SCBA manufacturers (e.g., MSA, Interspiro and Survivair) sell fit testing adaptors for this purpose that allow for fit testing of their SCBA facepieces.

Final paragraphs (f)(8)(i) and (f)(8)(ii) describe the specific ways in which these alternatives apply for performing QLFT and QNFT measurements, respectively. If the respirator facepiece has been modified for fit testing, final paragraph (f)(8)(iii) requires that the modifications must be completely removed and the respirator restored to its NIOSH-approved configuration before it is used in the workplace. These requirements replace the similar provisions in proposed paragraph (f)(6), and should clearly inform employers of the requirements for fit testing tight-fitting atmosphere-supplying or powered air-purifying respirators. These provisions are designed so that the testing reflects the conditions of respirator use as accurately as possible. There were no significant objections to this provision in the record.

#### Proposed Paragraph (f)(9) -- Interim Use of QLFT

The final standard deletes proposed paragraph (f)(9), which would have allowed an employer initially to perform a qualitative fit test to fit the respirator user where an assigned protection factor greater than 10 is required if the employer had an outside party conduct quantitative fit testing within 30 days. OSHA

proposed this provision to address those few instances when contractors were not available to test employees who had been hired after the annual fit testing for a given establishment had been conducted. There was considerable opposition to this provision. John Hale of Respirator Support Services (Ex. 54-5) recommended that this provision be eliminated because the provision could be abused. The Exxon Company (Ex. 54-266) also recommended that the provision be deleted, suggesting that full facepiece respirators fit tested using a QLFT be limited to use in atmospheres containing 10 times the exposure limit of a hazardous substance until an adequate QNFT is performed. Other commenters stated that retaining the provision could result in overexposure of the employee to workplace contaminants (Exs. 54-280, 54-303, 54-408). The Los Alamos National Laboratory (Ex. 54-420) criticized the provision on the basis that it is the employer's responsibility to provide appropriate fit testing prior to assigning employees to work where respirators are required. The U.S. Army (Ex. 54-443D) stated that if employers have a functioning respirator program and know of the requirement for annual testing, then they should be able to schedule fit testing appropriately, with no need for an extra 30 days.

Some participants who supported the proposed requirement stated that QNFT has not been shown to be a better predictor of workplace protection than QLFT, and recommended that QNFT be an optional, rather than a required method, when fit factors greater than 10 are needed. Moldex Metric Inc. (Ex. 54-153) recommended that the provision be broadened to allow the employer some latitude in selecting which fit testing methods must be used. Bayer Corporation (Ex. 54-210) recommended the period be extended to 90 days, and that the provision be broadened to include repair and/or calibration of fit testing instruments; other participants also recommended a 60 or 90 day period (Exs. 54-222, 54-278, 54-330, 54-361, 54-424, Ex. 54-430).

OSHA has concluded that the rulemaking record demonstrates that proposed paragraph (f)(9) is unnecessary. Contractors who perform QNFT services are located throughout the country, and an employer can arrange a schedule to ensure that fit testing will be available when required. QNFT instruments are also available for rent and can be used by employers themselves after appropriate training if no contractor is available. Several different types of reasonably priced QNFT instruments are manufactured, and OSHA believes many employers can readily purchase one to perform their own QNFT. The instruments are highly portable and can be readily shipped to where they are needed. As the Army points out (Ex. 54-433D), an employer with a respirator program that requires annual fit testing can readily schedule fit testing appropriately.

In addition, the comments OSHA received urging that the provision be expanded increase OSHA's concern that leaving the option in the standard could expose employees unnecessarily to excessive concentrations of hazardous substances. The QNFT exemption as proposed was intended to be narrow in scope and to apply only when contractors were not readily available to test new employees who were hired after the annual fit testing session. The reasons advanced for extending this QNFT exemption were not convincing. OSHA believes that there are other ways to address the concerns raised by commenters in support of this QNFT exemption. For example, employers can schedule QNFT instrument calibration during times when fit testing is not scheduled and can obtain a substitute QNFT instrument when their own unit needs repair. OSHA concludes that this provision is not appropriately included in the final standard.

## Appendix A -- Mandatory Fit Test Protocols

Appendix A contains the fit test protocols that employers must follow in performing qualitative and quantitative fit testing for tight-fitting respirators. The Appendix also contains procedures OSHA will use

to evaluate "new" fit testing methods. Proposed Appendix A addressed the same subjects. Employers who have in the past performed fit tests pursuant to a substance-specific standard must now follow the protocols for OSHA-accepted fit tests that are set out in Appendix A. OSHA has removed the fit testing protocols in the substance-specific standards to eliminate duplication and consolidate all fit testing protocols in Appendix A.

Appendix A has been reorganized from its proposed format to improve clarity and usefulness. The provisions dealing with administering OSHA-accepted fit testing protocols have been moved to part I.

Section A of part I contains general provisions and test exercises that apply to both QLFT and QNFT.

Section B contains the OSHA-accepted QLFT protocols for isoamyl acetate, saccharin, Bitrex, and irritant smoke fit tests.

Section C contains the OSHA-accepted QNFT protocols for generated aerosol, ambient aerosol (CNC), and controlled negative pressure (CNP) fit tests.

Part II addresses the methodology OSHA will use to evaluate new fit test methods and technology.

Appendix A provides general instructions for performing fit testing which have been simplified and clarified by combining the common elements for both QLFT and QNFT and presenting them in Section A of Part I. This includes directions for such procedures as selecting a respirator for fit testing and performing the required test exercises. By combining common elements and eliminating the duplication of fit test protocols in the substance-specific standards, OSHA has reduced the number of pages in its regulations dedicated to fit testing. The purpose of the OSHA fit testing protocols is to tell fit test operators how to perform fit testing to ensure that an adequately fitting facepiece is selected. The protocols reflect the fit test elements (i.e., equipment and basic procedures) that were performed during the validation testing that initially led to their acceptance by OSHA. The protocols do not contain specific instructions on operating any particular fit test instrument because each instrument has specific manufacturer's operating instructions that must be followed to obtain valid results.

The fit testing procedures and specific requirements in the QLFT and QNFT protocols in Sections B and C of part I reflect both the experience that has been gained in performing fit testing and the validation testing that was done initially in order for each method to be accepted by OSHA. The OSHA-accepted methods were evaluated by comparing their performance with that of another accepted fit test to demonstrate that each new method would reliably identify adequately fitting facepieces. The OSHA-accepted protocols reflect the specific procedures and equipment that were used in validation testing, and they must be followed to ensure minimum reproducibility. These elements in the OSHA protocols are not written in performance-oriented language, since any significant variation from the required protocols would invalidate the reliability testing that was performed initially to gain OSHA acceptance and would add uncertainty to the validity of fit test results.

#### Fit Testing Procedures -- General Requirements

The general requirements for fit testing contained in Appendix A, part I.A apply to all OSHA-accepted fit test methods, both QLFT and QNFT. These provisions contain general requirements and instructions for both the person being fit tested, and the person conducting the fit testing. The provisions have been modified slightly from the proposal.

Provision A.1 requires that the test subject be afforded a selection of respirators of various sizes and

models from which to pick the most acceptable. The revised language of this provision reflects the substitution of the term "acceptable" for "comfortable" in paragraph (d)(1)(iv). Provision A.2 is identical to that proposed. The test operator shows the person being fit tested how to don the respirator properly. This instruction may complement the training required by paragraph (k) of this standard. Provisions A.3 to A.7 contain instructions for selecting the most acceptable respirator for fit testing.

Provision A.8 requires the subject to perform a "user seal check" before the fit test is performed. The language in this provision has been modified to reflect the use of the new definition for "user seal check." Provision A.9 restates that fit testing shall not be conducted if there is any hair growth between the skin and sealing surface of the respirator. If the test subject exhibits breathing difficulty during fit testing, provision A.10 requires that he or she be referred to a PLHCP. Minor revisions to this provision reflect changes made to paragraph (e) of the standard on medical evaluation. Provision A.11 requires retesting whenever the employee finds the fit unacceptable. Provision A.12 of Appendix A, Part II of the proposal regarding fit testing records has been moved to paragraph (m) of the final standard to consolidate all recordkeeping provisions.

Provisions A.12 through A.14 of this final standard describe the specific exercises to be performed under all qualitative and quantitative fit tests protocols. The exercises are mostly the same; however, the grimace exercise is not performed for QLFT protocols. In addition, a separate test regimen is prescribed in Section C for the CNP quantitative fit test. Except for minor modifications, the exercises are identical to those in the proposal and to those in OSHA's substance-specific health standards. Participant comments focussed on a few issues: the number and duration of fit test exercises (Exs. 54-158, 54-187, 54-206, 54-218, 54-219, 54-261, 54-271, 54-273, 54-350, 54-325, 155), and the need for the grimace, bending over/jogging-in-place, and talking exercises (54-153, 54-173, 54-175, 54-179, 54-208, 54-218, 54-219, 54-261, 54-273, 54-317, 54-363, 54-408, 54-420, 54-424). These comments are addressed below.

Provision A.14 requires the employee being fit-tested to perform eight exercises. Seven of the exercises must be performed for one minute, while the grimace exercise lasts for only 15 seconds. The test exercises and exercise sequence are: normal breathing; deep breathing; turning the head side to side; moving the head up and down; talking; grimacing; bending over (or jogging in place if the test unit is not large enough for the test subject to bend at the waist); and normal breathing.

Some participants complained that the number and length of the exercises required to be performed were excessive. For example, the 3M Company stated that OSHA has made numerous changes to accepted protocols without verifying the effect of the changes on test performance (Ex. 54-218). According to 3M, OSHA arbitrarily altered the fit tests by requiring the test exercises to be performed for one minute, rather than 30 seconds, and by including the grimace and the bending over/jogging-in-place exercises, and that this alteration violates the original validation of the fit test protocols. In fact, the protocols in this standard are virtually identical to those in other OSHA health standards that have been promulgated over the past fifteen years. The isoamyl acetate (IAA) QLFT test that was evaluated and adopted in the lead standard in 1982 has six exercises. Five of the exercises must be performed for one minute, and the talking exercise is performed for "several" minutes. Thus, the total test time for the six exercises is seven to eight minutes, compared to the seven minutes and 15 seconds that completion of the exercises in this standard will take. Since the length of the two test protocols is similar, OSHA concludes that the IAA concentration at the end of the fit test under this standard would be the same as if the fit test was performed under the IAA QLFT protocol contained in the lead standard.

The grimace exercise drew a number of comments. The test is intended to simulate the type of normal

facial movements that could break a respirator seal. It was developed in the asbestos standard in 1986 and has been incorporated into subsequent OSHA standards. Participants questioned the need for the grimace exercise, particularly with QLFT, where a break in the facepiece seal could cause sensory fatigue (Exs. 54-153, 54-208, 54-218, 54-219, 54-263, 54-273, 54-363, 54-408, 54-424). Several commenters (Exs. 54-173, 54-179, 54-261, 54-317) stated that the grimace exercise cannot be described so that its effects are standardized and reproducible. DuPont (Ex. 54-350) recommended that the standard incorporate only six exercises, deleting both the grimace and bending/jogging exercises. DuPont stated that if the grimace remained in the fit test protocol, it should be performed last, with the results excluded from the calculations. Allied Signal (Ex. 54-175) also recommended that the grimace exercise be deleted; however, if retained, it should be performed at the completion of the other test exercises. In contrast, the Los Alamos National Laboratory (Ex. 54-420), which originated fit testing protocols, stated that their researchers included the grimace exercise as part of the test exercises for full facepieces in the early 1970s. Los Alamos stated that an exercise that simulates a worker's normal facial movements should not be excluded from the test exercises, and recommended that it be retained.

These comments have persuaded OSHA to delete the grimace exercise as one of the required fit testing exercises for QLFT, but to retain it for QNFT. A break in the facepiece seal during a QLFT could cause sensory fatigue that would invalidate the results of the grimace test and any remaining fit test exercises. Performing the exercise as the final element of the qualitative fit test would not address this concern because one purpose of the test is to determine whether the respirator reseals after the seal has been broken, and performing the grimace test after all the others have been completed will not allow a determination of whether the respirator has resealed effectively after the test.

The concern about sensory fatigue does not exist with quantitative fit tests, however, and OSHA believes the grimace exercise is a valuable aspect of these tests. Because the exercise stresses the facepiece seal, it allows the test to determine whether the facepiece reseats itself during subsequent exercises. The results from the grimace exercise are not to be used in calculating the fit factor for QNFT (provision C(2)(h)(1)), since breaking of the seal would necessarily produce a low fit factor for the grimace exercise. However, if the respirator facepiece fails to reseat itself, the fit factors measured for the subsequent exercises would reflect this failure, causing the employee to fail the fit test. Therefore the grimace exercise has been retained as one of the required QNFT fit testing exercises.

The Air Conditioning Contractors of America (Ex. 54-248) questioned the need to require employees to read from a text, such as the Rainbow Passage. Members of the association stated that their technicians had their own methods of determining fit. As stated above, however, OSHA believes that standardized fit testing protocols provide important safety benefits to employees. To the extent that employers develop other valid fit test methods, Part II of Appendix A provides a procedure through which they can seek OSHA approval of those fit test protocols. The talking exercise requirement is also not onerous. To perform this exercise, the employee must either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song. These alternatives provide employers and employees with some flexibility when performing this exercise.

## Qualitative Fit Test (QLFT) Protocols -- Appendix A, Paragraph B

**B.1. General.** Provision B.1.(a) of Part I of Appendix A on qualitative fit test protocols contains two general provisions relating to QLFT. The provisions are substantively the same as in the proposal. The term "assure" has been replaced by "ensure," reflecting a change that has been made throughout the regulatory text.

Provision B.1.(a) requires the employer to ensure that the person administering QLFT be able to perform tests correctly, to recognize invalid tests, and to ensure that the test equipment is in proper working order. This applies regardless of whether the tester works directly for the employer or for an outside contractor. When QLFT is performed by the employer's own personnel, the testers must be properly trained in the performance of the particular QLFT protocol that will be used. If outside contractors are used to provide fit testing support, the employer must ensure that the test operators performing the fit testing protocols are trained, and can competently administer the QLFT according to the OSHA protocols. This provision is performance oriented, since it lists the abilities the test operator needs, but does not describe a specific training program. The type of QLFT operator training needed is specific to the QLFT method selected, and new methods may be developed in the future that require additional training.

The second provision, B.1.(b), requires that the QLFT equipment be kept clean and well maintained so it operates within its designed parameters. For example, the nebulizers used for the saccharin and Bitrex QLFT protocols can clog when not properly cleaned and maintained, resulting in invalid tests. The test operator must maintain the equipment used for fit testing to ensure proper performance. The requirement is again performance oriented, since the QLFT equipment used will vary with the type of QLFT selected.

There are four qualitative fit test protocols approved in this Appendix. The isoamyl acetate (IAA) test determines whether a respirator is protecting a user by questioning whether the user can smell the distinctive odor of IAA. Both the saccharin and Bitrex tests involve substances with distinctive tastes, which should not be detected through an effective respirator. The irritant smoke test involves a substance that elicits an involuntary irritation response in those exposed to it.

***B.2 -- Isoamyl acetate protocol.*** The IAA test protocol included in the final standard evolved out of the IAA protocol OSHA originally adopted for the lead standard (29 CFR 1910.1025). It requires that an employee first be tested to determine if the employee can detect the odor of IAA, often called banana oil because it gives off a distinctive banana-like smell. The fit test is only to be conducted on employees who can detect this odor. An employee passes the fit test with a particular respirator if he/she cannot detect the IAA odor while wearing the respirator. The primary drawback of the test is the strong ability of IAA to induce "odor fatigue," so that an individual quickly loses the ability to detect the odor if exposed to it for any period of time. Odor sensitivity is the key to the IAA fit test, and any decrease in the employee's odor sensitivity due to background levels of IAA could invalidate IAA fit testing. For this reason several provisions of the protocol are intended to minimize the possibility of background exposure to IAA that could impair the test subject's ability to detect the odor in the fit test.

IAA vapor easily penetrates a particulate filter, and the IAA protocol therefore cannot be used to fit test particulate respirators unless the respirator is equipped with an organic vapor filter. The protocol requires that separate rooms be used for the odor screening and fit tests, and that the rooms be ventilated sufficiently to ensure that there is no detectable odor of IAA prior to a test being conducted. In prior standards, OSHA has required that separate ventilation systems, in addition to separate rooms, be used for these functions (e.g., Lead [47 FR 51114]). OSHA proposed to do the same in this standard. However, OSHA has been convinced by the comment of Mobil Oil Corporation (Ex. 54-234) that this elaborate precaution against odor fatigue and general background contamination is burdensome and unnecessary. OSHA agrees with Mobil that the ventilation simply needs to be adequate to prevent IAA odor from becoming evident in the rooms where odor sensitivity testing and respirator selection and donning take place, and that the need to have separate ventilation systems for IAA fit testing will make it unnecessarily difficult to find an acceptable building in which to perform fit testing. OSHA is therefore removing the requirements that the odor threshold screening test and fit test rooms not be connected to the same

ventilation system. Instead, the ventilation requirement is stated in performance language in the final standard: the testing rooms must be sufficiently ventilated to prevent the odor of IAA from becoming evident to the employee to be tested. OSHA believes that this performance-based language will be sufficient to alert employers to the requirement to prevent olfactory fatigue among workers being fit tested by preventing a buildup of IAA in the general room air.

The proposed IAA protocol required that the test atmosphere be generated by wetting a paper towel or other absorbent material with 0.75 cc of pure IAA and suspending the towel from a hook at the tip center of the test chamber. Two commenters stated that the standard should also allow the test atmosphere to be generated by the use of commercially prepared test swabs or IAA ampules as long as these methods generate the required airborne concentrations of IAA (Mobil Oil (Ex. 54-234); Bath Iron Works (Ex. 54-340)).

OSHA agrees that alternative methods of generating the IAA test atmosphere should be permitted as long as those methods have been shown to reproducibly generate the minimum concentration of IAA needed for a successful fit test. The National Bureau of Standards (Ex. 64-182), in its report on fit testing of half mask respirators using the IAA protocol in the OSHA lead standard, found that the minimum IAA concentration inside the test chamber was 100 ppm during fit testing. Accordingly, the IAA protocol in Appendix A of the final standard has been modified to permit the use of test swabs or ampules as long as these have been shown to generate a test atmosphere concentration comparable to that generated by the towel-saturation method in the proposed standard. An employer who wishes to use test swabs or ampules would need to demonstrate that the swabs or ampules generate an acceptable test atmosphere. For this purpose, the employer may rely on data obtained from the manufacturer of the swabs or ampules as long as the employer uses the products in a way that reproduces the concentrations obtained by the manufacturer under the manufacturer's test conditions.

OSHA has also added a provision recommended by the American Industrial Hygiene Association (Ex. 54-208) to reduce the possibility of test area contamination from used paper towels. AIHA recommended that B.2.(b)(10) be revised to ensure that the used towels are stored in self-sealing bags to prevent test area contamination. OSHA adopted the language changes the AIHA proposed; the final standard requires that used IAA towels be removed from the test chamber to avoid test area contamination.

AIHA (Ex. 54-208) also recommended that OSHA remove the language in B.2.(b)(2) of the IAA fit test protocol requiring that organic vapor cartridges be changed at least weekly. AIHA stated that a fit test operator who is competent to implement an adequate QLFT program will be able to determine an adequate cartridge change schedule. OSHA agrees, and has removed the language requiring weekly filter changes, because weekly changes may overstate or understate appropriate frequencies. However, the program administrator or the fit test operator must replace the cartridges as appropriate to ensure their proper function.

After the close of the NPRM comment period and the hearings, during the post-hearing comment period, the ISEA (Ex. 54-363B) submitted a report on fit testing for full facepiece respirators using an IAA QLFT protocol for which the test concentration of IAA was raised to 10 times the concentration used in the OSHA-accepted IAA protocol. ISEA reported that the pass/fail cutoff for the modified IAA QLFT was a required fit factor of 1000, and that this increased IAA concentration fit test could therefore be used to test full facepiece respirators for use where ambient exposures were 100 times the PEL. ISEA stated that the validation data that it submitted for this new IAA fit test meet the validation requirements of the September 17, 1989 ANSI Z88.10 draft standard entitled "Respirator Fit Test Methods." OSHA notes,

however, that all draft provisions of the draft ANSI fit testing standard are still subject to change until published as part of the final ANSI Z88.10 standard. Further, ISEA did not indicate that the test met the validation criteria proposed by OSHA. In addition, no comments were received from the regulated community on this modified IAA protocol. Since the proposed, ISEA-modified, IAA qualitative fit test was submitted as a post-hearing comment, an opportunity did not exist for the regulated community to comment on it as part of this rulemaking record. The revised IAA fit test, therefore, has not received the review and public comment to which the other new fit tests (i.e., Portacount, CNP, Bitrex) were subjected during this rulemaking. Accordingly, OSHA is not adding the modified IAA fit test for full facepieces to the final standard's fit test protocols. This Appendix establishes procedures for OSHA acceptance of new fit test protocols, and a proponent of the modified IAA fit test may submit it for review under those procedures.

### ***B.3 and B.4 -- Saccharin Solution and Bitrex™ (Denatonium benzoate) Solution Aerosol Protocols.***

The protocols for the saccharin and Bitrex solution aerosol fit test methods are similar. Both involve test agents that a test subject will taste if his or her respirator is not functioning effectively. Saccharin is a sugar substitute with a sweet taste, and Bitrex is a bitter taste-aversion agent. In both cases, the subjects are first tested to ascertain that they are in fact able to taste the test agent being used, and then are tested with a respirator. During the fit test the subjects are instructed to breathe with their mouths slightly open and their tongues extended. If they can taste the test agent during the fit test, the test has failed.

The proposal included the saccharin protocol but not the Bitrex protocol, which was not validated until after the proposal was issued. The saccharin protocol was identical to that contained in the Lead standard (29 CFR 1910.1025, Appendix D II; 29 CFR 1910.1027 (Cadmium); 29 CFR 1910.1028 (Benzene); 29 CFR 1910.1048 (Formaldehyde); 29 CFR 1910.1050 (Methylenedianiline); 29 CFR 1910.1051 (1-3 Butadiene)). Several commenters (Exs. 54-208, 54-218, 54-219, 54-363) recommended minor revisions to the language of the protocol to correct specific problems, and to clarify the procedures. In response to these comments, the formula for preparing the threshold check solution has been revised to remove an error in dilution contained in the lead standard protocol. OSHA has also changed the requirement that employees being tested open their mouths wide to a requirement that they open their mouths slightly, since opening the mouth wide could distort normal facepiece fit and invalidate the test results. Opening the mouth slightly is sufficient to allow the employee to detect leakage of the test agent into the respirator when testing for facepiece seal leakage.

The final standard also does not restrict employers to using a DeVilbiss Model 40 nebulizer but also allows them to use an equivalent test nebulizer. Allowing the use of alternative nebulizers that can produce an acceptable test atmosphere is a change from the lead standard protocol, which allowed only the use of the DeVilbiss nebulizer. Finally, the protocol now states clearly that, to elicit a taste response, a minimum of ten nebulizer squeezes is required during the threshold screening. This matches the minimum number of squeezes of the fit test nebulizer required by the protocol.

NIOSH (Ex. 54-437) was the only participant to object to the saccharin aerosol protocol. NIOSH is concerned that saccharin is a potential carcinogen, and it believes that Bitrex is an acceptable alternative test agent. Although saccharin is suspected of being a carcinogen when ingested in large quantities over long periods of time, it is not a substance that OSHA has regulated, and even NIOSH does not have a Recommended Exposure Limit for it. A test subject would be exposed to saccharin only for a brief time during the pre-test sensitivity check, and again either upon failing the test or during the post-test sensitivity check. Either exposure would likely occur only once a year. These exposures would be very low, at or near the threshold of detectability, and it is extremely unlikely that they pose a significant risk to the health of

employees or that they would exceed any realistic exposure limit that may be established.

Moreover, although the Bitrex fit test protocol is an acceptable alternative for situations in which the saccharin protocol is used, Bitrex is not as widely available as saccharin, and the test is not as widely accepted. The Bitrex QLFT protocol was developed by 3M (Ex. 54-218). The test protocol is essentially the same as that for the saccharin QLFT, with changes made in preparing the threshold check solution and the fit test solution to account for the non-linear taste sensitivity of Bitrex. A recent paper by Mullins, Danisch, and Johnston (Ex. 178) in the November 1995 AIHA journal describes the development of the Bitrex QLFT method. Validation testing consisted of 150 paired qualitative and quantitative fit tests, with test volunteers using half mask respirators. The Bitrex fit test was evaluated against the saccharin fit test and found to have a test sensitivity of 0.98 and a predictive value for passing of 0.98 at a fit factor of 100. The overall test results were identical for the Bitrex and saccharin fit test methods.

Only one rulemaking participant objected to the possibility that OSHA would approve the Bitrex test. Robert daRoza of the Lawrence Livermore Laboratory (personal communication with John Steelnack, OSHA, 6/4/97) stated that this method has not been adequately tested by multiple facilities, and that the ratio of the concentrations specified does not follow the same logic used in the saccharin method. Until the method is validated by multiple facilities and the logic of the specified concentrations determined, Mr. daRoza believes that the test should not be incorporated into the final standard.

In contrast, NIOSH has recommended Bitrex as an acceptable alternative test agent for saccharin (Ex. 54-437). OSHA has reviewed the validation studies (Ex. 178) in depth, and believes that they establish the Bitrex protocol as an appropriate fit test method. Therefore, OSHA is approving this protocol.

#### Irritant Smoke (Stannic Chloride) Protocol

The irritant smoke protocol (also called irritant fume) uses stannic chloride smoke tubes to produce a smoke containing hydrochloric acid. Exposure to this test agent causes irritation resulting in coughing. Because the response to irritant smoke is involuntary, the irritant smoke fit test is the only QLFT method that does not rely on the subjective response of the employee being tested (Exs. 54-325, 54-424). The protocol contains a number of provisions intended to minimize employee exposure to the irritant smoke, which can be harmful to some individuals at high exposure levels.

Irritant smoke is the oldest method of fit testing still in use. It was developed at the Los Alamos National Laboratory more than fifty years ago (Ex. 25-4). OSHA has approved the protocol in all of its health standards that allow QLFT (See 29 CFR 1910.1025 (Lead); 29 CFR 1910.1027 (Cadmium); 29 CFR 1910.1028 (Benzene); 29 CFR 1910.1048 (Formaldehyde)).

The irritant smoke protocol also has the drawback, however, that excessive exposure to irritant smoke can cause severe irritation and, in some cases, permanent harm. For this reason, NIOSH (Ex. 54-437) recommended against the continued use of irritant smoke for qualitative fit testing. NIOSH has conducted the only study known to OSHA that assessed the concentrations of hydrogen chloride produced from irritant smoke tubes. When smoke tubes were attached to an aspirator bulb, NIOSH measured concentrations of hydrochloric acid that ranged from 100 ppm (measured at a distance of six inches from the end of the smoke tube) to 11,900 ppm (measured at a distance of two inches). The use of a low-flow pump produced hydrogen chloride concentrations ranging from 1500 ppm to more than 2000 ppm within 10 seconds of turning on the pump. NIOSH did not measure the amount of irritant smoke inside any respirator facepieces (Tr. 411). The OSHA PEL for hydrogen chloride is a ceiling limit of 5 ppm, which may not be exceeded at any time (29 CFR 1910.1000(a)). NIOSH has established an IDLH value of 50

ppm and notes that a concentration of 309 ppm has been reported as the level of hydrogen chloride causing a severe toxic endpoint in laboratory animals. NIOSH also cited a recommendation by a National Academy of Sciences committee to limit emergency exposure to 20 ppm (Ex. 54-437R at p. 6).

NIOSH performed these measurements after evaluating irritant smoke testing at the request of the Anchorage Alaska Fire Department (Ex. 54-437R) because four firefighters had reported experiencing either skin or eye irritation during irritant smoke fit testing inside a test enclosure. NIOSH additionally described a telephone report it had received of vocal chord damage caused by exposure to hydrochloric acid during an irritant smoke fit test. OSHA notes, however, that this fit test was performed inside a test enclosure and that the test subject failed four consecutive fit tests using this challenge agent (Tr. 411).

TSI, Inc. (Ex. 54-303), the manufacturer of the Portacount QNFT system, also recommended that the irritant smoke QLFT protocol be deleted from the final standard. Like NIOSH, TSI was concerned that employees being fit tested may be exposed to hydrochloric acid in excess of the PEL and, sometimes, in excess of the IDLH level. TSI also stated that the proposed protocol did not contain a threshold test to measure the employee's sensitivity to irritant smoke, and does not provide a means for generating a stable test-agent concentration. The 3M Company (Ex. 137), citing the NIOSH recommendation that irritant smoke not be used for fit testing, also recommended against its use. In addition, 3M stated that "the irritant smoke test has not yet been completely validated. Neither the level of smoke necessary to evoke a response nor the challenge concentration during the fit test have been measured and shown to be reproducible."

In contrast, OSHA received comments urging that it continue to approve the irritant smoke protocol. The Organization Resources Counselors, Inc. (ORC) (Ex. 54-424) noted that the irritant smoke protocol is generally considered to be one of the easiest, cheapest, quickest, and most effective QLFT methods available, although ORC recognized that precautions must be taken to minimize exposures. For example, ORC pointed out that irritant smoke fit testing should not be performed in a small chamber, such as an inverted plastic bag or hood, since this could allow the accumulation of high concentrations of hydrogen chloride. SEIU (Ex. 54-455) supported the use of irritant smoke QLFT because of the benefits of its involuntary response. The SEIU stated:

SEIU objects to the use of non-irritant challenge agents (isoamly acetate and saccharine). We have found that many of our members are pressured to complete fit tests quickly and get back to work, and hence will not acknowledge when a respirator has leaked during a fit test. The reaction to an irritant fume is very difficult to disguise.

Willson Safety Products (Ex. 54-86) also supported the use of the irritant smoke fit test, citing "the thousands of businesses who now use the irritant smoke fit test procedure with a 50 ml squeeze bulb. They find the irritant fume protocol the least complicated and most easily performed of the QLFT protocols."

All of the comments urging OSHA not to approve the irritant smoke protocol were based on the possibility that the test could expose employees to high levels of hydrogen chloride. The irritant smoke protocol in Appendix A has been carefully designed to minimize such exposures. The initial and post fit-test sensitivity checks must be performed with "a small amount" of "a weak concentration" of irritant smoke, with care being taken to use "only the minimum amount of smoke necessary to elicit a response." (See provisions I.B.5(a)(4); and 5(b)(3)). Test subjects are to be instructed to close their eyes to prevent eye irritation during the test. The test must be performed in a well-ventilated area to prevent any build-up of irritant smoke in the general atmosphere (provision I.B.5(a)(5)). Unlike other QLFT methods, the irritant smoke test may not be performed inside a test enclosure or hood (provision I.B.5(a)(3)).

Persons being fit tested must pass a user seal check before the fit testing begins (See provision I.A.8). The

irritant smoke fit test starts with a small amount of the irritant smoke being produced from a smoke tube, and the person being tested wafting a small portion of the smoke toward his or her breathing zone to determine if any gross facepiece leakage occurs. Only after determining that the initial fit is adequate does the operator direct smoke at the facepiece seal area, starting at least 12 inches away from the head and working around the seal area and gradually approaching the test subject's face. Because the test is performed in an open area, the person being tested can step back into clean air any time irritant smoke is detected within the mask. This limits the maximum exposure to as little as one breath of irritant smoke.

Following this protocol would have avoided both of the adverse reaction incidents NIOSH described. In the Anchorage case, positive pressure SCBAs were fit tested by placing the users inside a test enclosure and pumping it full of irritant smoke. The users were apparently not warned to close their eyes during the fit test. The use of a test enclosure is expressly prohibited in the OSHA protocol, as is exposing test subjects to more than the minimum amount of smoke necessary to elicit a response. And test subjects must be instructed to close their eyes during testing. The test subject in the second incident who suffered damage to her vocal cords was also tested inside a test enclosure; in addition, she failed four consecutive fit tests involving this agent. Repeated testing of a subject who fails the test not once, but four consecutive times, inside a test enclosure filled with irritant smoke is prohibited by the OSHA protocol. Following the OSHA-accepted protocol would have reduced to substantially lower levels the exposures received by these employees.

In approving this fit test protocol, OSHA is not discounting the evidence that irritant smoke can cause adverse reactions in test subjects. All of the cases OSHA is aware of, however, involve tests that were not done in a way that OSHA considers acceptable, and consequently exposed the test subjects to excessive concentrations of irritant smoke. OSHA emphasizes the critical importance of following its approved protocol, including all of the safeguards against excessive exposure, when this test is used. Indeed, paragraph (f)(5) requires that employers follow these protocols and failure to do so constitutes a violation of the standard.

Participants also made a number of suggestions about specific aspects of the protocol. The proposed irritant smoke protocol, which was derived from protocols promulgated in other standards (29 CFR 1910.1025 and subsequent health standards), required the use of a low-flow air pump set to deliver 200 milliliters of irritant smoke per minute. Several participants commented that an aspirator bulb should be acceptable for generating an irritant smoke test agent, and that further justification was needed for requiring a low-flow air pump (Exs. 54-38, 54-86, 54-135, 54-309, 54-316, 54-324, 54-363, 54-424). The Coastal Corporation (Ex. 54-272) said that requiring only the low-flow air pump would impose an unnecessary financial burden, and recommended that OSHA allow for alternative methods, such as an orifice adapter on a compressed air system, for delivering a uniform stream of irritant smoke. The ISEA (Ex. 54-363) stated that its members were not aware of a commercially available low-flow air pump, and also recommended that an aspirator bulb, which it said was now used by many fit test operators, be allowed instead.

In response to these comments, the requirement that only a low-flow pump may be used to generate the irritant smoke has been changed in the final standard. In addition to the low-flow pump, an aspirator squeeze bulb may be used to generate the irritant smoke for fit testing. However, care must be taken by the fit test operator to ensure that the aspirator bulb produces irritant smoke at the required flow rate of 200 ml/minute. Since aspirator bulbs vary in size, the person performing the fit test must know the volume of the aspirator bulb being used to push air through the smoke tube. The number of bulb squeezes per minute will vary depending on bulb volume. For example, a large 50 ml bulb would need four squeezes per

minute to produce the required volume of irritant smoke, while a smaller 25 ml bulb would need eight squeezes per minute. The squeezes should be uniform, and evenly spaced out through each minute to maintain a relatively constant flow of irritant smoke. The use of an aspirator bulb to deliver the test agent at a stable, constant rate requires some skill on the part of the test operator, since each squeeze can be different, and care must be taken by the fit test operator to produce a steady stream of irritant smoke. An aspirator bulb can produce a large amount of irritant smoke during a single squeeze. However, the squeeze bulb method when properly performed can be an effective fit test for determining facepiece fit. Willson Safety Products (Exs. 54-86) submitted a March 4, 1991 letter of interpretation it had received from Thomas Shepich of the OSHA Directorate of Technical Support regarding the use of a squeeze bulb for performing the irritant smoke QLFT under the asbestos, lead, benzene and formaldehyde standards. Mr. Shepich stated:

In your letter you indicated that a majority of your customers use a 50 ml rubber squeeze bulb that is capable of delivering a flow of 200 ml of air per minute if used correctly. You also express concern over the need to spend \$500.00 or more to use a mechanical pump since the rubber squeeze bulb can adequately meet the intent of the OSHA standard.

The QLFT method is a pass/fail test. Since a rubber squeeze bulb generated challenge agent can be as effective as a mechanically aspirated one, the intent of the standards has been met. The training of individuals administering QLFT by the rubber squeeze bulb method must include techniques on the proper number of compressions per minute necessary to generate an appropriate air flow.

A few other modifications to the protocol have also been made. As the ISEA (Ex. 54-363) recommended, the term "irritating properties" has been substituted for "characteristic odor" in the irritant smoke protocol in Appendix A, since the term better describes what the employee experiences. Based on ORC recommendations (Ex. 54-424), the reference to the MSA smoke tube has been removed, and language has been added requiring that the end of the smoke tube be covered with a short length of tubing to prevent injury from any jagged glass where the tube has been opened. As the AIHA (Ex. 54-298) recommended, the description "involuntary cough" has been added to the description of the response to irritant smoke. A clear statement that no form of test enclosure or hood is to be used with irritant smoke has been added, as supported by ORC (Ex. 54-424), and in response to the problems described by NIOSH and TSI (Exs. 54-303; 54-437R).

### Quantitative Fit Test (QNFT)

Appendix A includes three quantitative fit test protocols, the generated aerosol protocol, the Portacount™ protocol that uses ambient aerosol as the test agent and a condensation nuclei counter (CNC) as the test instrumentation, and the controlled negative pressure (CNP) protocol (i.e., the Dynatech FitTester 3000™). Only the generated aerosol protocol was included in the proposal. Each QNFT method is described in a separate section of Appendix A.

Part I of section C contains general requirements for QNFT. The employer is to ensure that the individuals who perform the QNFT, whether employees or contractors, are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order. The employer is also responsible for ensuring that the QNFT equipment is cleaned, maintained, and calibrated according to the manufacturer's instructions so that it will operate as designed.

Respirators used for QNFT must be in proper working condition. Respirators are to be rejected if leakage is detected from exhalation valves that fail to reseat adequately, near the probe or hose connections, or if the respirator is missing gaskets. The requirement in paragraphs (h)(1)(iv) and (h)(3)(i)(A) that all respirators used in non-emergency situations be inspected for defects before each use and cleaned after

each use also apply to fit testing. The test operator must inspect the test respirator for: cracking, holes, or tears in the rubber body of the facepiece; cracks or tears in valve material and in the inhalation and exhalation valve assemblies; foreign material between the valve and valve seats; proper installation of the valve body in the facepiece; and warped or wrinkled valves. Respirators with any of these defects cannot be used for fit testing.

A user seal check must be conducted prior to starting QNFT to ensure that the respirator facepiece is properly adjusted. The use of an abbreviated, or screening, QLFT before QNFT fit testing to identify poorly fitting respirators is optional.

## Paragraph 2 -- Generated Aerosol QNFT

The procedures for conducting the generated aerosol quantitative fit test are widely recognized and accepted by the industrial hygiene community. The test is performed inside a test unit such as a hood, portable booth, or chamber. An aerosol of a test agent is generated inside the enclosure. A stable ambient test agent concentration must be achieved prior to beginning the test exercise regimen. The test unit must be large enough to permit the employee being tested to freely perform the QNFT exercise regimen without disturbing the test agent concentration, and the unit must effectively contain the test agent in a uniform concentration.

During the test, the respirators are fitted with filters, such as high efficiency HEPA, or P100 filters, that offer 99.97% efficiency against 0.3 micron aerosols as defined by NIOSH in 30 CFR part 11 or 42 CFR part 84. Therefore, virtually any measurable leakage should be the result of leaks between the respirator sealing surface and the respirator user's face. If test agents other than particulates are used, the sorbent/filters must offer a similar degree of collection efficiency against the test agent. The concentration of the test agent is measured both inside and outside the respirator. Commonly used detection methods include forward light-scattering photometry or flame photometry.

Three methods were proposed for using the results of these measurements to calculate fit factors: the average peak penetration method; the maximum peak penetration method; and the use of an integrator to calculate the area under the individual peak for each exercise (59 FR 58919). OSHA proposed that the fit factor derived from QNFT using test agents be calculated by dividing the average test agent concentration inside the chamber (i.e., the ambient concentration) by the average test agent concentration inside the respirator for each test exercise (excluding the grimace exercise). The average ambient concentration is derived from the measurement of the test agent concentration in the test chamber (i.e., outside the respirator) at the beginning and end of the test. TSI, Inc. (Ex. 54-8) stated that while the language proposed for determining the average test chamber concentration was correct, better accuracy could be obtained by averaging the chamber concentration before and after each exercise, and by allowing for continuous chamber concentration measurements. OSHA agrees that the standard should allow for these other methods of measuring average test chamber concentration, and has adopted the revised language submitted by TSI.

In the proposal, the average test agent concentration inside the respirator was to be determined from the aerosol penetration during each test exercise using one of three approved methods for calculating the overall fit factor. TSI, Inc. (Ex. 54-8) noted that the intuitive, but algebraically incorrect, method of computing the arithmetic average of the fit factors for all exercises (i.e., for instruments that report their exercise results as fit factors instead of peak penetrations) would result in an overestimation of the overall fit factor. This commenter suggested that OSHA adopt the equation from the draft ANSI Z88.10 fit testing standard that correctly states how to perform the fit factor calculation for instruments that report results as

exercise fit factors instead of peak penetration values. OSHA agrees and has added this equation to Appendix A in the final standard.

The test aerosol penetration measured for the grimace exercise is not to be used in calculating the average test agent concentration inside the respirator (See provision I.C.2(b)(8)(i)). The purpose of the grimace exercise is to determine whether the respirator being fit tested will reseal itself on the face after the respirator seal is stressed during the exercise. With a properly fitting respirator, the test instrumentation should record a rise in test agent concentration inside the mask during the grimace exercise, and a drop in test agent concentration when the respirator reseals itself. If the respirator fails to reseal itself following the grimace exercise, the subsequent normal breathing exercise will show excessive leakage into the mask and result in a failed fit test. Since even a properly fitting respirator may show increased test agent penetration during part of the grimace exercise, the penetration value measured during the grimace exercise is not to be used in calculating the overall fit factor.

A clear association is required between an event taking place during testing and the record of the event. This requirement is critical for the proper calculation of aerosol penetration for specific test exercises. Short duration leaks (displayed as peaks on the recording instrument) can occur during, and as a result of, each fit test exercise, and these leaks indicate poor respirator fit. These penetration peaks are used to determine the fit factor. An inability to measure these penetration peaks could result in the fit factor being overestimated, since averaging all the test exercise penetration peaks may obscure the high penetration levels that occur during a test exercise. An inability to clearly associate the exercise event with the recording makes correct calculation of the fit factor impossible.

Several factors can affect the time interval between an exercise event occurring during QNFT and the recording of the event, such as the diameter of the sampling line, sampling rate, and the length of the sampling line. Response time will increase with an increase in the length and/or diameter of the sampling line. Therefore, the length and inside diameter of the sampling line should be as small as possible. The line used for sampling the test chamber test agent concentration, and the line used for testing the test agent concentration inside the respirator, must have the same length and inside diameter so that aerosol loss caused by aerosol deposition in each sample line is equivalent for the two lines.

To minimize both contamination of the general room atmosphere and test operator exposure to the test agent, the generated aerosol protocol requires that air exhausted from the test unit must pass through a high-efficiency filter (or sorbent).

Since the relative humidity in the test chamber may affect the particle size of sodium chloride aerosols, the protocol further requires that the relative humidity of the test unit be kept below 50 percent. This requirement is consistent with manufacturer's instructions for sodium chloride units.

Prior to beginning the generated aerosol QNFT, a stable test agent concentration must be achieved inside the test unit. The concentration inside small test booths or waist-length hoods may be diluted significantly when the employee enters the booth. Normally, the test agent concentration will stabilize within two to five minutes.

Adjustments to the respirator must not be made during the QNFT. Any facepiece fit adjustments must be made by the employee before starting the exercise regimen. This requirement will prevent manipulation of the respirator during fit testing to achieve higher fit factors. The fit test is to be terminated whenever any single peak penetration exceeds two percent for half masks and quarter facepiece respirators, and one percent for full facepiece respirators. Such leaks correspond to fit factors below 100 for half masks and

500 for full facepiece respirators, and indicate an unacceptable respirator fit. In such cases, the respirator may be refitted or adjusted, and the employee retested. If a subsequent QNFT test performed after the respirator has been refitted or adjusted is terminated because of excessive penetration, then the respirator fit for that individual must be considered unacceptable, and a different respirator must be selected and tested.

OSHA had proposed that an employee successfully complete three separate fit tests with the same respirator using a QNFT protocol. The proposed requirement was derived from the fit testing protocols in OSHA's substance-specific standards, e.g., the Benzene standard (29 CFR 1910.1028). This proposed provision received more than 150 comments. Many commenters stated that only a single QNFT was needed, and that the additional tests would only increase the cost of fit testing without a corresponding improvement in attaining a successful fit (Exs. 54-11, 54-26, 54-35, 54-37, 54-41, 54-44, 54-63, 54-83, 54-114, 54-124, 54-139, 54-208, 54-289, 54-316, 54-359, 54-363). Some said that requiring three tests for QNFT would discourage employers from adopting QNFT (Ex. 54-164), or would force employers to use the less protective QLFT, which requires only one fit test (Exs. 54-316, 54-359, 54-363, 54-434). One commenter stated that three fit tests for QNFT would only be needed if OSHA allows higher APFs based on the results (Ex. 54-84). (OSHA notes that the concept of increasing the APF based on repeated fit testing, originally contained in the ANSI Z88.2-1980 respirator standard, was subsequently removed from the Z88.2-1992 revision of that standard (Ex. 54-443)). The Bath Iron Works (Ex. 54-340) stated that the variation between separate fit tests is significant, and recommended that this problem could be resolved by increasing the safety factor beyond 10. Other commenters suggested that increasing the fit factor required for passing a single QNFT was an alternative to requiring three fit tests (Exs. 54-139, 54-154, 54-173, 54-340).

The final standard does not include the requirement to perform three successful QNFTs because performing three tests has not been shown in this record to better detect poor respirator fit. Increasing the safety factor of 10, thereby raising the minimum fit factor required to pass a QNFT, also has not been adopted by OSHA because experience indicates a safety factor of ten is sufficient. While many employers have, on their own, decided to require higher fit factors during fit testing, data in the record do not support the suggestion that increasing the safety factor beyond 10 is appropriate. Using a safety factor of 10 is current practice in fit testing, and is used to account for the variability in fit testing procedures, as well as other variables (e.g., differences in respirator fit between the workplace and during fit testing).

The results of the fit test must be at or above the minimum fit factor required for that class of tight-fitting air-purifying respirator. The required fit factors are established by applying a safety factor of 10 to the APFs for that class of respirator. For example, quarter and half mask air-purifying respirators with an APF of 10 must achieve at least a fit factor of 100, and full facepiece air-purifying respirators with an APF of 50 require a minimum fit factor of 500.

### Paragraph 3 -- Condensation Nuclei Counter (CNC) QNFT

A protocol for the ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol (i.e., TSI, Inc. Portacount™) has been added to the final standard as an accepted QNFT method. Many commenters pointed to the need for a CNC QNFT protocol. Commenters, (Exs. 54-216, 54-326, 54-359) noted that the Portacount is the most commonly used method, and that sufficient data have been developed over the past several years to validate its effectiveness. The use of the Portacount has been allowed by OSHA under a compliance interpretation published in 1988. Commenters urged that the ambient aerosol CNC method be included in the list of accepted QNFT methods in the final standard (Exs. 54-216, 54-326,

54-359). OSHA agrees with these comments. The written instructions for performing the fit test in Appendix A are essentially the same as the instructions provided by the manufacturer.

#### Paragraph 4 -- Controlled Negative Pressure (CNP) QNFT

The protocol for the controlled negative pressure (CNP) quantitative fit test method (Dynatech Nevada FitTester 3000™) has also been added to the list of accepted QNFT methods. This fit test method involves the use of a fit test instrument to generate a controlled negative pressure inside the facepiece of the respirator to measure the resulting leak rate.

This fit test protocol is the same protocol allowed by OSHA under a compliance interpretation letter issued in 1994 and based on various studies on the performance of the CNP method conducted by its developer, Dr. Cliff Crutchfield (Exs. 71, 54-436). These studies reported results that were validated by comparing them to results from the existing aerosol fit test systems. The data showed that the fit factors measured with CNP are always lower than the fit factors measured with an aerosol QNFT. OSHA had reviewed these studies before issuing its compliance letter. OSHA believes that the CNP method, based on Dr. Crutchfield's validation data, constitutes adequate support for the method's reliability in rejecting bad fits. Although no body of data is available that describes employer experience using the CNP method in the workplace, OSHA is confident that the extensive validation data showing consistently conservative results using CNP means that this method will identify bad fits at least at the same rate as other accepted fit test protocols.

Several commenters urged OSHA to provide a protocol for the CNP method and to list it as approved (See, e.g., Exs. 54-167, 54-216). In addition, NIOSH in its comments and testimony stated that "NIOSH recommends that OSHA recognize \* \* \* the following fit test procedures as acceptable \* \* \* Quantitative fit tests using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit" (Tr. 359, Ex. 54-437). NIOSH further stated in its comment (Ex. 54-437) that "[o]nly the controlled negative pressure fit test system, which has been excluded in the OSHA proposal, has been subjected to limited validation" (Decker and Crutchfield, 1993). The State of Washington Department of Labor and Industries (Ex. 54-173) requested that OSHA provide performance criteria so that methods such as "Dynatech test equipment" described as "proven" and "accepted" may more easily be used.

Penelec/Genco reported favorable experience using the CNP method (Ex. 54-167). As stated in its comment:

Penelec/Genco recently quantitatively fit tested approximately 1500 employees on both half and full face respirator facepieces using the Dynatech/Nevada FitTester 3000. For the past 10 years we have performed fit tests using particle counting equipment. We are most pleased with the results provided by the FitTester 3000 \* \* \* We believe that the science is sound, the equipment is reliable, and the results are valid. When used as part of a complete respiratory protection program, we believe controlled negative pressure fit testing is an effective way of matching each person with the best-fitting, most comfortable facepiece respirator.

All the peer-reviewed studies consistently show that controlled negative pressure equipment and protocols always produce more conservative fit test results than particle counting equipment and protocols. Our experience totally supports this.

We find the Dynatech/Nevada FitTester 3000 to be durable, reliable and easy to use. Results are always reproducible, with minimum variation. Employee acceptance is excellent, especially because they get a direct perception of fit (leaks or lack of) which corresponds well to the machine's fit results.

Using the FitTester 3000 we are able to select more comfortable, better fitting respirators for our employees. We believe that certain respirator brands are far superior to others in terms of fit and comfort. As a result, we have switched brands. Our

employees are far more satisfied with the fit and comfort of their new respirators \* \* \* (Ex. 54-167)

TSI, Inc. (Exs. 54-229, 54-302) stated that OSHA should reject the CNP method as a valid QNFT, since employees who are tested using this method must hold their breath and remain motionless during the measurement, i.e., they cannot perform the required exercises simultaneously with the measurement. According to TSI (Ex. 171), dynamic exercises are necessary to simulate the face seal stresses imposed by workplace conditions. Dr. Crutchfield, in his post-hearing submission (Ex. 134), responded to statements made by Jeff Weed of TSI at the hearing and in TSI's submissions to the record regarding the CNP fit test method. He discussed the ability of aerosol-based fit test methods to measure transient leaks, stated that leakage occurs with inhalation, and that the CNP method measured more respirator leakage than aerosol-based systems, and further, that CNP fit factors "tend to align more closely with workplace protection factors than do aerosol-based fit factors." Dr. Crutchfield stressed the importance of being able to effectively measure fundamental leakage into the respirator, stating that "most dynamic exercises do not seem to have a statistically significant effect on measured fit factors."

OSHA recognizes the need to perform fit testing exercises to stress the facepiece seal, and has included a full range of exercises in the CNP protocol in Appendix A. They differ from the exercises for the CNC method, since test results are not taken while the test exercise is being performed, but are taken after the exercise is completed. However, since the CNP method cannot distinguish changes in facepiece volume that are related to movement during an exercise from leakage into the facepiece caused by poor respirator fit, the CNP protocol requires that the employee remain motionless during the short sampling period that is required after each exercise. OSHA believes that any changes in fundamental fit caused by the test exercises should, consequently, be measured by the CNP method during the 10-second sampling period following each exercise, and that this does not affect the test's ability to detect poor fits when the seal is stressed.

In addition to the OSHA-accepted CNP fit test protocol, Dr. Crutchfield (Tr. 254) testified about a new fit test protocol for the CNP method. This new protocol is substantially different from the OSHA-accepted protocol, which requires the performance of test exercises followed by CNP measurements. The new protocol was also described in detail in a letter from Senator John McCain of Arizona on behalf of Dr. Crutchfield (Ex. 54-460). The new protocol submitted after the close of the post-hearing comment period is described as consisting of three exercises and two redonnings. The first exercise measured "fundamental respirator fit" with the head facing forward. The second exercise was a bending exercise, with the respirator parallel to the floor. The third exercise consisted of vigorously shaking the head from side-to-side for three seconds, followed by a "fundamental fit" measurement. The respirator user then is required to remove and redon the respirator twice, with "fundamental fit" measured after each redonning. This protocol results in five CNP measurements, from which a harmonic mean fit factor is calculated and used to make a pass-fail determination for the fit test.

The information on the new protocol was not submitted to the rulemaking docket in time to allow an opportunity for public comment. OSHA, therefore, cannot include it in this final standard. Appendix A, Part II establishes procedures by which OSHA will approve new fit testing protocols after allowing opportunity for public comment. A proponent of the revised CNP fit test protocol may submit it for approval in accordance with Appendix A, Part II.

Proposed part (II)(A)(12) of Appendix A required that the employer maintain a record of the qualitative or quantitative fit test administered to an employee. This requirement has been moved to paragraph (m)(2) in the final standard to consolidate the standard's recordkeeping requirements. The fit test record must

include the date and type of fit test performed, employee information, and type of respirator. When a QNFT is administered, a record of the test (e.g., strip charts, computer integration) must be retained. The fit test records are to be maintained until the next fit test is administered. A record is necessary for OSHA to determine compliance by verifying that: the employee has been fit tested, both prior to starting respirator use and at least annually thereafter; the tested employee passed the qualitative fit test or achieved a sufficiently high fit factor to pass the quantitative fit test for the required assigned protection factor; the quantitative fit test was correctly performed, and the fit factor calculated properly; and the model and size of the respirator used during fit testing are the same as the model and size of the respirator used by the employee in the workplace.

### New Fit Test Protocols

Paragraph (f)(3) of the proposed rule stated that OSHA would evaluate new fit test protocols under criteria specified in Section I of Appendix A and would initiate rulemaking under section 6(b)(7) of the OSH Act if the proponent of a new fit test method submitted the method and validation testing data to OSHA for evaluation. The section listed detailed criteria OSHA would apply in determining whether to approve the new protocol.

Some commenters recommended alternative approaches for approving new fit test protocols. Mobil Oil (54-234) and the American Petroleum Institute (Ex. 54-330) suggested that NIOSH should be the reviewer of alternative fit test methods. Exxon (Ex. 54-266) questioned the role OSHA would have in the approval of new fit test protocols, stating that NIOSH or other agencies or laboratories could better review new fit test methods. The American Association of Occupational Health Nurses (Ex. 54-213) supported the use of other new fit test methods, provided that they have been demonstrated to be statistically equivalent to the existing OSHA-accepted methods, but stated that the administrative rulemaking procedure OSHA had proposed would result in delays and paperwork that would discourage the development of new methods. The Composites Fabricators Association (Ex. 54-295) also stated that subjecting new fit test methods to rulemaking would discourage an employer from developing or adopting any fit test method not already approved by OSHA. The Society of the Plastics Industry (Ex. 54-310) stated that rulemaking on new methods was unnecessary, and that OSHA should publish criteria for fit tests and allow employers to adopt new methods without cumbersome rulemaking. The National Association of Manufacturers (Ex. 54-313) proposed that publication of a new fit test method in a peer-reviewed journal should be *prima facie* evidence that the method had been validated.

OSHA cannot accept the suggestion by some commenters that it should accept new fit test protocols without following the OSH Act's rulemaking procedures. Appendix A was adopted under the OSH Act's rulemaking procedures and, under section 6(b) of the Act, can only be modified through the same rulemaking procedures. Modifications to Appendix A to add new fit test protocols would therefore have to undergo the same type of rulemaking scrutiny, including the opportunity for public comment, that the approved protocols have received.

In response to comments received, OSHA has modified Appendix A from the version contained in the proposal. These changes streamline the process of approving new fit test protocols by assuring that any new method proposed is supported by data of high quality. As modified, Appendix A also takes a more performance-oriented approach to the approval process than did the proposal. Rather than listing the detailed criteria a new fit test protocol must satisfy, final Appendix A requires that a proposed new protocol be supported either by test results obtained by an independent government research laboratory or by publication in a peer-reviewed industrial hygiene journal.

Both of these options will assure that any new fit test protocol proposed will have a sound scientific basis before being submitted to OSHA. Government research laboratories such as Los Alamos National Laboratory and Lawrence Livermore National Laboratory have considerable expertise in reviewing new fit test protocols to determine whether they are safe, accurate, and statistically valid. A favorable recommendation by such a laboratory, along with the supporting data gathered by the laboratory, will provide a solid basis on which OSHA can base its evaluation. Moreover, because the laboratory's report and recommendation will be in the public record when the OSHA rulemaking proceeding begins, the public will have the opportunity to examine the data supporting the proposed new method and to provide any additional data either in support of or in opposition to the proposed method.

An application for a new test protocol that has been published in a peer-reviewed industrial hygiene journal will similarly provide a sound basis for rulemaking on the new method. Like review by a national research laboratory, the peer-review process assures that the data supporting the method has been scrutinized and found acceptable by a neutral party with expertise in evaluating fit test methods. The published article would be available to the public when the rulemaking commences, and interested members of the public would therefore be apprised of all relevant aspects of the proposed method and would be well-positioned to comment on the method.

OSHA believes that the final rule's approach will streamline the process of accepting new fit test protocols and avoid discouraging the development of new methods. A rulemaking on a new protocol would thus only begin after the protocol's proponent has established a solid basis for seeking the Agency's approval. At the time the rulemaking begins, interested members of the public would know the scientific basis on which approval is sought and would be able to afford OSHA the benefit of their views. The rulemaking process should therefore be able to proceed more quickly than if OSHA were to evaluate data that had not previously been scrutinized by an expert body and were to base the approval process on the detailed criteria contained in Appendix A of the proposed rule. And because the rulemaking process can be expected to proceed expeditiously once a qualifying application has been submitted, parties interested in developing new protocols should not be discouraged from doing so.

New fit test methods are to undergo notice and comment rulemaking. This decision reflects OSHA's long experience in evaluating fit test methods, which includes, in this rulemaking, such fit test methods as the "condensation nuclei counter" (CNC) method and the "controlled negative pressure" (CNP) method and, in past rulemakings, the "saccharin QLFT" method and the "isoamyl acetate QLFT" method. In the past 20 years there have only been a few new methods, but each has required the evaluation of supporting data, and each new method has generated wide public interest and comment. New fit test methods, particularly those that involve new scientific principles and new techniques for evaluating respirator performance, require full consideration and public discussion of the issues by the regulated community, competitive interests, respirator experts, and labor groups. The notice and comment rulemaking process will ensure that OSHA receives the necessary public input, as well as data required for open evaluation, and that all interested parties have a chance to comment publicly on any new method. Publishing a new fit test method in the **Federal Register** should: elicit public comment and debate over the merits of the method; notify the regulated community of the possible availability of a new method; and solicit any additional information that would be relevant for consideration before OSHA makes its final decision. OSHA does not intend the rulemaking process to be cumbersome or involved, but such a process will ensure that all information and comments are available to the public, and that any known problems with the new method are addressed before final acceptance.

Adopting an approach that allows for the acceptance of new fit test methods is a fundamental change to

this standard. Fit test methods directly impact a worker's health, since fit tests are designed to identify poorly fitting respirators. Without the careful evaluation that a new fit test method will receive during the rulemaking process, OSHA cannot be sure that a flawed fit test method would not be developed and marketed to respirator users. If used to select respirators, a flawed method would lead to unnecessary worker exposure to hazardous substances, since poorly fitting respirators would not be detected by the method. Determining the reliability of new fit test methods requires more evaluation, for example, than do new respirator cleaning methods or new user seal check methods, which can be developed by the respirator manufacturer (See Appendix B). New cleaning methods and user seal checks need not undergo rulemaking to become accepted methods. The more rigorous evaluation through notice and comment is required only for new fit testing methods, where OSHA experience has shown the need for a public review of performance.

Moldex (Ex. 54-153) Mobil Oil (Ex. 54-234), Exxon (Ex. 54-266), and the American Petroleum Institute (Ex. 54-330), recommended that OSHA allow interested parties other than employers to submit new fit test methods for OSHA acceptance. In the past, OSHA has allowed other interested parties, such as the developers of new fit test equipment, to submit new test protocols and methods for OSHA approval, and will continue to do so. To make this explicit, the final rule states that a proposed new protocol may be submitted by any person.

### ***Paragraph (g) -- Use of Respirators***

The final rule requires employers to establish and implement procedures for the proper use of respirators. Paragraph (g)(1) contains specific requirements for ensuring an adequate facepiece seal each time a respirator is used. Paragraph (g)(2) requires employers to reevaluate respirator effectiveness when there are changes in environmental or user conditions, as well as requiring that employees leave the respirator use area if they detect any signs that respirator effectiveness has been compromised or to perform any adjustments. Paragraphs (g)(3) and (g)(4) address procedures for the use of respirators in IDLH atmospheres and in interior structural fire fighting, respectively.

Paragraph (g) of the proposal addressed the same issues in the context of requiring employers to develop and implement written standard operating procedures. As suggested by a number of commenters, OSHA has deleted the requirement for written procedures in light of the fact that paragraph (c) already requires a written respiratory protection program (Exs. 54-38, 54-163, 54-226, 54-428). In addition, OSHA has moved to paragraph (d), governing respirator selection, the proposed paragraph (g) requirement that employers ensure that SCBAs are certified for a minimum service life of 30 minutes if they are to be used in IDLH atmospheres, for emergency entry, or for fire fighting. Final paragraph (g) thus contains only those requirements necessary for the appropriate use of respirators in non-IDLH, IDLH, and interior structural fire fighting atmospheres.

### **Paragraph (g)(1) -- Facepiece Seal Protection**

Paragraphs (g)(1)(i) and (g)(1)(ii) are intended to ensure that facial hair, other conditions potentially interfering with the facepiece seal or valve function, and eyewear or other personal protective equipment does not interfere with the effective functioning of the respirator. Paragraph (g)(1)(iii) requires employees to perform a user seal check each time they put on a respirator for use in the workplace.

Paragraph (g)(1)(i)(A) prohibits an employer from allowing respirators with tight-fitting facepieces to be worn by employees who have "facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function." Paragraph (g)(1)(i)(B) prohibits tight-fitting facepieces to be

worn by employees who have any condition that interferes with the face-to-facepiece seal or with valve function. The prior standard prohibited the wearing of respirators "when conditions prevent a good face seal. Such conditions may be a growth of beard [or] sideburns \* \* \*." The proposed requirement would similarly have prohibited employers from allowing tight-fitting respirator facepieces to be worn by employees "with conditions that prevent such fits." "Facial hair that interferes with the facepiece seal" was listed as one example of such a condition. The final rule thus clarifies the language of the NPRM.

OSHA's final standard affords employers more flexibility than the ANSI Z88.2-1992 standard, Section 7.5.1, which prohibits the use of any respirator equipped with a facepiece, whether tight or loose-fitting, if the user has facial hair that comes between the sealing surface of the facepiece and the face. Although some commenters recommended that OSHA adopt the language of the ANSI standard (Exs. 54-218, 54-219), OSHA has determined that it is only necessary to apply the facial hair prohibition to tight-fitting respirators.

The rulemaking record (Exs. 15-11, 15-26, 15-28, 15-27A, 15-30, 15-33, 15-35, 15-36, 15-41, 15-52, 15-58, 15-62, 15-73, 15-77) also contains strong evidence that facial hair can interfere with tight-fitting facepiece seals. According to the study by Hyatt and Pritchard, discussed further below, facial hair includes stubble (Ex. 23-5). A number of studies and comments that were submitted to the record (Exs. 23-5, 36-49, 36-31, 36-45, 36-47, 54-443D, 54-408) addressed the effect of facial hair on respirator performance. McGee and Oestenstad (Ex. 23-2) tested eight volunteers on a closed-circuit, pressure-demand, self-contained breathing apparatus. The volunteers were clean-shaven at the beginning of the study. They underwent quantitative fit tests at two-week intervals over an eight-week beard growth period. Beard growth had a profound, negative effect on the observed fit factors. Most of the volunteers started with fit factors of 20,000 when first fit tested; after eight weeks, these same workers achieved fit factors ranging only from 14 to 1067.

In another study, E.C. Hyatt, J.A. Pritchard and others (Ex. 23-5) investigated the effect of facial hair on the performance of half-mask and full-facepiece respirators. Quantitative fit tests were performed on test volunteers with varying amounts of facial hair, including stubble, sideburns, and beards. The results showed that facial hair can have a range of effects on respirator performance, depending on factors such as the degree to which the hair interferes with the sealing surface of the respirator, the physical characteristics of the hair, the type of respirator, and facial characteristics. In general, the presence of beards and wide sideburns had a detrimental effect on the performance of the respirators. The authors concluded that:

- Individuals with excessive facial hair, including stubble and wide sideburns, that interfere with the seal cannot expect to obtain as high a degree of respirator performance as clean shaven individuals.
- The degree of interference depends on many factors (e.g., the length, texture, and density of facial hair) and the extent to which those factors interfere with the respirator's sealing surface.
- Short of testing a bearded worker for fit daily, the only prudent approaches are to require that facial hair not interfere with the respirator seal surface (e.g., shave where the seal touches the face) or to prohibit the employee from working in areas requiring respiratory protection.

Other fit testing studies also show that non-bearded workers have significantly higher fit factors than bearded workers. Skretvedt and Loschiavo (Ex. 23-3) tested both half-mask and full facepiece respirators on 370 male employees who were fit tested both qualitatively and quantitatively; 67 of the employees had full beards. The bearded workers consistently failed qualitative fit testing. Bearded employees using half-masks had a median fit factor of 12, while clean-shaven employees had a median fit factor of 2950. For full facepiece respirators, bearded workers had a median fit factor of 30 and clean-shaven employees

had a fit factor of greater than 10,000.

Only one study found no significant difference in respirator performance for employees with or without beards. Fergin (Ex. 23-1) studied workplace protection factors, but not fit factors, for three different types of disposable respirators used by carbon setters during carbon setting and ore bucket filling operations. The study, which involved a total of 75 samples collected from 38 non-bearded and 22 bearded workers, compared ambient concentrations with "in-mask" concentrations. Beard types were classified as light, medium, heavy, fine, soft, coarse, and curly. Results showed no clear relationship between type of beard and respirator protection factor. The authors recommended that, "\* \* \* where acceptable protection factors can be demonstrated for subjects with facial hair, the no-beard rule should be waived."

OSHA does not find this study a persuasive basis for changing its position on facial hair. The fact that an acceptable protection factor can be obtained for a bearded respirator wearer in a workplace protection factor study does not mean that the worker can achieve the same protection level each time the respirator is used. First, protection factor studies are designed to minimize program defects and are often conducted under very tight supervision, which is generally not typical of conditions in real workplaces. Second, beards grow and change daily, resulting in variability of protection from one day to the next.

Fergin based his conclusion that respirator performance is similar for bearded and non-bearded workers on a statistical comparison of geometric means, calculated separately for each type of respirator for bearded and non-bearded workers. OSHA is more concerned about the wide range of values than the geometric mean values. The protection factors observed by Fergin varied greatly and ranged from 1-1041 (no beards) and 4-332 (beards) for a 3M-9910 respirator; 12-36 (no beards) and 7-30 (beards) for a 3M-8706 respirator; and 5-1006 (no beards) and 42-391 (beards) for a 3M-9906 respirator. OSHA notes that the protection factors of 5 and lower that Fergin achieved for both bearded and clean-shaven workers are below the NIOSH recommended protection factors for disposable respirators of the types tested by Fergin (NIOSH Respirator Decision Logic, 1987, Ex. 9).

There are several other weaknesses in this study that undermine its use as a counterweight to so much other evidence and expert opinion. The study did not account for particle size or the differences between protection factors obtained when the respirators were used in high as compared to low ambient concentrations. Moreover, two of the three respirators involved lacked adjustable face straps, which makes any sort of tightening impossible. Finally, the author himself cautioned that facial hair can significantly impair respirator seal effectiveness in atmospheres that are highly toxic or IDLH.

In fact, most rulemaking participants (Exs. 3, 13, 15-50, 23-2, 23-3, 23-5) agreed that facial hair can be a problem for respirator users, although they suggested different approaches to address this issue. A few commenters recommended that OSHA simply prohibit the use of respirators by bearded workers, based on the ANSI rationale that beards interfere with the functioning of all respirators (Exs. 54-443, 54-408). In general, these commenters were opposed to any requirement in the standard that would have required employers to provide bearded workers with loose-fitting respirators to accommodate their beards. Other commenters stated that OSHA should require employers to provide loose-fitting respirators (e.g., supplied-air hoods, helmets, or suits) for use by employees with beards (Exs. 15-14, 15-31, 15-34, 15-46, 15-47, 15-48, 15-54, 15-55, 15-79, 15-81, 54-427, 54-387, 54-363). For example, NIOSH recommended that, when the situation permits, employers should be allowed to accommodate bearded workers by providing respirators that will not be affected by facial hair (Ex. 54-437). Daniel Shipp of the Industrial Safety Equipment Association (ISEA) also stated that, in situations where employers do not intend to enforce policies against facial hair, the ISEA would recommend that employers provide respirators that do

not rely on a tight facepiece fit (Ex. 54-363).

Richard Uhlar and Michael Sprinker of the International Chemical Workers Union (ICWU) stated that there should be some provision in the standard to notify employees that respirators other than tight-fitting respirators can be used by bearded workers (Ex. 54-427). This comment is in basic agreement with NIOSH's recommendation that there should be some provision in the standard to notify employees that other respirators that can be worn with beards exist (Ex. 54-437).

In contrast, other commenters (Exs. 54-408, 54-443) recommended that OSHA prohibit the wearing of beards by employees who use respirators on the grounds that employers should not have to supply loose-fitting respirators because an employee is unwilling to shave off his beard. More specifically, George Thomas of Duquesne Light Company (Ex. 54-408) stated that his company does not support a requirement that employers should provide workers with loose-fitting respirators when employees have facial hair. According to Mike Rush of the Association of American Railroads, requiring employers to provide respirators other than tight-fitting air-purifying respirators would be cost-prohibitive, because PAPRs cost 50 times as much as half masks (Ex. 54-286). A. Gayle Jordan of Norfolk Southern Corporation quoted the cost of a PAPR as \$700 (Ex. 54-267).

This standard does not interfere directly with employer policies regarding facial hair. Instead, it requires employers to take the presence or absence of facial hair into consideration in developing policies for a given workplace; different policies may affect the range of choices available. However, OSHA notes that several respiratory protection alternatives, such as loose-fitting hoods or helmets, are available to accommodate facial hair.

Some commenters focused on the specific language in the proposal. One commenter said that the term "any hair growth" should be substituted for "facial hair" (Ex. 54-69). Another urged OSHA to specify what acceptable facial hair growth was (Ex. 54-138). OSHA believes that the term "facial hair" is appropriate because the record shows that any facial hair, including beard stubble, can interfere with facepiece seal (Exs. 23-5, 54-69). By prohibiting hair that "comes between the sealing surface of the facepiece and the face," as well as hair that "interferes with valve function," OSHA believes it is being as precise as possible. OSHA believes that the second phrase is necessary because employees with large beards may shave the skin area where the facepiece of the respirator seals to the face but the fullness or length of the beard could still block the valve or cause the valve to malfunction.

In a standard that will apply as broadly as this one will, it is not possible for OSHA to specify every condition under which respirator use may be affected by an employee's facial hair. Workplace situations are variable, as is hair growth. OSHA has instead written the standard in performance-oriented terms, stressing the importance of the face-to-facepiece seal and conditions that might interfere with that seal. The thrust of the entire standard is on making sure that the fit and the performance of the respirator are not compromised. Employers, therefore, must ensure that respirators fit and perform properly.

Paragraph (g)(1)(i)(B) prohibits an employer from allowing respirators with tight-fitting facepieces to be worn by employees who have any condition that interferes with the face-to-facepiece seal or valve function. Examples of these conditions include, but are not limited to, missing dentures, the presence of facial scars, the wearing of jewelry, or the use of headgear that projects under the facepiece seal. As with the facial hair requirements, the intent of this provision is to prevent an employee from wearing a respirator if there is any factor that could prevent an adequate facepiece-to-face seal. Therefore, conditions such as missing dentures or facial scars will not prevent an employee from using a respirator where it can be demonstrated that those conditions do not prevent an adequate seal.

Paragraph (g)(1)(ii) requires employers to ensure that corrective glasses or goggles or other personal protective equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user. The proposal contained a similar provision that addressed only eyewear. The prior standard contained a similar provision, but also prohibited the use of contact lenses with respirators. Final paragraph (g)(1)(ii) is consistent with the 1992 ANSI standard, which allows the use of corrective lenses, spectacles, and face protection devices, providing that these items do not interfere with the seal of the respirator; ANSI also allows the use of contact lenses where the wearer has successfully worn such lenses before and practices wearing them with the respirator.

Most comments supported the proposed provision (Exs. 54-68, 54-266, 54-286, 54-150, 54-155, 54-177, 54-189, 54-196, 54-209, 54-214, 54-219, 54-222, 54-346, 54-402, 54-408, 54-267, 54-286, 54-361, 54-232, 54-234, 54-244, 54-245, 54-263, 54-265). Some commenters, however, addressed specific pieces of corrective eyewear. For example, Barbara Price of the Phillips Petroleum Company recommended, based on the company's experience with successful quantitative fit testing of employees while wearing sports goggles, that prescription sports goggles be permitted with full facepiece respirators (Ex. 54-165). Darrell Mattheis of the Organization Resources Counselors (ORC) also supported the use of prescription sports goggles, such as the mask-adaptable goggles (MAG-1) by Criss Optical, with a full facepiece respirator, based on ORC companies' successful quantitative fit testing experience (Ex. 54-424).

Again, the standard is written in performance terms so that any particular piece of equipment may be used as long as it does not interfere with the facepiece seal. This has consistently been OSHA's position under the prior standard as well. For example, in a compliance interpretation letter dated April 7, 1987, OSHA addressed the use of eyeglass inserts or spectacle kits inside full facepiece respirators. OSHA stated that eyeglass inserts or spectacle kits are acceptable if the devices: (1) Do not interfere with the facepiece seal; (2) do not cause any distortion of vision; and (3) do not cause any physical harm to the wearer during use (Ex. 64-519).

OSHA again addressed the appropriateness of using the MAG-1 goggles with full facepiece respirators and SCBAs in a September 20, 1995, letter to the Excelsior Fire Department. By 1995, OSHA had the benefit of four quantitative fit testing studies of MAG-1 goggles, two funded by the goggle manufacturer and the other two funded by OSHA itself. The letter to Excelsior stated that since the MAG-1 straps project under the facepiece, use of the MAG-1 could in some cases violate paragraph (e)(5)(i) of the previous standard. The letter concluded that obtaining a fit with these goggles is quite complex because the respirator user may be able in some cases to control the factors determining whether a seal can be obtained. (For a full discussion, see letter, 9/20/95, Ex. 64-520, Docket H-049a.) In a post hearing comment submitted by the Exxon Company, Steve Killiany commented about Criss Optical Mag Spectacles with thin rubber straps (Ex. 183). Mr. Killiany stated that the spectacles can safely be worn with full facepiece respirators as long as users are fit tested with the spectacles in place during fit tests. In its program, Exxon prohibits eyeglasses with temple pieces for users of full facepiece respirators. Exxon also prohibits hard contact lenses, but users are allowed to wear soft contact lenses.

The NPRM contained a lengthy explanation of OSHA's proposal not to include a prohibition against the use of contact lenses with respirators in the final rule (59 FR 58921, 11/15/94). Although a few participants requested that OSHA retain the prohibition, or at least prohibit contact lenses in certain situations (Exs. 54-334, 54-387, 54-437), most of the commenters agreed with OSHA's conclusion that contact lenses can be used safely with respirators (Exs. 54-68, 54-266, 54-286, 54-150, 54-155, 54-177, 54-189, 54-196, 54-209, 54-214, 54-219, 54-222, 54-232, 54-234, 54-244, 54-245, 54-263, 54-265,

54-346, 54-402, 54-408, 54-267, 54-286, 54-361). For example, NIOSH specifically recommended that OSHA allow respirator users to wear contact lenses (Ex. 54-437). Larry DeCook, President of the American Optometric Association, stated that the Association was not aware of any reports of injury because of the use of contact lenses with respirators (Ex. 54-235). Similarly, a study by the Lawrence Livermore National Laboratory showed that far fewer firefighters who wore contact lenses with their SCBAs had problems that necessitated the removal of their facepieces than did firefighters wearing glasses (Ex. 38-9). Finally, OSHA's review of the record identified no evidence that the use of contact lenses with respirators increases safety hazards.

OSHA notes that employers of employees who wear corrective eyewear must be sure that the respirator selected does not interfere with the eyewear, make it uncomfortable, or force the employee to remove the eyewear altogether. Employers should use the respirator selection process to make accommodations to ensure that their respirator-wearing employees can see properly when wearing these devices.

In this final rule, OSHA has also expanded the requirements of paragraph (g)(1)(ii) to cover personal protective equipment other than goggles and glasses. Other forms of personal protective equipment are required by OSHA under specific circumstances (See, e.g., Subpart I -- Personal Protective Equipment, and Section 1910.133 -- Eye and face protection). Like eyewear, this equipment may interfere with the fit of respiratory protection equipment. The generic phrase "other personal protective equipment" applies to faceshields, protective clothing, and helmets, as well as to any other form of personal protective equipment that an employee may wear that could interfere with safe respirator use.

Paragraph (g)(1)(iii) requires employers to ensure that their employees perform user seal checks each time they put on a tight-fitting respirator, using the "user seal check" procedures in Appendix B-1 or equally effective procedures recommended by the respirator manufacturer. The proposal would also have given employers the option of using either the Appendix B-1 procedures or those recommended by the manufacturer, which is also the approach recommended by the ANSI standard. Although the prior standard also required a fit check each time the worker used a respirator, it mandated that the manufacturer's instructions be followed when performing the check.

OSHA's prior respirator standard referred to respirators being "fit \* \* \* checked." The NPRM used the phrase "facepiece seal check," and this has been changed in the final standard to "user seal check." The three phrases are synonymous, and all three were used interchangeably by rulemaking participants (e.g., Exs. 54-218, 54-219, who recommended that the term "fit check" be used to be consistent with the ANSI Z88.2-1992 definition). Other commenters (Exs. 54-5, 54-408) used the term "seal check" or "facepiece seal check." The final standard uses the term "user seal check" because OSHA believes that this phrase best describes the actual procedure to be performed by the respirator wearer. Also, commenters stated that the similarity between the terms "fit check" and "fit test" might lead to confusion, causing employers erroneously to conclude either that complete fit testing must be done each time an employee puts on a respirator or that the fit check can be substituted for a fit test.

In general, commenters (Exs. 54-221, 54-185, 54-321, 54-427, 54-414, 64-521) agreed with OSHA that user seal checks are necessary. Although these checks are not as objective a measure of facepiece leakage as a fit test, they do provide a quick and easy means of determining that a respirator is seated properly. If a user seal check cannot be performed on a tight-fitting respirator, the final rule prohibits that respirator from being used. Appendix B-1, which derives from the 1992 ANSI standard, contains procedures for user seal checking of negative pressure and positive pressure devices. It states that a check is to be performed every time the respirator is donned or adjusted to ensure proper seating of the respirator to the face.

Participants expressed diverse views on whether the negative/positive fit check procedures in Appendix B-1 should be the exclusive means of compliance with this requirement or whether procedures recommended by respirator manufacturers should also be allowed. John Hale of Respirator Support Services stated that the only way to perform a fit check is to use the negative/positive fit check methods in Appendix B-1 (Ex. 54-5). George Notarianni of Logan Associates also recommended that reference to manufacturers' procedures for fit checking be deleted, because he was unaware of any effective fit check methods other than those described in Appendix B (Ex. 54-152). Richard Miller of the E.D. Bullard Company, however, stated that the manner in which fit checks are conducted should be left up to the manufacturer (Ex. 54-221).

The positive/negative user seal checks described in Appendix B-1 cannot be performed on all tight-fitting respirators. William Lambert of the Mine Safety Appliances Company (MSA) (Ex. 54-414) stated that respirators for which negative or positive pressure tests cannot be performed should not be used. He also recommended that OSHA work cooperatively with NIOSH to develop a testing protocol that would preclude approval of respirators that cannot be easily checked using a positive/negative fit check.

The rulemaking record, however, contains evidence that effective user seal checks can be performed in several ways. OSHA reviewed a study by Myers (1995) in which the authors described several ANSI fit check methods, an AIHA/ACGIH negative/positive pressure check, and manufacturer-recommended check methods (See Myers et al., "Effectiveness of Fit Check Methods on Half Mask Respirators," in *Applied Occupational Environmental Hygiene*, Vol. 10(11), November 1995) (Ex. 64-521). In addition, the authors briefly explained that manufacturers of disposable, filtering facepieces recommended covering the mask with both hands, exhaling, and checking for air flow between the face and the sealing surface of the respirator. Since it was not the intent of the authors to evaluate different fit check methods, they did not present any comparison data; however, they did conclude that employing the manufacturer's recommended fit check procedure will help detect and prevent poor respirator donning practices. OSHA is also aware that some manufacturers make a fit check cup that can be used to perform a user seal check even with valveless respirators. The final rule thus allows for the use of the methods in Appendix B-1 as well as manufacturers' recommended procedures for user seal checks where these are equivalently effective. This means that respirator manufacturers' recommended procedures may be used for user seal checking if the employer demonstrates that the manufacturer's procedures are as effective as those in Appendix B-1. The intent of the "equally effective" phrase is to ensure that the procedures used have been demonstrated to be effective in identifying respirators that fit poorly when donned or adjusted. OSHA believes that the use of performance language will provide incentives to respirator manufacturers to develop new user seal check methods and to develop respirators for which user seal checks can be performed.

There are also respirators for which no user seal checks can be conducted. A number of rulemaking participants argued that the inability to seal check a respirator should disqualify these respirators from use (See, e.g., Exs. 54-152, 54-408, 54-427, 54-321). For example, William Lambert of MSA (Ex. 54-414) pointed out that, since respirators are not put on and taken off the same way each time, the seal check is essential to verify that the user has correctly donned the respirator.

OSHA agrees with those commenters who stated that OSHA should not allow the use of respirators that cannot be fit checked. Without the ability to perform user seal checks, employees may be overexposed to respiratory hazards as a result of the respirator leakage caused by multiple redonnings and adjustments. OSHA believes that user seal checks are important in assuring that respirators are functioning properly. If no method exists to check how well a respirator performs during multiple redonnings under actual workplace conditions, OSHA does not consider the respirator acceptable for use.

Richard Olson of the Dow Chemical Company raised another issue about paragraph (g)(1)(iii). He stated that use of the word "ensure" was inappropriate in this instance, because employers cannot "ensure" that user seal checks are performed:

This is impossible for the employer to do in all cases because the employer is not there. Supervision is not at the work site at all times, sometimes the employee is the only person in the facility. The employee can be trained to do this however the employer can not personally be there to observe and ensure every time the employee wears a respirator (Ex. 54-278).

OSHA has stated consistently, in connection with the use of the word "ensure" in other standards, that it is not OSHA's intent that each employee be continually monitored. Further, OSHA case law has held that employers are required by the use of the word "ensure" to take actions that will result in appropriate employee behavior. These actions consist of: rules with sanctions, training employees in behaviors required, and exercising diligence in monitoring the safety behavior of their employees. The past enforcement history of the use of the word "ensure" in other OSHA standards, including the respirator provisions in substance specific standards, shows that employers who demonstrate this level of responsibility are in compliance with provisions that use the term "ensure."

### Paragraph (g)(2) -- Continuing Respirator Effectiveness

Paragraph (g)(2) contains three sub-paragraphs. Paragraph (g)(2)(i) requires employers to be aware of conditions in work areas where employees are using respirators. Paragraph (g)(2)(ii) requires employers to ensure that their employees leave the respirator use area to perform any activity that involves removing or adjusting a respirator facepiece or if there is any indication that a respirator may not be fully effective. Paragraph (g)(2)(iii) requires employers to replace, repair, or discard respirators if there is any indication that they are not functioning properly.

The prior standard did not contain any of these provisions; however, OSHA proposed them after including similar requirements in a number of OSHA substance-specific health standards. OSHA believes that these provisions are important because the effectiveness of even the best respirator program is diminished if employers do not have procedures in place to ensure that respirators continue to provide appropriate protection.

Final paragraph (g)(2)(i), which states, "Appropriate surveillance shall be maintained of work area conditions, and degree of employee exposure or stress," reiterates paragraph (b)(8) of the prior standard. This means that employers are required to evaluate workplace conditions routinely so that they can provide additional respiratory protection or different respiratory protection, when necessary. By observing respirator use under actual workplace conditions, employers can note problems such as changes in the fit of a respirator due to protective equipment or conditions leading to skin irritation. The employer can then make adjustments to ensure that employees continue to receive appropriate respiratory protection.

Paragraph (g)(2)(ii) requires employers to ensure that employees are allowed to leave the respirator use area in several circumstances. The intent of this requirement is to ensure that employees leave the area when necessary. The final standard stipulates that, in these cases, employees are to leave the "respirator use" area, not the work area or workplace. This language is intended to give employers the flexibility to establish safe areas in their workplaces that will minimize interruptions in work flow and production while ensuring that the area where respirators are removed is free of respiratory hazards or contamination.

Paragraph (g)(2)(ii)(A) requires employers to ensure that their employees leave the respirator use area to wash their faces and respirator facepieces as necessary to prevent eye or skin irritation; such irritation occurs frequently with the wearing of tight-fitting respirators. Many of OSHA's substance

specific-standards, such as the cadmium (29 CFR 1910.1027) and arsenic (29 CFR 1910.1018) standards, as well as the ANSI Z88.2-1992 standard, contain provisions allowing employees to leave the respirator use area to wash their faces and respirator facepieces to prevent the skin irritation that is often associated with the use of respirators. Paragraph (g)(2)(ii) is thus consistent with these requirements of the Agency's substance-specific standards, as well as with the ANSI Z88.2-1992 standard.

A number of participants (Exs. 54-6, 36-47, 54-362) questioned the need for this provision, however. For example, Christopher Seniuk of Lovell Safety Management Company stated that allowing employees to leave the area to wash their faces is counterproductive because allowing frequent breaks increases the chance of contamination while putting on and removing the respirator (Ex. 54-6). Richard Boggs of ORC (Ex. 36-47) also recommended that this requirement be dropped, on the grounds that the frequency with which employees leave their work areas is a "labor relations" issue. Kevin Hayes of ABB Ceno Fuel Operations (Ex. 54-362) expressed a similar concern; he suggested that employees be allowed to leave the work area periodically, rather than on an "as necessary" basis, and asked that OSHA quantify the extent of skin irritation that needed to be present for employees to leave the area for washing and cleaning. Mr. Hayes was concerned that disgruntled employees could use this requirement to "establish a revolving door from the work area."

Dr. Franklin Mirer, director of safety and health for the United Auto Workers, supported this provision, however; he stated that allowing employees to leave the area to wash would lead to fewer hygiene problems (Ex. 54-387). OSHA agrees with Dr. Mirer: if employees are allowed to wash their faces and respirators, the amount of contamination will be reduced, employees' hands and respirators will be cleaner, and employees will be donning cleaner respirators. OSHA believes that, to protect employee health, employees must be able to wash their faces and facepieces as often as necessary. The skin irritation caused by dirty respirators can interfere with effective respirator use (Ex. 64-65). Clearly, any skin irritation that causes the wearer to move the respirator in a way that breaks the facepiece-to-face seal is sufficient to warrant an employee leaving the respirator use area to wash. Whenever eye or skin problems interfere with respirator performance, the wearer should be able to leave the use area.

Paragraphs (g)(2)(ii)(B) and (C) require the employer to ensure that employees leave the respirator use area if they detect vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece, and to replace the respirator or the filter, cartridge, or canister elements when these have been exhausted. These requirements are consistent with the NIOSH Respirator Decision Logic (Ex. 9, page 8), which states that workers who suspect respirator failure should be instructed to leave the contaminated area immediately to assess and correct the problem. In addition, employees may need to leave the respirator use area to change the cartridge or canister when the end-of-service-life indicator (ESLI) or change schedule demands a change in canister or cartridge. (See the Summary and Explanation for paragraphs (c) and (d).) The requirements in paragraph (g)(2)(ii)(B) are essential to ensure the continuing effectiveness of the protection provided to the wearer by the respirator. If, for example, the wearer can detect the odor or taste of a vapor or gas, the cartridge or canister is clearly no longer providing protection. Similarly, if a filter element is so loaded with particulates that it increases the work-of-breathing, it clearly must be changed to continue to be effective. The leakage of air through the facepiece also requires immediate attention, because it is a sign that the facepiece-to-face seal has been broken and that the wearer is breathing contaminated air.

Paragraph (g)(2)(ii)(C) requires employers to ensure that respirator wearers leave the use area when the filter element, cartridge, or canister must be changed in order for it to continue to provide the necessary protection. In the proposal, the term "filter elements" was used instead of the more specific language

"cartridge" and "canister," and the proposed language generated several comments requesting the Agency to clarify this terminology (See, e.g., Ex. 54-173). A representative from Monsanto Company suggested that OSHA should change the language from "filter" to "cartridge" or "canister" (Ex. 54-219) because filters apply only to particulates, not vapors and gases. Larry Zobel, Medical Director of 3M, made a similar comment (Ex. 54-218). OSHA has amended the language in final paragraph (g)(2)(ii)(C) to make it more precise, and the final rule uses the terms "cartridge," "canister," and "filter" as these specifically apply.

Paragraph (g)(2)(iii) requires the employer to replace, repair, or discard a respirator that is not functioning properly. This requirement applies in addition to the provisions in paragraphs (d) and (h) of this section that address the routine replacement of respirators and respirator parts. The language of this paragraph has been changed from the proposal to emphasize that a malfunctioning or otherwise defective respirator must be replaced or repaired before the user returns to the work area.

Rulemaking participants agreed that respirators should not be used if they are defective in any way (See, e.g., Ex. 54-362, Kevin Hayes of ABB Combustion Engineering Nuclear Operations). However, one commenter, Peter Hernandez of the American Iron and Steel Institute, objected to the proposal's requirement that defective respirators be repaired "immediately." Mr. Hernandez stated that it is necessary immediately to replace, but not immediately to repair or discard, a defective respirator (Ex. 54-307). OSHA agrees that employers can delay repairing or discarding respirators so long as the affected employees have been issued proper replacement respirators. This was the intent of paragraph (g)(8) in the NPRM, and this point has been clarified in the final regulation by placing the word "replace" first and deleting the word "immediately." The intent of final paragraph (g)(2)(iii) is to ensure that employees receive the necessary protection whenever they are in a respirator use area. This paragraph means that employers must ensure that employees in the respirator use area are wearing respirators that are in good working order.

The proposed rule would have required disposables to be discarded at the end of the task or workshift, whichever came first (See paragraph (g)(9) of the NPRM). A number of commenters (See, e.g., Exs. 54-309, 54-307, 54-442) discussed the use of, and the criteria for discarding, disposable respirators. OSHA has deleted specific references to the term "disposable" in the final rule and has instead required, in paragraph (g)(2)(iii), that employers replace, repair, or discard respirators if employees detect vapor or gas breakthrough, a change in breathing resistance, or leakage of the facepiece, or identify any other respirator defect, before allowing the employee to return to the work area. This requirement thus focuses on the need for respirators to function properly to provide protection to employees rather than on a time schedule for discarding particular respirators.

Some commenters stated that disposable respirators should be allowed to be used until the physical integrity of the respirator is compromised, which may take longer than one work shift (Exs. 54-190, 54-193, 54-197, 54-205, 54-214, 54-222, 54-241, 54-253, 54-268, 54-271, 54-307, 54-357, 54-171). For example, Peter Hernandez, representing the American Iron and Steel Institute, stated that employees may perform 20 different tasks in a work day (Ex. 54-307). The implication of Mr. Hernandez' comment is that workers who perform short duration tasks would have been required by the proposed requirement to use many disposable respirators in the course of such a day, which would be unnecessarily expensive. Suey Howe, representing the Associated Builders and Contractors, recommended that employees be allowed to keep their disposable respirators in clean containers on days when the same task may be performed intermittently (Ex. 54-309). Homer Cole of Reynolds Metals Company stated that some workplace situations exist where the environment is clean enough for disposable respirators to be reused (Ex.

54-222). Randy Sheppard, Battalion Chief of Palm Beach County Fire-Rescue (Ex. 54-442), stated that disposing of HEPA disposable respirators after each use would be extremely costly for large fire departments that respond to many emergency calls. He noted that these respirators should be discarded, however, when they are no longer in their original working condition, whether this condition results from contamination, structural defects, or wear. In a post hearing comment submitted by the North American Insulation Manufacturers Association (NAIMA), Kenneth Mentzer, Executive Vice President, and others stated that OSHA should make it clear that NIOSH-approved disposable respirators may be used when they provide adequate protection factors for the exposures encountered. The authors of this submission also stated that NIOSH-approved disposable respirators provide protection and have some advantages over reusable respirators (Ex. 176).

Richard Niemeier of NIOSH (Ex. 54-437) recommended that dust-mist and dust-mist-fume disposable respirators not be reused, on the grounds that many of these models degrade in oil mist and humid environments. He also recommended that only filters approved under 42 CFR Part 84 be considered for use beyond one shift.

OSHA has considered all of these comments in revising the language in final paragraph (g)(2)(iii) to reflect a more performance-oriented approach to the replacement, repair, or discarding of respirators. Nonetheless, employers still have the responsibility, in paragraph (a)(2), to ensure that respirators are suitable for each use to which they are put. [See also discussion in NPRM, 59 FR 58922.]

#### Paragraphs (g)(3) and (g)(4) -- Procedures for IDLH Atmospheres and Interior Structural Fire Fighting

Paragraphs (g)(3) and (g)(4) of the final rule contain requirements for respirator use in IDLH atmospheres. Paragraph (g)(3) addresses all IDLH atmospheres, and paragraph (g)(4) contains three additional requirements applicable only to the extra-hazardous environments encountered during interior structural fire fighting. These two paragraphs, which deal with requirements for standby personnel outside the IDLH atmosphere and communication between those standby personnel and the respirator users inside the atmosphere, are intended to ensure that adequate rescue capability exists in case of respirator failure or some other emergency inside the IDLH environment.

Paragraphs (g)(3) (i), (ii), and (iii) require that at least one employee who is trained and equipped to provide effective emergency rescue be located outside the IDLH respirator use area, and that this employee maintain communication with the respirator user(s) inside the area. Paragraphs (g)(3) (iv) and (v) require, respectively, that the employer or authorized designee be notified before the standby personnel undertake rescue activity and that the employer or designee then provide appropriate assistance for the particular situation. Paragraph (g)(3)(vi) addresses emergency equipment needed by the standby personnel so that they can perform their duties effectively.

The prior standard, Sec. 1910.134(e), did not distinguish between types of IDLH atmospheres. Instead, it distinguished between IDLH and potentially IDLH atmospheres. It stated that only one standby person was necessary when a respirator failure "could" cause its wearer to be overcome, but that standby "men" (plural) with suitable rescue equipment were required when employees must enter known IDLH atmospheres wearing SCBA. Under this provision, at least two standby personnel were required for known IDLH atmospheres (See, e.g., May 1, 1995 memo from James Stanley, Deputy Assistant Secretary, to Regional Administrators and state-plan designees). In IDLH atmospheres where airline respirators are used, the prior standard required that users be equipped with safety harnesses and safety lines to lift or remove them from the hazardous atmosphere and that "a standby man or men," equipped with suitable SCBA, be available for emergency rescue.

The proposal would have required that, for all IDLH atmospheres, at least one standby person, able to provide emergency assistance, be located outside any IDLH atmosphere, and that this person must maintain communication with the employee(s) in the IDLH atmosphere.

The need for standby personnel when workers use respirators in IDLH atmospheres is clear. The margin for error in IDLH atmospheres is slight or nonexistent because an equipment malfunction or employee mistake can, without warning, expose the employee to an atmosphere incapable of supporting human life. Such exposure may disable the employee from exiting the atmosphere without help and require an immediate rescue if the employee's life is to be saved. Accordingly, the standard requires that, whenever employees work in an IDLH atmosphere, at least one standby person must remain outside the atmosphere in communication with the employee(s) inside the atmosphere. It also requires that the standby personnel be trained and equipped to provide effective emergency assistance.

A number of reports from OSHA's investigative files demonstrate the types of failures that can give rise to the need for immediate rescues of workers in IDLH atmospheres. These cases illustrate that the absence of properly equipped standby personnel greatly increases the risk to the employees who enter the IDLH atmosphere. For example, a fire in a cold-rolling mill triggered a carbon dioxide fire extinguishing system and created an oxygen deficient atmosphere in the mill's basement. Two security guards descended a stairway into the basement to reset the system. Although the employees had been provided SCBAs, they left those respiratory devices in their vehicle and took only a single self-rescuer with them. The workers collapsed upon reaching the bottom of the stairway. No standby personnel were present and, as a result, the workers were not discovered until 30 minutes had elapsed. Attempts to revive them failed. This case illustrates that the suddenness with which workers can be disabled in an IDLH atmosphere can prevent the workers from leaving the atmosphere under their own power and underlines the need for employers to provide standby personnel whenever workers enter such atmospheres. If a properly trained and equipped standby person had been present, that person could have notified the employer that help was needed when the two workers collapsed and could have initiated rescue efforts immediately.

In another case, two mechanics entered a corn starch reactor to perform routine maintenance and repair. Employee No. 1 detected the odor of propylene oxide and then observed the chemical running out of an open vent. Employee No. 1 managed to escape, but employee No. 2 was overcome and died. A standby person equipped with proper rescue equipment would have been able to provide immediate, effective assistance once employee No. 2 was overcome and might have saved that employee's life.

Some cases from OSHA's investigative files involve fatalities that occurred when standby personnel were present but were unable to prevent the fatalities from occurring. These cases illustrate both the types of failures that can give rise to the need for immediate rescue efforts in IDLH atmospheres and the importance of standby personnel being trained and equipped to provide effective rescue capability.

In one case, an employee (No. 1) was working in a confined space while wearing an SCBA. A standby person (No. 2) advised employee No. 1 that the respirator's air supply was low and that he should leave the confined space. However, employee No. 1 collapsed and died before he could exit. Employee No. 2 had no equipment with which to extricate employee No. 1 from the confined space. This example illustrates, first, that even an employee who is properly equipped when entering an IDLH atmosphere may need to be rescued as a result of human error and/ or equipment failure. It also illustrates the need for the standby person to be equipped to be able to provide effective emergency rescue.

In yet another case, an employee (No. 1) was sandblasting inside a rail car wearing an airline respirator

with an abrasive blasting hood. A standby person (No. 2) was stationed outside the car. During the operation, employee No. 1 swallowed a dental appliance and lost consciousness. Employee No. 2 had not maintained constant communication with employee No. 1 and only discovered that employee No. 1 had been overcome too late to save his life. This case shows that the demanding work often required by a worker constrained by respiratory equipment in an IDLH atmosphere may lead to accidents that can disable the worker and require immediate rescue efforts. It also illustrates that the need for emergency assistance can arise at any time and without warning, and that standby personnel must therefore maintain constant communication with the worker(s) inside the IDLH atmosphere.

Standby personnel must also be adequately trained and equipped to protect themselves against the IDLH atmosphere if an emergency arises. In a recent case, two employees (Nos. 1 and 2) were installing a blind flange in a pipeline used to transfer hydrogen sulfide. As the flange was opened, the hydrogen sulfide alarm sounded. Employee No. 1 tried to remove his full-facepiece respirator, was overcome, and died. Employee No. 2 had previously loosened the straps on his respirator to test for the smell of hydrogen sulfide and was also overcome. A standby person (No. 3) equipped with an SCBA was on the ground outside the area and attempted an immediate rescue. Unfortunately, his respirator caught on an obstruction and tore as he attempted to enter the atmosphere and he, along with employee No. 2, was overcome and required hospitalization. The case is another example of the type of human and equipment failures that can endanger employees who must work in IDLH atmospheres. Although the rescue effort in this case faltered, the presence of a standby person equipped with an SCBA increased the chance that the employees in the IDLH atmosphere could have been rescued before they were killed or seriously injured, and the availability of appropriate respiratory equipment reduced the risk to the standby person who attempted the rescue. It illustrates the benefit of having standby personnel who can undertake immediate rescue efforts and the need for such personnel to be trained and equipped properly for their own protection as well as the protection of the workers in the IDLH atmosphere.

The proposed provision would have required only a single standby person in most IDLH situations. However, firefighter representatives urged OSHA (Ex. 75, Tr. 468-469) to retain the prior standard's requirement for two standby personnel and to expand the provision to cover all IDLH atmospheres. OSHA has determined, however, that outside of the fire fighting and emergency response situations, which are discussed in connection with paragraph (g)(4), environments containing IDLH atmospheres are frequently well-enough characterized and controlled that a single standby person is adequate. In most fixed workplaces, the atmosphere is known, i.e., has been well characterized either through analysis of monitoring results or through a process hazard analysis. For example, employers in chemical plants have conducted comprehensive process hazard analyses as required by OSHA's Process Safety Management standard, 29 CFR 1910.119, to determine which of their process units pose potential IDLH hazards. In such situations, effective communication systems and rescue capabilities have been established. In addition, in many industrial IDLH situations, only one respirator user is exposed to the IDLH atmosphere at a time, which means that a single standby person can easily monitor that employee's status. Even in situations where more than one respirator user is inside an IDLH atmosphere, a single standby person can often provide adequate communication and support. For example, in a small pump room or shed, even though two or three employees may be inside an IDLH atmosphere performing routine maintenance activities such as changing pump seals, one standby person can observe and communicate with all of them. In this type of situation, one standby person is adequate and appropriate.

In other cases, however, more than one standby person may be needed; paragraph (g)(3)(i) of the final standard therefore states the requirement for standby personnel in performance language: "one employee or, when needed, more than one employee \* \* \* [shall be] located outside the IDLH atmosphere." For

example, to clean and paint the inside of a multi-level, multi-portal water tower, a process that often generates a deadly atmosphere as a result of cleaning solution and paint solvent vapors, employees often enter the tower through different portals to work on different levels. In such a situation, there will be a need for good communications at each entry portal, and more than one standby person would be needed to maintain adequate communication and accessibility.

Several commenters (Exs. 54-6, 54-38, and 54-266) requested clarification of the proposed requirements that employers ensure that communication is maintained between the employee(s) in the IDLH atmosphere and the standby personnel located outside the IDLH environment. For example, Exxon (Ex. 54-266) requested that OSHA make clear that, in addition to voice communication, visual contact and hand signals may be used. In response, paragraph (g)(3)(ii) of the final rule clarifies that visual, voice, or signal line communication must be maintained between the employee(s) in the IDLH atmosphere and the employee(s) located outside the IDLH atmosphere.

Under final paragraph (g)(3)(iv), employers must ensure that before entering an IDLH environment to provide emergency rescue, standby personnel notify the employer, or a designee authorized by the employer to provide necessary assistance, that they are about to enter the IDLH area. The employer will have determined, in advance, as part of the written respirator program's worksite-specific procedures, the procedures standby personnel will follow and whom they must notify in rescue situations. The employer's emergency response team may provide the necessary support, or other arrangements may have been made with local firefighting and emergency rescue personnel. The language used requires that the employer be notified, which provides the employer great flexibility in determining who will respond to such emergency rescue situations.

Paragraph (g)(3)(iv) responds to concerns expressed by several participants (Exs. 54-6, 54-266, 54-307, 54-330) about the obligation of standby personnel to provide effective emergency rescue. A number of comments emphasized that standby personnel should not attempt any rescue activities without making sure that their own whereabouts are known and monitored. According to Exxon (Ex. 54-266), "the "stand-by" person should be able to summon effective emergency assistance and only *then provide* the assistance." Christopher Seniuk of Lovell Safety Management Company also stated that a standby employee should have a telephone or radio to summon help and should not be expected to enter an IDLH environment for rescue until additional help arrives (Ex. 54-6). The American Iron and Steel Institute (Ex. 54-307) agreed, stating that the standby person should be in communication with the employee(s) in the IDLH atmosphere and be "able to assist in providing or obtaining effective emergency assistance." The American Petroleum Institute (Ex. 54-330) also stated that when the employee wears a respirator in an IDLH atmosphere, the employer must ensure that adequate provisions have been made for rescue.

OSHA agrees that standby personnel should contact the employer or employer's designee before undertaking any rescue activities in an IDLH atmosphere. Accordingly, final paragraph (g)(3)(iv) includes an employer or designee notification requirement. Although this requirement was not contained in the NPRM, a similar requirement has been included in other OSHA standards, e.g., the Permit Required Confined Spaces standard, 29 CFR 1910.146, and the Hazardous Waste Operations and Emergency Response standard, 29 CFR 1910.120. By including this requirement, OSHA is pointing to the need for the employer or authorized designee to take responsibility for ensuring that rescue operations are carried out appropriately, that rescuers are provided with proper respiratory equipment, and that employees are adequately prepared to facilitate rescue attempts.

On the other hand, the notification provision is not intended to suggest that standby employees should wait

indefinitely for their employer or designee to respond to notification before entering the IDLH atmosphere when employees inside are in danger of succumbing and standby personnel are appropriately trained and equipped to provide assistance. OSHA is aware that this practice is followed in fire fighting situations (See paragraph 6-4.4, NFPA 1500 standard, 1997.) In the majority of cases, however, rescuers should not enter the IDLH environment until receiving some response to the notification that rescue is necessary, i.e., the employer or designee should know that the rescuers are entering, and emergency response units should be on their way to the incident. OSHA believes that these requirements are consistent with current industry practice (Exs. 54-266, 54-307, 54-6) and with other OSHA standards (e.g., the permit-required confined spaces standard).

This practice is consistent with OSHA's interpretations of other standards. (See letter of interpretation of the Hazardous Waste and Emergency Response Standard 29 CFR 1910.120 regarding the number of standby personnel present when there is a potential emergency); " \* \* \* process operators who have (1) informed the incident command \* \* \* of the emergency \* \* \* (2) [have] adequate PPE (3) [have] adequate training \* \* \* and (4) employed the buddy system, may take limited action \* \* \* once the emergency response team arrives, these employees would be restricted to the action that their training level allows \* \* \* this has been OSHA's long standing policy for operators responding to emergencies \* \* \*" McCully to Olson; July 11, 1996.

Failure to follow such practices can result in employee death. For example, recently, one employee (No. 1) was working inside a reactor vessel, attempting to obtain a sample of catalyst. He was wearing a supplied air respirator with an escape bottle. The standby "attendant" informed the employee inside that it was time to exit to change the air supply cylinder; witnesses said the inside employee (No. 1) did not appear to hear this instruction. When the air supply became critical, other workers outside "yelled" to the inside employee to hurry outside; by then, the inside employee was moving slowly and then fell. The attendant tried to check the air pressure while another employee, a bystander welder (No. 2), entered the vessel without a breathing apparatus and tried to help the inside employee (No. 1). The welder also fell down. Other bystanders were partially overcome by the nitrogen coming out of the vessel. The air hose on the respirator on the inside employee (No. 1) was disconnected. Neither the first employee inside (No. 1) nor the welder (No. 2) was wearing a harness or lifeline. The inside employee later died. [OSHA citation text abstracts for unscheduled investigations of accidents involving fatalities (one or more) and catastrophic injuries during calendar years 1994 and 1995].

Once the employer or designee has been notified, paragraph (g)(3)(v) requires the employer or designee to provide the necessary assistance appropriate to the situation. Such assistance does not always require that additional standby personnel enter the hazardous atmosphere; in some cases, the appropriate assistance could be, for example, the provision of emergency medical treatment. If standby employees do need to enter the hazardous environment to perform rescue operations, however, the employer must ensure that those rescuers are fully protected.

Final paragraphs (g)(3)(vi) (A), (B), and (C) require that standby personnel have appropriate equipment to minimize the danger to these personnel during rescue efforts. They stipulate that standby employees be equipped with pressure demand or other positive pressure SCBA, or a pressure demand or other positive pressure supplied-air respirator with auxiliary SCBA, according to final paragraph (g)(3)(vi)(A). This requirement was contained in paragraph (g)(2)(i) of the proposal, and was not objected to by any participants. It is also consistent with requirements in clause 7.3.2 of ANSI Z88.2 -- 1992.

The requirements that address appropriate retrieval equipment and means of rescue in paragraphs

(g)(3)(vi)(B)-(C) are written in performance-based language. Established rescue procedures are well known, and retrieval equipment is readily available. OSHA therefore believes that it is necessary merely to state that this equipment must be used unless its use would increase the overall risk associated with entry into or rescue from the IDLH environment. OSHA acknowledged in the Permit-Required Confined Space standard, 58 FR 4530, that situations exist in which retrieval lines (harnesses, wristlets, anklets) may pose an entanglement problem, especially in areas in which air lines or electrical cords are present in the work areas in which the IDLH atmosphere occurs. Most of the time, however, rescue with retrieval equipment is effective, and much safer for the rescuers (Ex. 54-428).

Paragraph (g)(4) applies only to respirator use in the ultra-hazardous context of interior structural fire fighting; the requirements in this paragraph apply in addition to those in paragraph (g)(3). OSHA has included this provision in its standard in response to the record evidence about the extreme hazards of this activity. Paragraph (g)(4)(i) requires that workers engaged in interior structural fire fighting work in a buddy system: at least two workers must enter the building together, so that they can monitor each other's whereabouts as well as the work environment. In addition, for interior structural firefighting, paragraph (g)(4)(ii) retains the requirement that there be at least two standby personnel outside the IDLH respirator use area, i.e., outside the fire area. Paragraph (g)(4)(iii) requires that all personnel engaged in interior structural fire fighting use SCBA respirators. Finally, the notes to paragraph (g)(4) clarify that these requirements are not intended to interfere with necessary rescue operations, and the extent to which the standby personnel can perform other functions.

Paragraph (g)(4) of this Federal standard applies to private sector workers engaged in firefighting through industrial fire brigades, private incorporated fire companies, Federal employees through Section 19 of the OSH Act, and other firefighters. It should be noted that Federal OSHA's jurisdiction does not extend to employees of state and local governments; therefore, public sector firefighters are covered only in the 25 states which operate their own OSHA-approved occupational safety and health state programs and are required to extend the provisions of their state standards to these workers. These states and territories are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Eighteen (18) of these states under certain circumstances also consider "volunteers" to be employees and thus may provide protection to private or public sector volunteer firefighters, subject to specific interpretation of state law. State and local government employees, including firefighters, in States which do not operate OSHA-approved state plans, are not covered by these requirements, unless voluntarily adopted for local applicability.

Although the proposed rule did not distinguish between interior structural fire fighting and other IDLH situations, OSHA decided to include separate requirements for the former activity in the final standard in response to evidence in the record that safeguards that may be adequate for well-controlled and well-characterized IDLH situations are not adequate in the uncontrolled and unpredictable situation presented by a burning building. The firefighting community already recognizes that one person alone cannot be sent safely into a structure to fight a fire that is beyond the incipient stage. The final rule's staffing requirements for fire fighting are consistent with OSHA's current enforcement practice for employers subject to federal OSHA enforcement, and assure that firefighters will not be subject to any diminution in protection as a result of the more flexible requirements for IDLH respirator use included in other paragraphs of the final rule.

OSHA has previously recognized that emergency situations analogous to interior structural fire fighting

require additional safeguards for employees involved in emergency response activities. For example, the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, at 29 CFR 1910.120(q), requires the use of a "buddy system" in responding to IDLH atmospheres. This means that employees involved in such operations are to be organized into workgroups in such a manner that each employee of the work group is designated to be observed continuously by at least one other employee in the work group. Paragraph (q)(3)(v) of Sec. 1910.120 requires operations in hazardous areas to be performed using the buddy system in groups of two or more; paragraph (q)(3)(vi) of that standard specifies that back-up personnel shall stand by with equipment ready to provide assistance or rescue. OSHA has made clear that these provisions require more than one standby person to be present.

The final standard is also consistent with relevant National Fire Protection Association (NFPA) standards. The NFPA is recognized internationally as a clearinghouse for information on fire prevention, fire fighting procedures, and fire protection. A number of NFPA standards require firefighters using SCBA to operate in a buddy system. NFPA 1404, "Fire Department Self-Contained Breathing Apparatus Program," states, in paragraph 3-1.6, that members using SCBA are to operate in teams of two or more, must be able to communicate with each other through visual, audible, physical, safety guide rope, electronic, or other means to coordinate their activities, and are to remain in close proximity to each other to provide emergency assistance.

The NFPA 600 standard addressing industrial fire brigades requires in paragraph 5.3.5 that firefighters using SCBA "operate in teams of two or more who are in communication with each other \* \* \* and are in close proximity to each other to provide assistance in case of an emergency." Although this standard, which applies only to industrial fire brigades where firefighters are working in fixed locations that are well characterized and have established communications and rescue systems, requires only one standby person outside the fire area, another standard, NFPA 1500, "Standard on Fire Department Occupational Safety and Health Programs," which addresses fire department safety and health programs in the general sense, requires at least two standby personnel. This provision first appeared in 1992, as a Tentative Interim Amendment to NFPA 1500 requiring, in paragraph 6-4.1.1, that "[a]t least four members shall be assembled before initiating interior fire fighting operations at a working structural fire." In 1997, NFPA finalized the Amendment. Paragraph 6-4 of the current NFPA 1500 standard, "Members Operating at Emergency Incidents," addresses the number of persons required to be present, and requires at least four individuals, consisting of two persons in the hazard area and two individuals outside the hazard area, for assistance or rescue (paragraph 6-4.4). One standby member is permitted to perform other duties, but those other duties are not allowed to interfere with the member's ability to provide assistance or rescue to the firefighters working at the incident (paragraph 6-4.2).

In addition, a 1994 CDC/NIOSH Alert, titled "Request for Assistance in Preventing Injuries and Death of Firefighters," also recommends the use of a buddy system whenever firefighters wear SCBAs. The recommendation states:

Two firefighters should work together and remain in contact with each other at all times. Two additional firefighters should form a rescue team that is stationed outside the hazardous area. The rescue team should be trained and equipped to begin a rescue immediately if any of the firefighters in the hazardous area require assistance.

Similarly, in testimony on H.R. 1783 before the Subcommittee on Economic and Educational Opportunities, House of Representatives, 104th Congress (July 11, 1995, Chairman: Cass Ballenger), Harold A. Schaitberger, Executive Assistant to the General President of the International Association of Fire Fighters (IAFF), stated that "\* \* \* our organization understood from the outset that the regulation [29 CFR 1910.134(e)] required firefighters wearing self-contained breathing apparatus and involved in interior

structural fire operations to operate in a 'buddy system,' with two firefighters entering a burning building and two firefighters stationed outside the endangered area for assistance or rescue, and for accountability purposes \* \* \* The two-in/two-out rule has been the industry standard in the fire service for over 25 years."

The record in this rulemaking provides strong support for including this requirement in the final standard. Richard Duffy, Director of Occupational Health and Safety for the International Association of Fire Fighters (IAFF), argued strongly for provisions similar to those in the HAZWOPER standard for SCBA users working in IDLH situations. In his written testimony (Ex. 75), Mr. Duffy stated that the proposed requirements in paragraph (g)(2)(ii), which would not have required the buddy system or that two standby personnel be available outside the IDLH atmosphere, would place workers using respiratory protection in IDLH situations at considerable risk.

The IAFF recommended that a minimum of 4 individuals be present any time employees are using SCBA in an IDLH atmosphere: two individuals to work as a team inside the IDLH atmosphere and two identically trained and equipped employees to remain outside to account for, and be available to assist or rescue, the team members working inside the IDLH atmosphere (Tr. 468-469). The inside employees would use a buddy system and maintain direct voice or visual contact or be tethered with a signal line (Tr. 468-469).

According to Mr. Duffy, these changes were necessary:

to save workers' -- specifically firefighters' -- lives. Since 1970 \* \* \* 1,416 members of [IAFF] have died in the line of duty. Prohibiting employers from allowing employees to work alone while working in IDLH, potentially IDLH or unknown atmospheres \* \* \* would have saved many of these firefighters' lives \* \* \* [I]f there was a team in place that accounted for employees while they were working in IDLH \* \* \* many more firefighters would have been saved and [be] alive today (Ex. 75).

Mr. Duffy described several incidents in which firefighters had been injured or killed because of inadequate safety practices, and particularly the failure to have specific individuals assigned to keep track of employees in IDLH atmospheres. For example, he referred to a recent occurrence (Tr. 470) in which three firefighters died inside an IDLH atmosphere. In this incident, although many firefighters were on the scene, no one could account for the three firefighters who had been overcome by the IDLH atmosphere. Their bodies were later discovered inside the burned building. It appears that more stringent precautions, such as a buddy system and standby personnel specifically assigned to keep track of the firefighters' condition, could have prevented these deaths.

In addition, the Oklahoma Department of Labor submitted comments stating that it supports a two-in/two-out rule, especially for firefighters. Specifically, it stated that "Although we are not a state plan state, we operate a fully functional OSHA safety and health program in the public sector \* \* \* it would be unfortunate if the new respiratory protection standard's interpretation of the 'buddy system' \* \* \* confused this issue (two-out for firefighters) [Ex. 187]." However, some firefighter services and organizations urged OSHA to abandon its existing requirement for at least two standby personnel. For example, Truckee Meadows Fire Protection District in Nevada (Ex. 384) stated that:

there are circumstances where a three person \* \* \* company can safely and efficiently respond and aggressively attack a fire. Similarly, there are occasions where additional personnel and resources may be required before initiating an attack \* \* \* the emphasis must be practically placed upon assessment of the risk at the time of arrival and throughout the incident to determine the resources and precautions needed. The overriding concern should be \* \* \* safe egress or recovery of personnel should conditions change, regardless of the standby crew assembled.

A similar opinion was expressed by the fire chief of Sparks, Nevada (Ex. 54-129).

Even a comment from the County of Rockland Fire Training Center, Pomona, New York (Ex. 54-155) recommending removing the requirement for standby personnel from the final rule, noted that "in operations during a fire or emergency, it is a standard practice to utilize the team approach." The comment went on to state, however, that "removing the restriction of having persons outside the IDLH \* \* \* and allowing the incident commander the flexibility of moving personnel around as he or she sees fit at any given situation \* \* \* would actually enhance the safety of our forces operating at the scene of a fire or emergency." As discussed below, OSHA believes that the requirements in the final standard allow enough flexibility to maximize safety.

OSHA concludes that, for interior structural fire fighting, a buddy system for workers inside the IDLH atmosphere and at least two standby personnel outside that atmosphere are necessary. In fact, as noted above, OSHA has previously explained that under the prior standard and the OSH Act's general duty clause, there must be more than one person present outside and at least two firefighters inside when conducting an interior attack on an interior structural fire. Accordingly, special provisions have been included in this revised respiratory protection standard to clarify that firefighters may not enter an IDLH atmosphere alone during interior structural firefighting, and that two standby personnel are required for all interior structural fire fighting.

As discussed above, however, OSHA does not believe that similar practices are necessary in better controlled and characterized IDLH situations, such as those potentially arising in industrial environments. In those cases, where standby personnel can more easily track the precise movements of the respirator users and communication mechanisms are in place, OSHA believes that one standby person will often be sufficient, although paragraph (g)(3)(i) clearly recognizes that some nonfirefighting IDLH situations will require multiple standby personnel.

These additional requirements are necessary because fire fighting ranks among the most hazardous of all occupations, and interior structural fire fighting is one of the most dangerous fire fighting jobs (See, e.g., Jankovic et al. 1991). As the International Association of Fire Chiefs (Ex. 54-328) pointed out, "[t]he fire fighter is usually operating in a hostile environment where normal systems, facilities, processes and equipment to ensure safety have already failed." A very basic difference between firefighters -- particularly those involved in fighting interior structural fires -- and employees in other occupations is that the work site is always new and unknown. Firefighters do not report to a fixed location or work in a familiar environment. Heat stress also affects firefighters differently than other workers. Petrochemical workers and those in other high heat-stress occupations, such as highway workers, can deal with issues such as heat stress through other options, including acclimatization periods for new employees, scheduling high exertion work at night, and allowing frequent breaks (Smith 1996). Firefighters do not have these options.

Fire fighting is also extremely stressful mentally because of the sense of personal danger and urgency inherent in search and rescue operations. A firefighter regularly steps into situations that others are fleeing, accepting a level of personal risk that would be unacceptable to workers in most other occupations. Psychological stress is caused by the firefighter's need to focus on the protection of lives and property, as well as the need to maximize his or her own personal safety and that of his/her coworkers. Tenants and others in the process of being rescued have also been known to panic and attack firefighters to obtain air from the firefighter's respirator in an attempt to save their own lives (1994 NIOSH Alert).

Fire fighting is a high-risk occupation with a very narrow window of survivability for those who lose their

orientation or become disabled on the job. The terrible toll among firefighters is recorded in many different national data bases. For example, for the period 1980-1989, the NIOSH National Traumatic Occupational Fatalities (NTOF) Surveillance System reported 278 deaths among firefighters caused just by work-related traumatic injuries; NIOSH recognizes that this number is an underestimate because of the collection and reporting methods used by NTOF, which limit the kinds of events recorded. Data collected by the IAFF for the period 1970-1994 report 1,369 firefighter deaths, and data collected by the NFPA for the period 1990-1992 indicate that 280 firefighters died in this 2-year period alone (1994 NIOSH Alert). OSHA believes that the requirements of this respirator standard may prevent a significant number of these deaths and injuries. For example, in a recent incident, a team of two firefighters was operating inside a structural fire. Rapidly deteriorating conditions occurred in which there was dense smoke. Confusion ensued and the team lost contact, resulting in one firefighter death. (Incident number 2; OSHA Investigations of Firefighter Fatalities; 10/1/91-3/17/97; IMIS) In this situation, the need for additional accountability and monitoring of firefighters during interior structural fire fighting is clear. Multiple standby personnel and two-person teams inside an IDLH atmosphere are therefore necessary to check for signs of heat stress, other illnesses, disorientation, malfunctioning of respiratory and other protective equipment, and to assist in exit or rescue when needed (Smith, 1996).

OSHA emphasizes that the requirement for standby personnel does not preclude the incident commander from relying on his/her professional judgment to make assignments during a fire emergency. Although the standard requires at least two standby persons during the attack on an interior fire, there are obviously situations where more than two persons will be required both inside and outside the interior structure, a decision ultimately to be made by the incident commander. In addition, as is the case under the previous respiratory protection standard, one of the standby personnel may have other duties and may even serve as the incident commander. According to OSHA's letter to Chief Ewell, IFC, Oakland, CA, (J. Dear; 2/27/96), "\* \* \* one of the two individuals outside the hazard area may be assigned more than one role, such as incident commander in charge of the emergency or the safety officer. However, the assignment of standby personnel of other roles such as the incident commander, safety officer, or operator of fire apparatus will not be permitted if by abandoning their critical task(s) to assist in, or if necessary, perform a rescue clearly jeopardizes the safety and health of any firefighter working at the incident." OSHA has included specific guidance regarding other duties of standby personnel under paragraph (g)(4). These duties are consistent with OSHA's past enforcement policy and NFPA recommendations (NFPA 1500, 1977 Edition; Section 6-4.4.2).

It is important to have at least two standby people available so that in the event of an emergency in which both members of the interior team need rescue or other assistance, adequate personnel are available for rescue. As Harold A. Schaitberger testified, "\* \* \* The two-in/two-out rule has been the industry standard in the fire service for over 25 years. It is also based on common sense. If there are two firefighters inside a burning building when a roof caves in, at least two firefighters are required to assist and/or rescue them (Testimony on H.R. 1783 before the Subcommittee on Economic and Educational Opportunities, House of Representatives, 104th Congress (July 11, 1995, Chairman: Cass Ballenger)." Whenever possible, the use of the buddy system should also be maintained during rescue operations.

Moreover, the "two-in/two-out" requirement does not take effect until firefighters begin to perform interior structural fire fighting. While the fire is in the incipient stage, the incident commander or other person in charge may conduct an investigation or "size up" the situation to determine whether the fire has progressed beyond the incipient stage. During this investigative phase, the standard does not require two-member teams inside and outside the structure. Similarly, nothing in this rule is meant to preclude firefighters from performing rescue activities before an entire team has assembled. If there are fewer than four team

members available, and an individual inside the burning structure must be rescued immediately, this rule does not prevent the rescue from occurring, as the Note to the regulatory text makes clear. However, once firefighters begin the interior attack on an interior structural fire, the atmosphere is assumed to be IDLH and paragraph (g)(4) applies.

OSHA's requirement in no way is intended to establish staffing requirements with regard to, for example, the number of persons on a fire truck or the size of a fire company. Rather, the 2 in / 2 out provision specifies only the number of firefighters who must be present before the interior attack on an interior structural fire is initiated. Firefighters may be assembled from multiple companies, or arrive at the scene at various times. All that is intended is that an interior attack should not be undertaken until sufficient staff are assembled to allow for both buddy and standby teams.

These requirements are consistent with OSHA's past enforcement policy. OSHA has relied on the NFPA recommendations as a basis for determining an appropriate standard of care in fire fighting situations under the General Duty Clause of the OSH Act, 29 U.S.C. 654(a)(1). In its interpretative memoranda addressing requirements that are applicable to firefighters, OSHA noted that occupational exposure to fire is a well-recognized hazard, and that firefighters using SCBA in hazardous atmospheres should be operating in a buddy system of two or more personnel. The Agency explained that even under OSHA's previous respiratory protection standard, a minimum of four personnel should be used, with two members inside the hazardous area and two members outside the hazardous area who are available to enter the area to provide emergency assistance or rescue if needed. One memorandum also pointed out that there was no prohibition against the outside standby personnel having other duties, such as functioning as incident commander or safety officer, as long as it would not jeopardize the safety and health of any firefighter working at the incident if the standby personnel left those duties to perform emergency assistance and rescue operations.

OSHA notes that the requirements of paragraph (g)(4) apply in addition to the requirements of OSHA's specific fire protection standards, subpart L of 29 CFR 1910. OSHA intends to begin negotiated rulemaking on those fire protection standards in the near future.

#### Paragraph (h) -- Maintenance and Care of Respirators

This final standard for respiratory protection, in paragraph (h), addresses the elements of respirator maintenance and care that OSHA believes are essential to the proper functioning of respirators for the continuing protection of employees. As OSHA stated in the preamble to the NPRM (59 FR 58923), "a lax attitude toward this part of the respiratory protection program will negate successful selection and fit because the devices will not deliver the assumed protection unless they are kept in good working order." The maintenance and care provisions, which are divided into cleaning and disinfecting, storage, inspection, and repair, are essentially unchanged (with the exception of the cleaning and disinfecting provisions) from paragraph (f) of OSHA's prior respiratory protection standard. Some rearrangement and consolidation of the regulatory text and minor language changes have been made to this paragraph to simplify and clarify the requirements as a result of comments and concerns that were raised in response to the proposed rule.

Paragraph (h)(1) of the final standard requires that employers provide each respirator wearer with a respirator that is clean, sanitary, and in good working order. It further requires that employers use the procedures for cleaning and disinfecting respirators described in mandatory Appendix B-2 or, alternatively, procedures recommended by the respirator manufacturer, provided such procedures are as effective as those in Appendix B-2. The prior respiratory protection standard required that employers clean

and disinfect respirators in accordance with the maintenance and care provision of paragraph (f), but offered no specific guidance on how to perform these procedures. Mandatory Appendix B-2 presents a method employers may use to comply with the cleaning and disinfecting requirements of final paragraph (h)(1). The procedures listed in Appendix B-2 were compiled from several sources, including publications of the American Industrial Hygiene Association, ANSI Z88.2-1992 (clause A.4, Annex A), and NIOSH. Other methods may be used, including those recommended by the respirator manufacturer, as long as they are equivalent in effectiveness to the method in Appendix B-2. Equivalent effectiveness simply means that the procedures used must accomplish the objectives set forth in Appendix B-2, i.e., must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

Several commenters (Exs. 54-267, 54-300, 54-307) supported the cleaning and disinfecting provisions in general and the inclusion of manufacturers' instructions in particular. The American Iron and Steel Institute (AISI), for example, suggested the following language: "Respirators must be cleaned and maintained in a sanitary condition. The cleaning procedures recommended by the respirator manufacturer or in Appendix B, or a recognized standard-setting organization should be followed" (Ex. 54-307).

The need for appropriate cleaning and disinfecting procedures was also supported during the hearings. For example, James Johnson of Lawrence Livermore National Laboratories testified:

[P]rocedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, or otherwise maintaining respirators \* \* \* are elements of the respiratory protection program which are important and are addressed in the rule \* \* \*. I did some personal evaluation on the disinfecting procedures recommended by several U.S. respirator manufacturers. I found that they vary significantly. If you look in Appendix B of the proposed rule, the hypochlorite or bleach recommendation and the other disinfectants outlined there are certainly what is typically recommended and used (Tr. 184).

The Appendix B-2 procedures can be used both with manual and semi-automated cleaning methods, such as those using specially adapted domestic dishwashers and washing machines. As with most effective cleaning procedures, Appendix B-2 divides the cleaning process into disassembly of components, cleaning and disinfecting, rinsing, drying, reassembly and testing. Recommended temperatures for washing and rinsing are given in Appendix B-2, as are instructions for preparing effective disinfectants.

OSHA has made minor changes to the contents of Appendix B-2 in the final standard. For example, the cleaning procedures listed in the final rule are more consistent with the procedures suggested in Clause A.4, Annex A of the ANSI Z88.2-1992 standard than those proposed, particularly with regard to the temperatures recommended to prevent damage to the respirator. Additionally, automated cleaning, which is now being used by many larger companies, is allowed as long as effective cleaning and disinfecting solutions are used and recommended temperatures, which are designed to prevent damage to respirator components, are not exceeded.

Commenters (Exs. 54-91, 54-187, 54-330, 54-389, 54-309, Tr. 695) generally supported the need for a respirator maintenance program but took differing approaches to the provisions proposed in paragraph (h)(1) (i)-(iii) dealing with the frequency of cleaning and disinfecting respirators. One commenter (Ex. 54-187) agreed with the provisions as proposed. Others (Exs. 54-208, 54-67, 54-91, 54-408) recommended a more performance-oriented approach.

For example, Darell Bevis of Bevis Associates International objected to the proposed requirement that respirators that are issued for the exclusive use of an employee be cleaned and disinfected daily by stating:

[D]iffering workplace conditions will require that cleaning and disinfection may be required more frequently or even less frequently than daily. A requirement for daily cleaning when unnecessary results in considerable additional respirator

program costs with no benefit. A more realistic and still enforceable requirement would be routinely used respirators issued for the exclusive use of an employee shall be cleaned and disinfected as frequently as necessary to ensure that the user has a clean, sanitary, properly functioning respirator at all times (Tr. 695).

Other commenters (Exs. 54-67, 54-91, 54-234, 54-271, 54-278, 54-286, 54-289, 54-293, 54-334, 54-350, 54-374, 54-424, 54-435, Ex. 163) also objected to cleaning and disinfecting respirators at the end of each day's use if the respirator is issued for the exclusive use of a single employee. These comments were in general agreement with the American Industrial Hygiene Association's statement:

The performance-oriented language of the existing standard is more reasonable [than the proposed language]. Cleaning and disinfecting of individually assigned respirators should be done "as needed" to assure proper respirator performance and to preclude skin irritation or toxicity hazards from accumulation of materials. Disinfecting an individually issued respirator is probably not necessary at all unless the "contaminant" is biological in nature (Ex. 54-208).

Several other commenters (See, e.g., Exs. 54-330, 54-389, 309) were in favor of cleaning individually assigned respirators at the end of each day's use, but recommended disinfecting or sanitizing only after longer periods or when necessary. Michael Laford, Manager of Industrial Hygiene and Safety at Cambrex, commented as follows:

It is important to clean all personal protective equipment, preferably after each use as needed, and not just once a day. However, is the additional requirement for daily disinfection \* \* \* where respirators are individually assigned, supported with valid studies or data? In the absence of data that supports a real benefit of this requirement, the language should revert to "periodic" disinfecting of respirators (Ex. 54-389).

The need for flexibility with respect to maintaining clean and sanitary respirators was also discussed during the hearings. For example, in response to a question asked by a member of the OSHA panel regarding how often a respirator mask should be cleaned, James Centner, Safety and Health Specialist with the United Steel Workers of America (USWA), replied that it depended on the length of time the respirator is worn and the workplace conditions. He stated, "If you're working in a smelter where it's hot and dirty and dusty, workers probably need to take that respirator off about every 30 minutes and do a good, thorough job of washing the grit and dirt off their face and . . . do a quick maintenance clean-up job on the sealing surface of the respirator so it maintains an adequate fit" (Tr. 1068). Darell Bevis of Bevis Associates International (Tr. 747-748) responded similarly when asked this question; he contrasted dusty workplaces, such as fossil fuel power generation plants where respirators become filthy with hazardous particulates, to workplaces involving exposure only to gases and vapors where respirators may remain clean for long periods.

OSHA agrees with these commenters that the necessary frequency for cleaning a respirator can range from several times a day to less than daily. Therefore, OSHA has restated paragraph (h)(1)(i) in performance-based language, which will provide employers with flexibility in maintaining clean and sanitary respirators when the respirator is used exclusively by a single employee. Final paragraph (h)(1)(i) now reads as follows: "Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition." Final paragraph (h)(1)(i) is complemented by the respirator use provision in final paragraph (g)(2)(ii)(A), which requires that employers ensure that workers leave the respirator use area to wash their faces as necessary to prevent eye or skin irritation. OSHA believes that compliance with final paragraphs (h)(1)(i) and (g)(2)(ii)(A), as well as the training provisions in paragraph (k) regarding maintenance of the respirator, will provide effective employee protection against hazardous substances that accumulate on the respirator, interfere with facepiece seal, and cause irritation of the user's skin.

Proposed paragraphs (h)(1)(ii)-(iii) specified that respirators used by more than one employee or

respirators issued for emergency use be cleaned and disinfected after each use and were the subject of a number of comments (See, e.g., Exs. 54-67, 54-234, 54-361, 54-408, 54-424 and Tr. 695). For example, the Service Employees International Union (Ex. 54-455) suggested that OSHA replace the phrase "after each use" with "before they are worn by another user." OSHA agrees with this suggestion as it applies to the shared use of respirators in non-emergency situations, and has revised final paragraph (h)(1)(ii) to require cleaning and disinfecting of respirators prior to their use by other individuals. OSHA believes that this modification provides flexibility in those areas where respirators are assigned to more than one employee. This requirement is also consistent with the parallel provision of ANSI Z88.2-1992. However, if the respirator is to be used in an emergency situation, it should be in a clean and sanitary condition and immediately ready for use at all times. Emergency personnel cannot waste time cleaning and sanitizing the respirator prior to responding to an emergency. Thus, if the respirator is one that is maintained for emergency use, the final standard in paragraph (h)(1)(iii) retains the requirement to clean and disinfect the respirator after each use.

Final paragraph (h)(1)(iv) requires the cleaning and disinfecting of respirators used in fit testing and training exercises. This provision was added in response to a recommendation made by the Public Service Company of Colorado (Ex. 54-179) that respirators be cleaned and disinfected after each fit test. Additionally, representatives of Electronic and Information Technologies (Ex. 54-161) pointed out that, although the proposal addressed cleaning and disinfecting procedures for respirators worn during routine and emergency use, it did not specify how respirators should be cleaned/disinfected during fit testing or training activities. Since these conditions involve shared use, OSHA has emphasized in final paragraph (h)(1)(iv) the need to properly clean and disinfect or sanitize respirators used for training and fit testing after each use.

OSHA noted in the proposal that it was not stating who should do the cleaning and disinfecting, only that it be done (59 FR 58924). However, as with all other provisions of the standard, the employer is responsible for satisfying the cleaning and disinfecting requirements. The final standard requires that the employer ensure that cleaning is done properly, and that only properly cleaned and disinfected respirators are used. The employer is allowed to choose the cleaning and disinfecting program that best meets the requirements of the standard and the particular circumstances of the workplace. Richard Uhlar, an industrial hygienist for the International Chemical Workers Union (ICWU), commented that workers should be given paid time to clean, disinfect, and inspect respirators; otherwise, in the view of this commenter, respirators will not be taken care of properly (Ex. 54-427). OSHA notes that if the employer elects to have employees clean their own respirators, the employer must provide the cleaning and disinfecting equipment, supplies, and facilities, as well as time for the job to be done.

Commenting on a preproposal draft of the standard, the United Steelworkers of America (USWA) (Ex. 36-46) recommended that OSHA require the employer to clean and repair respirators. The USWA stated that programs in which employers require employees to return their respirators at the end of each shift to a central facility for inspection, cleaning, and repairs by trained personnel are more effective than programs in which employees are responsible for cleaning their own respirators. OSHA agrees that such a centralized cleaning and repair operation can ensure that properly cleaned and disinfected respirators are available for use, but this approach is not the only way to fulfill this requirement. For example, central facilities may be inappropriate in workplaces where respirator use is infrequent, or where the number of respirators in use is small.

Final paragraph (h)(2), which establishes storage requirements for respirators, does not differ substantively from the corresponding requirements in the proposal. However, some of the proposed provisions have

been consolidated to simplify understanding and interpretation of the requirements. Final paragraph (h)(2)(i) sets forth the storage requirements for all respirators, while final paragraph (h)(2)(ii) addresses additional requirements for the storage of emergency respirators. Specifically, final paragraph (h)(2)(i) requires that all respirators be stored in a manner that protects them from damage, contamination, harmful environmental conditions and damaging chemicals, and prevents deformation of the facepiece and exhalation valve. Respirators maintained for emergency use also must be stored in accordance with the requirements of final paragraph (h)(2)(i) and, in addition, must be kept accessible to the work area, be stored in compartments or covers that are clearly marked as containing emergency respirators, and be stored in accordance with any applicable manufacturer's instructions (paragraph (h)(2)(ii)).

There was general support in the record for the performance approach that OSHA took in the proposal with regard to storage requirements. For example, the Industrial Safety Equipment Association (ISEA) commented: "[B]ecause the degree of severity of an environmental condition that would cause deterioration would be related to the tolerance of the particular equipment in question and would thus vary from model to model, there is no need to specify conditions of storage in more detail" (Ex. 54-363). The comment submitted by the Mobil Oil Corporation (Ex. 54-234) agreed with OSHA's proposed approach on respirator storage, but went further to state that "[t]o place storage requirements in specific language may actually contradict specific recommendations of the manufacturer." Other commenters also supported OSHA's provisions as proposed (See Exs. 54-172, 54-250, 54-273, 54-408, 54-424, and 54-455).

There were, however, some suggested changes that commenters believed would clarify final paragraph (h)(2). One commenter (Ex. 54-32) suggested that, in addition to requirements for accessibility and maintenance of emergency respirators, there should be a requirement for specific "awareness training" to remind employees of the location of such respirators. OSHA agrees that such knowledge is vital. The training specified in paragraph (k), especially the provisions on how to use a respirator in emergency situations (final paragraph (k)(1)(iii)) and procedures for the maintenance and storage of respirators (final paragraph (k)(1)(v)), are designed to do this. In addition, paragraph (k) requires that employers retrain employees where it appears necessary to do so to ensure safe respirator use.

Two commenters recommended that employees, rather than employers, be held responsible for cleaning, sanitizing, and storing their respirators. The Grain Elevator and Processing Society (Ex. 54-226) recommended that, for most operations, the maintenance and care of respirators should be the responsibility of the employee once the employee has been trained. In another comment specific to the storage provision, the American Petroleum Institute (Ex. 54-330) pointed out that employers generally do not store respirators; instead, respirator storage is the responsibility of the employee. In response, OSHA notes that section 5(a)(2) of the OSH Act and case law interpreting that provision have specifically placed the burden of complying with safety and health standards on the employer because the employer controls conditions in the workplace. The employer is, therefore, responsible for the results of actions taken by others at the direction of the employer. For example, although an employee may physically store a respirator, a contractor may perform a fit test, or a physician may examine an employee at the employer's direction, the employer is ultimately responsible for ensuring that these actions are taken to comply with the standard.

Proposed paragraph (h)(2)(ii) would have required that compartments be built to protect respirators that are stored in locations where weathering, contamination, or deterioration could occur. The Westminster, Maryland Fire Department (Ex. 54-68) raised the following concern about this proposed provision:

This requirement may be appropriate for manufacturing but is not practical given the operations of the fire service. \* \* \* As OSHA is aware the fire service maintains its breathing apparatus in a ready posture on the apparatus. To require the

apparatus to be placed in a compartment would eliminate the precious time saved by donning the apparatus enroute to the emergency. This operation has been the backbone of our efficiency at rescue and suppression operations.

Similar concerns were raised by the National Volunteer Fire Council (Tr. 499) and the Connecticut Fire Chiefs' Association, Inc. (Ex. 180). In response to these concerns, OSHA has crafted language that the Agency believes fulfills the purpose of this provision and maintains the efficiency of emergency response workers such as firefighters. Instead of requiring emergency respirators to be stored only in compartments, final paragraph (h)(2)(ii)(B) permits them alternatively to be stored in covers that are clearly marked as containing emergency respirators. Walk-out brackets with covers that are mounted on a wall or to a stable surface (e.g., on a fire truck) may be used so long as the respirator is covered to prevent damage when not in use. Because a cover can be removed in seconds, OSHA believes that this change addresses the needs of firefighters and other emergency responders. It is important that the walk-out brackets are mounted within the vehicle. For example, they can be mounted directly to the fire truck to enable firefighters to rapidly don the respiratory equipment when needed. However, any means of storage used must be secure. If walk-out brackets are not mounted, there is a danger that the unsecured respirators could become damaged as a result of vehicle motion.

Final paragraph (h)(3) requires regular inspections to ensure the continued reliability of respiratory equipment. The frequency of inspection and the procedures to be followed depend on whether the respirator is intended for non-emergency, emergency, or escape-only use.

Final paragraph (h)(3)(i)(A) requires respirators for use in non-emergency situations to be inspected before each use and during cleaning. For respirators designated for use in an emergency situation, final paragraph (h)(3)(i)(B) requires that they be inspected at least monthly and in accordance with the manufacturer's instruction. In addition, emergency respirators must be examined to ensure that they are working properly before and after each use. Examining respirator performance before and after each use is not intended to be as extensive and thorough a process as respirator inspection. A basic examination conducted prior to each use will provide assurance to the wearer that the respirator which he/she is about to don in an emergency situation will work properly, e.g., that the cylinders on the SCBA are charged, that air is available and flowing. This examination can be done fairly quickly, and OSHA believes that this added measure of employee protection is both necessary and appropriate.

Respirators used for escape only are to be inspected prior to being carried into the workplace (paragraph (h)(3)(i)(C)). The Dow Chemical Company (Ex. 54-278) addressed the inspection of emergency escape respirators, stating, "Emergency escape respirators such as mouthbit respirators, usually stored in the box or bag they come in, do not need to be inspected monthly." OSHA agrees with this statement. Mouthbit or other emergency escape respirators are carried by an individual worker into the workplace for personal use in an emergency, and must be inspected for proper condition prior to being carried into the workplace. Additional monthly inspections of emergency escape respirators that are stored for future use are unnecessary, since they will be inspected prior to being carried into the workplace. Final paragraph (h)(3)(i)(C) therefore specifies that "escape-only" respirators need only be inspected before being carried into the workplace.

Although no commenters were opposed to the inspection requirements, some participants raised the issues that are discussed below with respect to inspection frequency and procedures. When respirators are inspected, the final rule (paragraph (h)(3)(ii)(A)) requires that the inspection include an examination to ensure that respirators are working properly, including an examination of the tightness of connections and the condition of the various components. Two comments were made with respect to respirator inspection procedures. John Clarke of Electronic and Information Technologies (Ex. 54-162) stated that checking for

proper function (examination to ensure that respirators work properly) presents a dilemma if use is to include sanitizing the facepiece. He pointed out that SCBAs reserved for use by multiple persons presents a special problem. Likewise, John O'Green of American Electric Power (Ex. 54-181) asked that "functional check" be better defined and clarified. He stated that requiring the actual activation of the respirator, including the flow of air to the facepiece, could be time consuming for all the emergency respirators in their facilities. OSHA does not intend that the respirator be physically placed on the employee to examine the respirator to ensure that it is working properly. Visual inspection can detect factors that would interfere with proper performance, e.g., distortion in shape (often the result of improper storage), missing or loose components, blockage, and improper connections. Alarms can also be examined without actually putting the respirator on the employee. In addition, examining elastomer parts for pliability and signs of deterioration, as required by final paragraph (h)(3)(ii)(B), can be performed without wearing the respirator.

Under paragraph (h)(3)(iii) of the final rule, SCBAs must be inspected monthly. The employer must ensure that the cylinders are fully charged. Recharging is required when the pressure falls below 90 percent of the manufacturer's recommended pressure level. The Westminster, Maryland Fire Department (Ex. 54-68) strongly recommended that the apparatus be inspected at the beginning of each shift or workday rather than monthly. OSHA notes that the final rule specifies only the minimum requirements for an effective respiratory protection program. Employers, however, are encouraged to exceed these minimum criteria if, by doing so, employee protection and operating efficiency are enhanced.

The final provision for recharging air and oxygen cylinders for SCBAs in paragraph (h)(3)(iii) is unchanged from proposed paragraph (h)(3)(i)(C). Although no commenters disagreed with this provision as proposed, a few commenters (Exs. 54-6, 54-220) asked OSHA to clarify the requirement that SCBA equipment be maintained in a fully charged state and recharged when the pressure falls to 90% or less of the manufacturer's recommended pressure level. By way of example, OSHA notes that if the manufacturer states that the cylinder is fully charged at 100 psi, the cylinder must be recharged when the pressure falls to 90 psi (i.e., 90% of the fully charged level). The 90 percent level was selected to ensure that sufficient air remains in the cylinder to allow emergency responders to perform their required duties in a contaminated or oxygen-deficient atmosphere and still have sufficient air available to escape from these conditions. The 90 percent level, and the requirement that cylinders be recharged once the pressure falls below 90 percent, was also recommended by the American Industrial Hygiene Association (Ex. 54-208).

In two separate submissions to the record (Exs. 54-121 and 54-135), Consolidated Engineering Services asked what type of training is required for employees who inspect respirators used for emergency response. OSHA notes that, under final paragraph (k), the specifics of an appropriate training program are left to the discretion of the employer. Regarding respirators for emergency use, final paragraph (k)(1)(iii) requires that employees be trained in how to use the respirator effectively in emergency situations, while final paragraph (k)(1)(iv) requires training on how to inspect the respirator. As these paragraphs make clear, OSHA requires the employer to develop appropriate training programs for employees who inspect emergency respirators.

As part of the inspection process for respirators that are maintained for use in emergencies, paragraph (h)(3)(iv) of the final standard requires certification of the inspection. Documentation of certification includes the date of inspection, the name or signature of the inspector, the findings of the inspection, any required remedial action, and a serial number or other means of identifying the inspected respirator. This information must be tagged to the respirator or its storage compartment, or otherwise stored in the form of inspection reports (i.e., paper or electronic), and be maintained until replaced following a subsequent

certification.

This requirement was included in the proposal, and several comments addressed it. Dow Chemical (Ex. 54-278) stated that it supports the proposed requirement. The American Petroleum Institute (Ex. 54-330) recommended that OSHA require "identification of the person that made the inspection" in lieu of a signature. However, OSHA believes that the inspector's name or signature is a clear and precise identification, and therefore has retained this requirement in the final rule as proposed.

The final provision of paragraph (h) deals with respirator repairs and adjustments. Final paragraph (h)(4) provides that respirators that fail inspections, or are otherwise defective, are to be removed from service and discarded, repaired, or adjusted according to the specified procedures. In addition, the employer shall ensure that repairs or adjustments to respirators are made only by persons appropriately trained to do so, and that they use only the respirator manufacturer's NIOSH-approved parts that are designed for the particular respirator. The repairs also must be made in accordance with the manufacturer's recommendations and specifications. Because components such as reducing and admission valves, regulators, and alarms are complex and essential to the safe functioning of the respirator, they are required to be adjusted and repaired only by the manufacturer or a technician trained by the manufacturer.

Several comments were submitted to the record regarding this particular provision. Consolidated Engineering Services (Exs. 54-121 and 54-135) and the Florida Department of Labor and Employment Security (Ex. 54-79) asked what type of training is required for employees who repair and adjust respirators. Motorola (Ex. 54-187) also addressed this point, but added that specialized training for most respirator repair work was not necessary, and that the training program required by the standard should provide employees with sufficient expertise to perform the necessary repair work, or at least to recognize when repair is beyond their ability. Another commenter (Ex. 54-293) asserted that, depending on the manufacturer's recommendation, a trained person may or may not be necessary to make repairs; for example, no training is required to replace a broken respirator strap.

In response to these concerns, OSHA does not believe that it is necessary or appropriate to specify in detail in the final rule the type of training that is required to qualify a person to repair and adjust respirators. However, because of the important health-related functions of respirators, the person making the repair needs to be properly trained. OSHA expects that such repair will often be performed by the manufacturer, particularly if special expertise is required. Where this is not the case, the employer must ensure that the employee or person repairing the respirator has the skills necessary to conduct the appropriate repair and adjustment functions. The use of the term "appropriately trained" refers to an individual who has received training from the respirator manufacturer or otherwise has demonstrated that he/she has the skills to return the respirator to its original state of effectiveness.

The AFL-CIO (Ex. 54-428) and Service Employees International Union (SEIU) (Ex. 54-455) recommended that OSHA require employers to tag as "out of service" those respirators that fail inspections. OSHA agrees that some means must be available for ensuring that only properly functioning respirators are introduced into the workplace. However, OSHA believes that the decision on how to handle respirators that fail inspection is most appropriately addressed in the employer's respirator protection program, as required under final paragraph (c). Specifically, final paragraph (c)(1)(v) would allow such procedures to be tailored to satisfy the needs of a particular workplace.

The SEIU (Ex. 54-455) recommended that OSHA require employers to keep an adequate supply of cartridges and other routine replacement parts in stock and readily accessible to employees so that they can replace needed parts. OSHA does not believe it is necessary to specify that employers must maintain an

adequate number of spare parts. Final paragraph (h)(4) requires that defective respirators be removed from service unless they are repaired or adjusted, and an employer who does not keep on hand sufficient parts to allow respirators to be repaired will need to remove those respirators from service until suitable repairs can be made. Thus, an employer who does not maintain an adequate inventory of parts will either need to keep extra respirators on hand or cease operations that require respirator use until parts can be obtained or installed.

#### Paragraph (i) -- Breathing Air Quality and Use

This paragraph of the respiratory protection standard requires that breathing air for atmosphere-supplying respirators be of high purity, meet quality levels for content, and not exceed certain contaminant levels and moisture requirements. The paragraph sets performance standards for the operation and maintenance of breathing air compressors and cylinders, establishes methods for ensuring breathing air quality, and sets requirements for the quality of purchased breathing air.

Paragraph (i)(1) of the final standard applies to atmosphere-supplying respirators that are being used to protect employees, and requires that breathing air supplied to these respirators be of high purity. This same requirement for breathing air quality was included in proposed paragraph (i)(1). Both the prior and final rules refer to a number of standard references that establish parameters for breathing air quality. For example, under (i)(1)(i), the final rule requires the employer to ensure that oxygen used for breathing purposes meets the requirements of the United States Pharmacopoeia (USP) for medical or breathing oxygen. This provision is the same as the requirement in OSHA's prior respiratory protection standard at paragraph (d)(1). The ANSI Z88.2-1992 respirator standard, in Clause 10.5.1, also requires that air be of high purity and that oxygen meet the USP requirements. Inclusion of this requirement in the final rule was strongly supported by the AFL-CIO (Ex. 54-428), which stated that the employer must ensure that "compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration is of high purity and in accordance with the specifications listed in [proposed paragraph] (i)(1)."

Under paragraph (i)(1)(ii) of the final standard, breathing air must meet at least the requirements for Type I -- Grade D breathing air, as described in the ANSI/CGA G-7.1-1989 standard, which is the latest revision of that reference standard and the one currently used by OSHA when determining breathing air quality. Final paragraph (i)(1)(ii) identifies the specifications for the contents of Grade D breathing air: oxygen content (volume/volume) of 19.5 to 23.5 percent; hydrocarbon (condensed) concentration of five milligrams or less per cubic meter of air; carbon monoxide level of 10 ppm or less; carbon dioxide level of 1,000 ppm or less; and a lack of noticeable odor.

The OSHA respiratory protection standard adopted in 1971 referenced the then-current CGA G-7.1-1966 breathing air quality standard. In 1973, and again in 1989, the CGA, in conjunction with ANSI, revised the G-7.1 standard. The Grade D specification was changed as part of the 1989 ANSI revision, at which time the carbon monoxide level was reduced from 20 ppm to 10 ppm. The OSHA Directorate of Compliance Programs subsequently issued letters of interpretation in 1991 and 1992 that required employers to use the updated Grade D specifications for breathing air quality.

The proposal requested comments on whether acceptable respirator breathing air quality should continue to meet the specifications for Grade D breathing air described in the ANSI/CGA G 7.1-1989 standard. Commenters supported inclusion of a requirement for use of the 1989 Grade D breathing air values in the final rule (Exs. 54-141, 54-189, 54-267, 54-286, 54-408, 54-443). For example, the Tennessee Valley Authority (Ex. 54-189) and Norfolk Southern (Ex. 54-267) supported the Grade D breathing air requirement, stating that, in their experience, the Grade D air they have been using is fully adequate and

safe, and that OSHA should not adopt more stringent requirements across the board.

Modern Safety Techniques, Inc. (Ex. 54-141) supported maintaining the Grade D breathing air quality requirement but recommended that the OSHA rule not specify the year of the ANSI/CGA standard, because, for example, employers were confused when the CGA revised the ANSI/CGA G-7.1 standard in 1989 and the OSHA standard referred to an earlier version of that standard. However, the regulations governing the incorporation of documents by reference (1 CFR 51) require that the revision date of incorporated references be specified when they are included in any new or revised standard. Where incorporated references are used in final paragraph (i), therefore, the latest revision dates for these references have been used.

The Los Alamos National Laboratory (LANL) (Ex. 36-52) recommended that Grade E air rather than Grade D air be used since most air that passes the Grade D requirements will also pass Grade E requirements. The Grade E specifications narrow the range of permitted oxygen content from 19.5-23.5 percent to 20 to 22 percent oxygen and lower the allowable carbon dioxide level from 1000 ppm to 500 ppm. LANL gave no specific safety or health reason for OSHA to adopt this more stringent recommendation. The Service Employees International Union (Ex. 54-455), however, points out that Grade E air of reliable quality may be difficult for employers to obtain. In addition, OSHA is not aware of any problems that have occurred as a result of breathing Grade D air, and believes that the Grade D specifications will fully protect employees who use atmosphere-supplying respirators. Therefore, OSHA is not convinced a higher grade of air is required, and the final rule specifies Grade D air.

OSHA has been informed that NIOSH has been working with the National Aeronautics and Space Administration (NASA) on a new "liquid air SCBA" that may be submitted for NIOSH certification in the future. In its revision of the 42 CFR 84 respirator certification standard, NIOSH incorporated the CGA Commodity Specification for Air in the CGA's G-7.1-1966 standard to maintain the quality verification category for Type II liquid compressed air, which had been removed from the updated ANSI/CGA G-7.1-1989 standard. NIOSH included this specification because a liquid compressed air quality category is needed for future evaluations of atmosphere-supplying respirators that use liquefied compressed air. NIOSH continues to recommend the use of the ANSI/CGA G-7.1-1989 standard for breathing air quality for currently issued respirator certifications.

Under paragraph (i)(2) of the final standard, employers are prohibited from using compressed oxygen in atmosphere-supplying respirators, including open-circuit SCBAs, that have previously used compressed air. This prohibition was proposed in the NPRM, and is intended to prevent the fires and explosions that could result if high pressure oxygen comes into contact with oil or grease that has been introduced to the respirator or the air lines during compressed air operations. Comments to the record (Exs. 10, 54-165, 54-208, 54-218) support this provision. Additionally, the prohibition is consistent with Clause 10.5.2 of the ANSI Z88.2-1992 standard.

Proposed paragraph (i)(3) would have prohibited the use of oxygen with supplied air respirators. This provision was intended to avoid the possibility of fires and explosions that can result when oxygen is used in high concentrations. However, some respiratory equipment is specifically designed to avoid fire and explosion hazards when used with oxygen in concentrations greater than 23.5%. Therefore, paragraph (i)(3) of the final standard specifies that oxygen in concentrations greater than 23.5% is to be used only with equipment designed specifically for oxygen service or distribution. Several commenters pointed out the need to specify a maximum oxygen concentration (Exs. 54-165, 54-208, 54-218, 54-219). Clause 10.5.2 of the ANSI Z88.2-1992 standard (Ex. 81) also states, "Oxygen concentrations greater than 23.5%

shall be used only in equipment designed for oxygen service or distribution." OSHA agrees with the recommendations made by the AIHA (Ex. 54-208), 3M (Ex. 54-218), and Monsanto (Ex. 54-219) that the final rule adopt the maximum oxygen concentration language from the ANSI standard, and the final rule reflects this recommendation.

Final paragraph (i)(4) requires that breathing air for respirators provided from cylinders or air compressors meet certain minimum standards. Under final paragraph (i)(4)(i), cylinders must be tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (DOT) (49 CFR parts 173 and 178); these DOT regulations are also required for NIOSH respirator certification. The DOT regulations in parts 173 and 178 cover the construction, maintenance, and testing of these compressed air cylinders, and are necessary to prevent the explosions that can result if high pressure breathing air cylinders rupture. The proposal referenced only 49 CFR part 178, but the AIHA (Ex. 54-208) recommended that the DOT requirements found in 49 CFR part 173 also be specified in the final rule because they apply to breathing air cylinders. Final paragraph (i)(4)(i) therefore includes a reference to part 173 in addition to part 178.

Paragraph (i)(4)(ii) of the final standard includes a provision requiring employers to ensure that cylinders of purchased breathing air are accompanied by a certificate from the supplier stating that the air meets the requirements for Type 1-Grade D breathing air contained in paragraph (i)(1)(ii) of the final standard. Employers must obtain a certificate of analysis of purchased breathing air from the supplier to ensure that its content and quality meet the requirements for Grade D breathing air. This will allow the employer to have assurance that the purchased breathing air being used by employees is safe. The proposal did not include a requirement for the certification of the quality of purchased breathing air. There was, however, support in the record (Exs. 54-234, 54-266, 54-273, 54-330, 54-408) for adding this requirement. For example, the American Petroleum Institute (Ex. 54-330) and Duquesne Light Company (Ex. 54-408) recommended that additional guidance, similar to that in ANSI Z88.2-1992, be provided to ensure the quality of purchased breathing air. Exxon (Ex. 54-266) stated that OSHA should not allow the direct blending of compressed nitrogen and oxygen gases by the employer to produce Grade D air, citing the "extreme consequences of having too little oxygen in a cylinder." Exxon further recommended that 100% of the cylinders be tested for oxygen content for all nitrogen/oxygen mixed cylinders (Ex. 54-266). The requirement that the employer obtain a certificate of analysis of purchased breathing air means that every cylinder will have been analyzed for oxygen content by the supplier and, therefore, the situation feared by Exxon will not arise.

Final paragraph (i)(4)(iii) requires that the moisture content of compressed air in air cylinders not exceed a dew point of -50 deg. F (-45.6 deg. C) at one atmosphere of pressure. This requirement will prevent respirator valves from freezing, which can occur when excess moisture accumulates on the valves. This provision has been revised from the proposed requirement to be consistent with the latest versions of the standard references for moisture content of compressed breathing air, the ANSI Z88.2-1992 and ANSI/CGA G-7.1-1989 standards. Consistency between the required value and the standard references will avoid confusion in measuring moisture content and, consequently, will enhance employee protection. This dew point value, as the AIHA (Ex. 54-208) recommended, has been taken from the ANSI/CGA G-7.1-1989 specifications for Grade D air and replaces the 27 ml/m<sup>3</sup> value for moisture content specified in the proposal.

Final paragraph (i)(5)(i) requires that compressors that supply breathing air are to be constructed and situated so that contaminated air cannot enter the air supply system. This provision from the prior standard is retained and also reflects the intent of the proposed requirement. The purity of the air entering the

compressor intake is a major factor in the purity of air delivered to the respirator user. The location of the intake is most important, and must be in an uncontaminated area where exhaust gases from nearby vehicles, the internal combustion motor that is powering the compressor itself (if applicable), or other exhaust gases being ventilated from the plant will not be picked up by the compressor air intake. Contaminated air or exhaust gases from internal combustion engines that are taken into the compressor are major hazards to the purity of breathing air from compressors, and these hazards occur with all compressors, not just oil-lubricated ones. Respirator users have died or been injured when the air intake was not properly located to avoid contaminants. Final paragraph (i)(5)(i), therefore, requires that air intakes for all compressors be located in a way that avoids entry of any contaminated air into the compressor.

Support for this requirement can be found in the Distler air compressor study (Ex. 32-1). This study recommended that engine exhaust gases should be piped upward or downwind from the compressor air intake, particularly where exhaust gases are not reliably dispersed, such as in partially enclosed spaces or in turbulent wind areas. The compressor exhaust piping used in the Distler study had to be repositioned several times to find a location where the exhaust gases would not be picked up by the compressor air intake. All of these findings reinforce the importance of locating the compressor's air intake in an area that ensures that only high-quality air can be taken in. No comments were received on the proposed requirement for the location of compressor air intakes.

Final paragraph (i)(5)(ii) has been slightly modified from proposed requirement (i)(4)(ii) to require that the moisture content of compressed air be minimized so that the dew point at one atmosphere of pressure is 10 degrees Fahrenheit (5.56 degrees Celsius) below the ambient temperature to prevent water freezing in valves and connections of the air supply system. Such freezing can block air lines, fittings, and pressure regulators. This final requirement is similar to the parallel provision of the previous standard, which required that breathing air meet the requirements of CGA G-7.1-1966. Two commenters (Exs. 54-208, 54-218) pointed out that the proposal specified a dew point of 10 degrees Celsius instead of the 10 degrees Fahrenheit specified in the ANSI/CGA G-7.1-1989 standard. The value in final paragraph (i)(5)(ii) has been revised to match the 10 deg. F provision in the G-7.1-1989 standard for Grade D air, with an equivalent value of 5.56 deg. C added to comply with a Federal government requirement (P.L. 100-418 and E.O. 12770) that scientific and technical measures are expressed as metric units.

Paragraph (d)(2)(ii) of the prior standard required air compressors to have a receiver of sufficient capacity to permit the respirator user to escape from a hazardous atmosphere in the event of compressor failure. However, under paragraph (d)(2) of the final standard, the only respirators that can now be used in IDLH atmospheres are either SCBAs or supplied-air respirators with an auxiliary self-contained air supply for escape. Consequently, a requirement for an air receiver to permit escape from IDLH atmospheres is no longer needed in the final rule. Also, the prior respiratory protection standard, in paragraph (d)(2)(ii), required compressors to have alarms to indicate compressor failure and overheating; this requirement was part of the same provision that specified that a receiver for escape from a contaminated atmosphere in the event of compressor failure be available. This alarm requirement was deleted from the proposal and is not part of the final standard. An alarm to indicate compressor failure or overheating is unnecessary in non-IDLH atmospheres since, as OSHA stated in the proposal, the respirator user can readily exit the hazardous area if the respirator fails.

The deletion from the final standard of the prior standard's requirement for compressors to be equipped with receivers if they were to be used in hazardous atmospheres will clarify an enforcement issue that has arisen in connection with ambient air movers. Ambient air movers have been developed to provide air to

supplied-air respirators. These units are small electric compressors that are not oil-lubricated and have no air receiver. Such compressors are used in non-IDLH atmospheres. The use of ambient air movers has been allowed under an existing OSHA compliance directive even though such devices do not have the air receiver required for air compressors by the prior respiratory protection standard. However, the final standard removes the air receiver requirement for compressors, and ambient air movers will therefore be treated like any other air compressor used in non-IDLH atmospheres.

Under final paragraph (i)(5)(iii), compressors must be equipped with suitable in-line air-purifying sorbent beds and filters to further assure breathing air purity. The Associated Builders and Contractors, Inc. (Ex. 54-309) recommended that the corresponding provision in the proposal be revised to add the requirement that employers change air-purifying sorbent bed and filters in accordance with the manufacturer's instructions. Also, clause 10.5.4.2 of the ANSI Z88.2-1992 standard recommends that maintenance and replacement or refurbishment of the air-purifying and filter media be performed periodically by trained personnel and in accordance with the manufacturer's recommendations and instructions. OSHA agrees with the Associated Builders and Contractors that sorbent beds and filters must be maintained properly, and has added language to paragraph (i)(5)(iii) that is similar to that in ANSI Z88.2-1992, and requires sorbent beds and filters to be maintained and replaced or refurbished periodically in accordance with the manufacturer's recommendations. The Associated Builders and Contractors also recommended that sorbent bed and filter changes be documented, that such documentation be retained for one year, and that it be made available to OSHA on request. However, OSHA is not generally requiring that records of respirator maintenance performed under this standard be kept and does not believe such a requirement is necessary here. Instead, OSHA is requiring in paragraph (i)(5)(iv) that a tag containing the most recent date of sorbent bed replacement or refurbishing, along with the signature of the person performing the change, be kept at the compressor. This tagging requirement is also consistent with OSHA's efforts, as required by the Paperwork Reduction Act of 1995, to reduce paperwork to the extent consistent with employee safety and health.

Paragraphs (i)(6) and (i)(7) address the control of carbon monoxide levels in breathing air. Paragraph (i)(6) requires that, for compressors that are not oil lubricated, the CO levels in the breathing air may not exceed 10ppm. Paragraph (i)(7) requires monitoring of CO levels for oil lubricated compressors. OSHA stated in the NPRM that one method to prevent contaminated air from reaching the breathing air supply was to require carbon monoxide filters with continuous alarms for all breathing air compressors. The agency requested comments on the use of carbon monoxide alarms, high-temperature alarms, and shutoff devices in the workplace (59 FR 58926). A number of comments were received that addressed the issue of carbon monoxide monitors and alarms.

Modern Safety Techniques, Inc. (MST) (Ex. 54-141) noted that in many workplaces it may be impossible or cost prohibitive to relocate the air intake to an area that would reduce the likelihood of carbon monoxide entering the system. In these cases, MST recommended continuous monitoring as the only method that would ensure breathing air quality. MST stated that the use of a carbon monoxide alarm or measuring device is necessary to tell whether carbon monoxide purifiers (e.g., Hopcalite filters) are functioning properly. MST stated, "Unless continuous monitoring is being conducted on the breathing air supply, "frequent" monitoring, or proper placement of the breathing air supply, only assures that the requirements are met at *that* particular instance in time." [Emphasis in original.] Eugene Satrun, an industrial hygienist who runs a respirator program in Illinois (Ex. 54-261), supported the need for continuous carbon monoxide monitors, noting that automatic compressors can be operated with a vehicle running nearby and may consequently pull significant levels of carbon monoxide into the intake.

Several commenters were opposed to OSHA adopting a requirement for continuous carbon monoxide monitoring and alarms (Exs. 54-234, 54-250, 54-408). They stated that the requirements for sorbent bed filtration, proper air inlet location, and Grade D air quality, confirmed by periodic sampling, would be sufficient to control the carbon monoxide hazard. Kodak (Ex. 54-265) stated that it has assessed the purity of compressed air for breathing use over a period of 18 years at its plants, collecting and analyzing more than 1200 samples, and that no incidents of carbon monoxide production involving oil-lubricated compressors have been reported. Carbon monoxide production, Kodak stated, is best prevented by adequate procedures, awareness, and certification. Kodak did not provide specific procedures for determining air system compliance, nor further clarification of what is meant by awareness or certification. The Duquesne Light Company (Ex. 54-408) stated that continuous monitoring was unnecessary, and that requiring filtration or purification of the air supply, proper location of the air intake, and Grade D air purity should be sufficient to ensure a safe breathing air supply. Meridian Oil (Ex. 54-206) opposed continuous monitors because these devices can generate false alarms.

Other commenters proposed alternatives to continuous monitoring. Niagara Mohawk Power (Ex. 54-177), in comments opposing carbon monoxide alarms, stated that carbon monoxide filters with color-change indicators are an appropriate method to monitor carbon monoxide. Monsanto (Ex. 54-219) stated that OSHA should not require all compressors to have carbon monoxide filters and alarms. Monsanto stated that high-temperature alarms or automatic compressor shut downs would only be needed when there was a reasonable possibility of carbon monoxide production in the compressor due to equipment problems. TU Electric (Ex. 54-250) stated that carbon monoxide filters or continuous monitoring alarms should not be required for all breathing air compressors, but that regular testing of breathing air prior to use, and testing in specific locations on a regular basis during compressor use, should be required. This commenter also recommended against a requirement for carbon monoxide filters or monitors for oil-free compressors.

Other commenters (Exs. 54-206, 54-234, 54-250) supported testing ambient air near the intake on a regular basis, but did not recommend a testing frequency. General guidance for periodic sampling of air quality for compressors is specified in Clause 10.5.4.3 and Table 4 of the ANSI Z88.2-1992 standard. The ANSI procedure was recommended by several commenters (Exs. 54-234, 54-250, 54-263, 54-273, 54-363). ANSI Z88.2-1992 recommends acceptance testing prior to initial use and representative sampling at distribution supply points on a periodic basis to ensure "a continued high-quality air supply." Norfolk Southern (Ex. 54-267) stated that OSHA should not require the use of carbon monoxide filters with compressor-supplied air, and that the employer should have the option of using a carbon monoxide detector. This commenter stated also that installing a carbon monoxide filter is not reasonable for those systems that already have a carbon monoxide detector and high-temperature alarm. St. Lawrence Gas (Ex. 54-402) commented that carbon monoxide alarms should not be required and noted that it has found the use of carbon monoxide-to-carbon dioxide converters (with color-change indicators) sufficient for detecting the presence of carbon monoxide. ORC (Ex. 54-424) stated that carbon monoxide alarms or high-temperature alarms are not needed for all compressors. ORC recommended that adequate procedures, awareness, and certification for installation are the best means to ensure that contaminated air does not enter the compressor. This language is similar to that used by Kodak (Ex. 54-265), and, like Kodak, ORC (Ex. 54-424) did not provide any elaboration of the phrase "adequate procedures, awareness, and certification for installation."

A carbon monoxide monitor with an alarm can be used to continuously measure the breathing air and warn respirator users when carbon monoxide levels exceed the 10 ppm limit set for Grade D breathing air. However, these alarms need to be properly maintained to function effectively. MST (Ex. 54-141) stated that the electrochemical type of sensors used today are specific for carbon monoxide, are relatively stable

during temperature and humidity changes, and are accurate enough to meet the CGA G-7.1-1989 requirements. These sensors have replaced the older metal oxide sensors that had problems with false alarms. However, the electrochemical sensors must be calibrated periodically (usually on a monthly basis) to perform accurately. The Service Employees International Union (Ex. 54-455) also recommended that the final standard address regular replacement of alarm sensors and filter media.

Carbon monoxide filters with color-change indicators are used to convert carbon monoxide in breathing air to carbon dioxide, which is less likely to pose a hazard to the respirator user. The source of the carbon monoxide can be from contamination of the intake air or from carbon monoxide generated by the compressor. However, the color change in the indicator results from moisture in the breathing air that is trapped in the filter element. The color-change indicator, therefore, does not indicate the presence of carbon monoxide, but instead signals only the presence of moisture, which can render the sorbent filters ineffective. Consequently, the color-change indicator cannot be used directly to detect carbon monoxide. In addition, these carbon monoxide filters, like carbon monoxide alarms, need periodic maintenance to ensure their continued effectiveness.

In summary, strong arguments favor a requirement for continuous carbon monoxide monitoring of compressor-generated breathing air. This is the case because preventing carbon monoxide contamination by locating the air intake for compressors in an area that is free of carbon monoxide contamination is difficult in many cases and impossible in others. Automatic compressors with poorly located air intakes may operate when a running vehicle is in the immediate area, thereby contaminating the air supply with carbon monoxide from the vehicle's exhaust. In addition, older compressors, which may still be operational after hundreds, if not thousands of operating hours, may allow increased oil blow-by due to piston ring and cylinder wear, which increases the possibility of carbon monoxide contamination.

The most convincing evidence against a requirement for continuous carbon monoxide monitoring comes from the 18-year collection of sampling results taken by Kodak (Ex. 54-265). OSHA notes, however, that Kodak's results are likely to be due to the company's careful observance of operating procedures, such as procedures ensuring the proper location of air intakes and regular and thorough maintenance and repair of all compressors. OSHA notes that Clause 10.5.4.3 of the ANSI Z88.2-1992 standard calls for periodic, rather than continuous, sampling of breathing air from the air supply.

The arguments for and against carbon monoxide alarms are less well defined than the case for carbon monoxide monitoring devices. Several commenters specifically recommended the use of carbon monoxide alarms whenever compressed air is being used as breathing air (Exs. 54-337, 54-428, 54-455). The AFL-CIO (Ex. 54-428) recommended the use of carbon monoxide alarms or monitors on all air supply systems that service respirators with Grade D breathing air. Both of these recommendations would assure an air supply uncontaminated by carbon monoxide. The proponents of carbon monoxide alarms (Exs. 54-141, 54-261, 54-337, 54-428, 54-455) state that they are needed to alert personnel that equipment is malfunctioning; the Exxon Company (Ex. 54-266) stated that gasoline- and diesel-powered compressors should be required to have carbon monoxide alarms to detect exhaust gases that enter the air supply, as well as compressor failure and high-temperature alarms; other commenters (Exs. 54-337, 54-428) would require the use of carbon monoxide alarms to prevent accidental carbon monoxide contamination whenever compressed air is being used as breathing air.

The opponents (Exs. 54-177, 54-206, 54-219, 54-234, 54-250, 54-265, 54-402) of carbon monoxide alarms cite the availability of alternate equipment and procedures that they claim are as effective as alarms in protecting the purity of breathing air. Examples of these alternatives are filters with color-change

indicators, carbon monoxide-to-carbon dioxide converters, oil-free compressors, proper air intake placement, certification of air compressor systems, and periodic monitoring (Exs. 54-177, 54-206, 54-219, 54-250, 54-265, 54-330, 54-402, 54-408, 54-424).

OSHA believes that it is essential for the employer to ensure that excessive carbon monoxide is not in the compressed breathing air supplied to respirators. Final paragraphs (i)(6) and (i)(7), therefore, require that the employer prevent carbon monoxide levels in the breathing air from exceeding 10 ppm. For compressors that are not oil-lubricated, this requirement can be met by several different methods, including the use of continuous carbon monoxide alarms, carbon monoxide filters, proper air intake location in an area free of contaminants, frequent monitoring of air quality, or the use of high-temperature alarms and automatic shutoff devices, as appropriate. No single method will be appropriate in all situations, and several methods may need to be combined, *e.g.*, the use of carbon monoxide alarms with carbon monoxide filters where conditions are such that a reliable carbon monoxide-free area for compressor air intakes cannot be found. As the comments to the record show, there was no agreement on the most appropriate method for ensuring that carbon monoxide would not contaminate the breathing air coming from compressors. OSHA has decided that a performance-based requirement ensuring that carbon monoxide does not contaminate breathing air will give employers flexibility in selecting the method(s) most appropriate for conditions in their workplace.

Oil-lubricated compressors can produce carbon monoxide if the oil enters the combustion chamber and is ignited. This can be a particularly severe problem in older compressors whose piston rings and cylinders are worn. Final paragraph (i)(7) requires that such compressors have a high-temperature or carbon monoxide alarm, or both. If only a high-temperature alarm is used, the air from the oil-lubricated compressor must be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm. The latter requirement ensures that carbon monoxide that enters a poorly located compressor air intake, as well as carbon monoxide generated by the compressor itself, is detected.

Final paragraph (i)(7) is similar to a provision in the previous standard. In the NPRM, OSHA proposed to delete the requirement from the previous respirator standard that oil-lubricated compressors be equipped with carbon monoxide alarms and high-temperature shutoff devices. However, a number of commenters (Exs. 54-144, 54-219, 54-266) stated that precautions against excessive carbon monoxide were needed when oil-lubricated compressors were used. Modern Safety Techniques (Ex. 54-144) stated that oil-lubricated compressors used by industry to supply breathing air often have hundreds of hours of use, allowing greater oil blow-by and therefore greater potential for carbon monoxide production, was reported in the Distler study. That study found that properly functioning air compressors are unlikely to reach temperatures at which carbon monoxide production occurs. Exxon (Ex. 54-266) encouraged OSHA to include a requirement for in-line carbon monoxide alarms for diesel- or gasoline-powered compressors, since its experience indicates that the use of these compressors increases the risk of carbon monoxide contamination from the compressor's exhaust. Monsanto (Ex. 54-219) stated that high-temperature alarms or automatic compressor shutoffs would be needed when there was a reasonable possibility of carbon monoxide production in the compressor due to equipment problems. The Service Employees International Union (Ex. 54-455) argued that the requirements specifying Grade D breathing air purity and location of the compressor air intake in an uncontaminated atmosphere were not sufficient to ensure that carbon monoxide is not entrained in the system.

An incident of carbon monoxide production by an oil-lubricated compressor was described in a MSHA Accident Investigation Report issued in January 1985 (Ex. 38-12). An oil-cooled, diesel-powered, two-stage, rotary air compressor overheated during a sandblasting operation at a limestone quarry. The air

compressor thermo-bypass valve, which should have directed the oil through a cooling radiator once the oil had reached a temperature of 185 deg.F, failed, which allowed the temperature of the cooling oil to rise above its flashpoint of 420 deg.F. The oil ignited, producing carbon monoxide. The compressor was equipped with a high-temperature shutoff switch set for 235 deg.F, but it had been disconnected for at least 30 days prior to the incident. The compressor was not equipped with a carbon monoxide filter or alarm. The sandblaster collapsed from carbon monoxide poisoning. Monsanto (Ex. 54-219) stated that this incident resulted from a failure to follow the provision in the previous standard requiring that oil-lubricated compressors have a functional high-temperature or carbon monoxide alarm, or both. OSHA believes that this incident, as well as the comments described above, supports carrying the previous standard's requirement forward in the final rule.

Final paragraph (i)(8) requires that air line couplings be incompatible with outlets for non-respirable worksite air or other gas systems to prevent the inadvertent provision of nonrespirable gases to airline respirators. Breathing air couplings, therefore, are to be made incompatible with outlets from nonrespirable plant air and other gas systems. This requirement is similar to the provision in paragraph (d)(3) of the previous respiratory protection standard and proposed paragraph (i)(5) of the NPRM. Martin Marietta (Ex. 54-410) stated that there have been documented cases in which cross-connections have introduced hazardous contaminants into breathing air lines. To avoid this problem, Martin Marietta recommended that OSHA add a provision to the final standard that prohibits connecting breathing air lines to any nonrespirable gas source or process. Consistent with this recommendation, OSHA has added a sentence to paragraph (i)(8) requiring that no asphyxiating substance be introduced into breathing air lines. This requirement will cover not only the contamination of the breathing air system from cross-connections, but will also cover other potential contaminating conditions, *e.g.*, using nitrogen to blow out worksite air lines where the worksite air source is also used for breathing air.

The final standard also requires that the employer prevent utility oxygen, *i.e.*, oxygen supplied to meet other manufacturing needs, from entering the respirator air supply system. As discussed above, the standard permits oxygen to be used in respirators designed for oxygen service. The final standard prohibits the introduction of utility oxygen into breathing air systems that supply respirators that are not designed for oxygen service; this provision is needed to prevent the fires and explosions that could result if high-pressure oxygen comes into contact with oil or grease that has been introduced to the respirator or the air lines during compressed air operations.

Final rule paragraph (i)(9) requires employers to use breathing gas containers marked in accordance with the NIOSH respirator certification standard at 42 CFR part 84. This requirement differs from proposed paragraph (i)(6), which listed several additional standards for breathing gas containers. These additional standards have been incorporated into 42 CFR part 84, making reference to them in the final rule unnecessary.

#### Paragraph (j) -- Identification of Filters, Cartridges, and Canisters

The final rule provides that the employer only use filter cartridges and canisters that are labeled and color coded with the NIOSH approval label and that the label not be removed or made illegible. This is similar to the parallel requirement in the proposal, which was supported by commenters (Exs. 54-361, 54-428, 54-455). OSHA has modified the proposed language in certain respects to add compliance flexibility while retaining the original objective, *i.e.*, assurance that these elements meet NIOSH's stringent requirements. These comments and modifications are discussed below.

OSHA proposed to eliminate from the previous respiratory protection standard the language in paragraphs

(g)(1) to (g)(6), which described labeling requirements, and Table I-1, which listed color codes assigned to canisters and cartridges. These requirements were adopted from the original national consensus standard (i.e., ANSI K13.1, "Standard for Identification of Air-Purifying Respirator Canisters and Cartridges") adopted by OSHA in 1971. In place of these requirements, proposed paragraph (j)(1) would have required employers to ensure that all filters, cartridges, and canisters bear a NIOSH approval label before being placed into service.

Proposed paragraph (j)(2) specified that the label not be removed, obscured, or defaced while the filter, cartridge, or canister was in service to ensure that the label provided information to the employee about the protection being afforded by the respirator. In the final standard, OSHA has combined proposed paragraphs (j)(1) and (j)(2) into a single paragraph (j). The changes from the previous standard recognize that employers who use respirators should be able to rely on labeling and color coding by respirator manufacturers for assurance that the respirators meet NIOSH requirements.

This position is consistent with that taken by many commenters, who noted that the labeling and color coding of filters are the responsibility of the respirator manufacturer (Exs. 54-208, 54-218, 54-219, 54-278, 54-289) and are required by NIOSH for certification. OSHA agrees that color coding and the attachment of NIOSH approval labels to respirators are the responsibility of the manufacturer. However, it is still the employer's responsibility to use only components bearing a NIOSH approval label, and to ensure that the NIOSH approval labels are not removed from the filters, cartridges, and canisters that are used in the workplace and remain legible.

The NIOSH label serves several purposes. It ensures selection of appropriate filters for the contaminants encountered in the workplace and permits the employee using the respirator to check and confirm that the respirator has the appropriate filters before the respirator is used. David Lee, a CIH, CSP, and respirator consultant (Ex. 54-304), commented that, once a filter selection is made and the respirator is donned, the label becomes meaningless. However, the employee is not the only one who uses the color coding and label. Color coding and labeling also allow fellow employees, supervisors, and the respirator program administrator to readily determine that the appropriate filters are being used by the employee. Cartridges that are appropriate for one operation may be inappropriate for another, and color coding and labeling allow respirator users with inappropriate filters to be identified in the workplace and potential respiratory hazards to be avoided.

Proposed paragraph (j)(2) required that the NIOSH approval label not be "removed, obscured or defaced" while respirators are being used. 3M (Ex. 54-218) and Monsanto (Ex. 54-219) urged OSHA to add the word "intentionally" before "removed, obscured or defaced," since they believe that an employer would be in violation of this provision if, for example, a label is covered with paint overspray during use. Monsanto also stated that some OSHA substance-specific standards require that cartridges be dated by the employee to indicate when they were first put into service and that some employers could use this dating method to control cartridge use even when not required by OSHA. Accordingly, Monsanto urged OSHA to add the phrase "except if it is to record initial use information" to paragraph (j)(2) to clarify that adding a date to the NIOSH label is allowed and will not be regarded as defacing the label. David Lee (Ex. 54-304) was concerned that dirt, dust, and debris can easily obscure the label once the respirator is in use and that employees would be required by the proposed provision to leave the area to clean the label to make it legible. Dow (Ex. 54-278) stated that, because of the small size of the label on some cartridges, the employer cannot date the cartridges without obscuring some of the information on the label. To resolve this problem, Dow suggested that the words "pertinent information" be added before "obscured."

OSHA has not added the term "intentional" to final paragraph (j) because it would be difficult, if not impossible, to determine if the removal or obscuring of a NIOSH label was accidental or intentional. Also, the final provision does not include an exemption for documenting the initial use date on cartridge and canister labels, since OSHA already permits this practice. OSHA's experience indicates that the initial use date can easily be added to a filter, cartridge, or canister without obscuring the label, and this procedure has not proven to be a problem in the substance-specific standards that require such dating. The term "pertinent information" has not been included in final paragraph (j) because OSHA believes that all of the information on the NIOSH approval label is pertinent. The degree of cleanliness required of the label while the respirator is in service should not be an issue because the label only needs to be legible and reasonably clean to provide the required information. Any dust, dirt, paint overspray, or other substance that completely obscures the label would also affect respirator cleanliness and the service life of the filter, resulting in replacement of the filter with new filters that have unobscured labels, as required by paragraph (g).

In summary, final paragraph (j) combines into a single provision the proposed requirements that employers ensure that the manufacturer's NIOSH approval label is on the cartridge, filter, or canister, and that employers maintain the labels in legible condition while the cartridge, filter, or canister is in service. As with the proposed paragraphs, this provision is a performance-based requirement that permits employers to adopt whatever procedures are appropriate to ensure that the label remains on the filter and is not removed, defaced, or obscured during respirator use.

#### Paragraph (k) -- Training and Information

Paragraphs (k)(1)-(3) of the final standard require employers to provide effective training for employees required by the employer to wear respirators. Employees must be trained sufficiently to be able to demonstrate a knowledge of why the respirator is necessary; how improper fit, usage, or maintenance can compromise the protective effect of the respirator; the limitations and capabilities of the selected respirator; how to deal with emergency situations involving the use of respirators or with respirator malfunction; how to inspect, don and remove, and check the seal of the respirator; procedures for maintenance and storage of the respirator; the medical symptoms and signs that may limit or prevent the effective use of respirators; and the general requirements of this standard.

Paragraph (k)(4) allows for the "portability" of previous respirator training, and paragraph (k)(5) specifies the requirement for at least annual retraining. Also, as discussed earlier under the Summary and Explanation for paragraph (c), Respiratory Protection Program, final paragraph (k)(6) requires employers to provide the basic advisory information presented in Appendix D of this section to employees who voluntarily use respirators in their workplace.

The final standard requires that training be understandable and be given to the employee prior to using a respirator in the workplace, and annually thereafter. Additionally, if the employer has reason to believe that any employee who has already been trained does not have sufficient understanding and skill to use the respirator, the employer must retrain the employee in those areas in which his or her knowledge or skill is deficient. Retraining is also required when changes in the workplace or in the type of respirator used render previous training obsolete.

Section 1910.134(e)(5) of the previous standard required training in the selection, use, and maintenance of respirators and required respirator wearers to be provided an opportunity to handle the respirator, have it fitted properly, test its facepiece seal, and wear it in normal air for a familiarity period. The final training paragraph retains many of these provisions. However, the format of the final training provisions is

different, and specific provisions for annual training and retraining are included in the final standard. Although the previous standard's requirement for a familiarity period has not specifically been retained, the final standard requires the respirator wearer to be trained sufficiently to demonstrate the ability to use the respirator properly, which may or may not necessitate wearing the respirator in normal air "for a long familiarity period."

The record shows widespread agreement that employee training is a critical part of a successful respiratory protection program and is essential for correct respirator use (Exs. 15-13, 15-18, 15-19, 15-22, 15-30, 15-33, 15-41, 15-45, 15-50, 15-53, 15-54, 15-67, 15-79, 54-5, 54-68, 54-91, 54-92, 54-165, 54-172, 54-208, 54-219, 54-278, 54-361, 54-387, 54-428, 54-455, Tr. 186, 387, 595, 1011, 1063, 1083, 1103, 1226).

For example, James Johnson of the Lawrence Livermore National Laboratory testified:

The training element of the respiratory protection program is one of the most important elements to assure the respirator is properly used and is performing as intended \* \* \*. This is the only time that the worker has a chance to interact with a trained professional who can properly instruct that person on the correct use of the respirator, the employee can see what is right, what doesn't work, and can understand this item that is given to him to wear throughout a year to help protect his health \* \* \* (Tr. 186)

Dan Faulkner of the United Steelworkers of America concurred, commenting that: Training must be seen as a critical component of respiratory protection. This is an area that is grossly ignored under the current regulation \* \* \*. The very first step in the education process must be to empower workers to identify the hazardous substances involved and at what levels they are exposed. In order for the workers to have confidence that his/her respirator is providing the necessary protection from the hostile work environment they must have a thorough knowledge of this entire process. Once this is understood, the worker can make an informed decision on what type of respirator to wear. (Tr. 1062)

ASARCO, Inc. (ASARCO) agrees about the importance of training and reports that its company Respiratory Protection Program Manual states: "For the safe use of any respirator, it is essential that the user be properly instructed in the respirator's purpose, selection, fitting, use, and limitations' (Ex. 163).

OSHA agrees with the many commenters who urged OSHA to mandate a program that is performance oriented and can be presented informally (Exs. 15-13, 15-18, 15-22, 15-30, 15-41, 15-47, 15-62, 15-73, 15-75, 54-213, 54-265, 54-275, 54-455). The final standard does not specify how the training is to be performed nor the format to be used by the employer. As suggested by commenters (Ex. 15-53, Tr. 837, Tr. 1087), the employer can use whatever training method is effective for the particular worksite, provided that the method addresses the required topics. Employers can use prepared materials such as audio-visual and slide presentations, formal classroom instruction, informal discussions during safety meetings, training programs developed or conducted by unions or outside sources such as respirator manufacturers, or a combination of these methods.

As in the proposal, several categories of training information must be addressed in the final rule. The final provisions have been simplified since the proposal, but the information to be covered is essentially the same as that proposed.

Paragraph (k)(1) requires the employer to ensure that before the employee uses the respirator in the workplace, the employee demonstrates that he/she has learned the information communicated under the training program. The employer can comply with this provision by reviewing with the employee, either in writing or orally, the informational part of the training program and by reviewing the employee's hands-on use of respirators.

OSHA's personal protective equipment standard (Sec. 1910.132(f)(2)) also requires that employees

demonstrate effectiveness in using PPE before workplace use. When that standard was adopted in 1994, OSHA stated that "in order for training to be successful, clear and measurable objectives must be set, and employees must demonstrate that the training objectives have been reached by showing that they understand the information provided and that they can use the PPE properly" (59 FR 16339). This reasoning applies equally to respiratory protection. In the NPRM for the respiratory protection standard (proposed paragraph (k)(1)(iii)), OSHA proposed a similar requirement, which stated that the training itself was to include "sufficient practice to enable the employee to become \* \* \* effective in performing tasks [relating to inspection, donning and removal, checking the fit and seals, and in wearing the respirator.]"

The final standard's requirement that employees "demonstrate" competence in using respiratory equipment is supported by the recommendation of commenters that the PPE standard's similar requirement replace the less direct provision in the respiratory protection proposal (Exs. 54-213, 54-319). OSHA's enforcement of the PPE standard has reinforced the Agency's belief that training effectiveness must be evaluated by demonstrating how well employees use equipment on-the-job. OSHA believes that adopting a provision in the respirator standard that is worded similarly to the corresponding requirement in the PPE standard will promote compliance with both standards and uniformity of interpretations and enforcement actions. Moreover, measuring the adequacy of training by evaluating the employee's knowledge gained from the training is consistent with the performance orientation of the final standard and with the absence of specific hourly training requirements in the final standard.

The first category of information to be included in the training program, specified in final paragraph (k)(1)(i), is a discussion of why the use of the respirator is necessary. Proposed paragraph (k)(1)(i) specifically set forth that this discussion was to include information on the nature, extent, and effects of the respiratory hazards to which the employee may be exposed while using the respirator. The language of final paragraph (k)(1)(i) has been simplified; OSHA believes that training in why the respirator is necessary will include information on the nature, extent, and effects of the respiratory hazards. For example, such training would address the identification of the hazardous chemicals involved, the extent of employee exposures to those chemicals, and the potential health effects of such exposure. Much of this information will be available on the Material Safety Data Sheets that chemical manufacturers provide to employers under the Hazard Communication standard (29 CFR 1910.1200). Employee training on the health effects of hazardous chemicals is also required under the Hazard Communication standard, and the same training could help satisfy this respirator training requirement. Many commenters agreed that hazard information is an essential element of training (Exs. 15-10, 15-14, 15-18, 15-19, 15-27A, 15-41, 15-46, 15-53, 15-62, 15-73, 54-5, 54-68, 54-91, 54-165, 54-172, 54-208, 54-278, 54-361, 54-428, 54-455).

Information regarding the consequences of improper fit, usage or maintenance on respirator effectiveness must also be provided to employees under final paragraph (k)(1)(i). Improper attention to any of these program elements would obviously defeat the effectiveness of the respirator. Employees must understand that proper fit, usage and maintenance of respirators is critical to ensure that they can perform their protective function.

Under final paragraph (k)(1)(ii), employers are to explain the limitations and capabilities of the respirator selected for employee use. A discussion of the limitations and capabilities of the respirator must address how the respirator operates. This training would include, for example, an explanation of how the respirator provides protection by either filtering the air, absorbing the vapor or gas, or providing clean air from an uncontaminated source. Where appropriate, it also should include limitations on the use of the equipment, such as prohibitions against using an air-purifying respirator in IDLH atmospheres and an explanation of

why such a respirator should not be used in such situations.

Paragraph (k)(1)(iii) requires that employees be provided with information on respirator use in emergency situations, including those in which the respirator malfunctions. This training requirement was included in proposed paragraph (k)(1)(v). Respirators malfunction on occasion, work routines change, and emergency situations occur that require a different respirator. The training program must discuss these possibilities and the procedures the employer has established to deal with them. Commenters concurred that comprehensive training is necessary where respirators are to be used in IDLH situations, including oxygen-deficient atmospheres, such as those that occur in firefighting, rescue operations and confined area entry (Exs. 15-18, 15-19, 15-26, 15-31, 15-33, 15-37, 15-41, 15-48, 15-50, 15-54, 15-55, 15-56, 15-59, 15-70).

The employee should be able to thoroughly understand the operation of the respirator as a result of this training and demonstrate the ability to properly use the respirator selected. Numerous commenters supported the elements in the training program provided for under final paragraphs (k)(1) (ii) and (iii) (Exs. 61-3, 15-14, 15-18, 15-27A, 15-41, 15-46, 15-53, 15-62, 15-73, 54-5, 54-68, 54-91, 54-172, 54-208, 54-361, 54-428, 54-455). For example, Michael P. Rehfeld, Safety Officer, Westminster Fire Department, stated that:

In section (k) of the NPRM dealing with training, I strongly believe OSHA should put the strongest emphasis. It has been my experience that the stronger the employer training program the less likely that an employee would become injured or dies from a respiratory protection failure. OSHA has historically put a strong emphasis on training (1910.120, 1910.1200, 1910.138, 1910.146). The same emphasis should appear in this rule (Ex. 54-68).

Final paragraph (k)(1)(iv) requires the employer to provide specific instruction on how respirators are inspected, donned, removed, positive/negative pressure checked, and worn. Although the employer is required to ensure that respirator inspections are performed, employees using the equipment may frequently be responsible for inspecting the respirators assigned to them. In this case it is necessary that respirator users have this process explained and demonstrated to them so that they are capable of recognizing any problems that may diminish the protective capability of the respirator. The training must include the steps employees are to follow if they discover any problems during inspection, such as to whom problems should be reported and where replacement equipment can be obtained if needed. If, however, the employer routinely has extensive inspections done by separate personnel, individual respirator wearers are not required to be trained in how to perform full inspections. Training only in those parts of the inspection process that may be their responsibility would be sufficient.

The training under this paragraph must also include the procedures for donning and removing the respirator, checking the fit and seals, and using the respirator. Respirator fit in the workplace must be as close as possible to the fit obtained during fit testing; therefore, employees must know how to follow procedures that will improve fit in the workplace. The fit testing procedures can also help in training employees. For example, employers can use quantitative fit testing procedures to demonstrate to employees the dramatic improvement in measured fit when the respirator is adjusted properly (See the discussion above of paragraph (f) and Ex. 15-44, Tr. 1083).

Final paragraph (k)(1)(iv) requires training in how to check the respirator seal. Appendix B-1 describes methods for checking the seal of positive and negative pressure facepieces. Employees must be trained in the methods set forth in Appendix B-1 or in alternative methods that are equally effective. The training requirements set forth in paragraph (k)(1)(iv) were widely supported in the record (Exs. 15-10, 15-14, 15-22, 15-27A, 15-41, 15-46, 15-50, 15-62, 15-73, 54-5, 54-68, 54-91, 54-165, 54-172, 54-208, 54-219,

54-278, 54-361, 54-428, 54-455).

Final paragraph (k)(1)(v), like proposed paragraph (k)(1)(iv), requires the employer to explain the procedures for maintenance and storage of respirators. The extent of training required under this provision may vary according to workplace conditions. In some cases, where employees are responsible for performing some or all respirator maintenance and for storing respirators while not in use, detailed training in maintenance and storage procedures may be necessary. In other facilities where specific personnel or central repair facilities are assigned to perform these activities, employees may need only to be informed of the maintenance and storage procedures without having to learn significant technical maintenance information. The importance of providing some knowledge to all employees regarding maintenance and storage of respirators was recognized by a number of commenters. Those commenters stated that employees must be able to identify respirator deficiencies that can result from improper maintenance and storage of respirators so that they will not use improperly functioning respirators (Exs. 61-3, 61-8, 15-10, 15-14, 15-27A, 15-41, 15-46, 15-50, 15-62, Tr. 1063).

Final paragraph (k)(1)(vi) requires that employees be instructed in ways to recognize the medical signs and symptoms that may limit or prevent the effective use of respirators. This provision was not included in the proposed standard. However, the Agency agrees with the AFL-CIO (Ex. 54-428) that employee knowledge of this information is important to ensure implementation of a successful respirator program. An employee's knowledge of the medical problems that may preclude the employee from using some types of respirators or from wearing a respirator under certain workplace conditions helps assure that the employee receives the protection intended by the standard. Examples of medical conditions and signs and symptoms that may affect an employee's ability to use a respirator are provided in mandatory Appendix C of the final standard. Training in these signs and symptoms need not be medically sophisticated or burdensome. Employees must be provided only with medical information sufficient for them to recognize the signs or symptoms of medical conditions (e.g., shortness of breath, dizziness) that may affect their use of respirators. This information will also enable employees to understand the purpose of the medical assessment procedures required under paragraph (e) of the final standard, will improve the ability of employees to recognize and report medical signs and symptoms, and will give them the knowledge they need to initiate the follow-up medical evaluations required under paragraph (e) of this section, if necessary.

Final paragraph (k)(1)(vii) requires the employer to inform employees of the general requirements of this section. OSHA agrees with Organization Resources Counselors (Ex. 54-424) that "general requirements" better describes the substantive purpose of this provision than did the word "contents," which was used in proposed paragraph (k)(1)(vi). OSHA believes it is necessary to ensure that employees know, in general, the employer's obligations under the standard with respect to employee protection. This discussion need not focus on the details of the standard's provisions but could, for example, simply inform employees that employers are obligated to develop a written program, properly select respirators, evaluate respirator use, correct deficiencies in respirator use, conduct medical evaluations, provide for the maintenance, storage, and cleaning of respirators, and retain and provide access to specific records.

Proposed paragraph (k)(1)(vi) would have required that employees be provided with information on the written respiratory protection program, as well as the location and availability of the written program and the standard. These elements are omitted from final paragraph (k)(1)(vii) because they are addressed in other provisions of the final standard. For example, employee access to the standard and written program is required under final paragraph (m)(4), and employee knowledge about the written respirator program will be imparted to employees under the training required by final paragraph (k)(1), which specifies the

elements to be included in the written respirator program.

All of the training elements are important. They are presented in performance language to give the employer flexibility to adapt the training to specific workplace conditions and to the respirators used. Unless the training information is presented in a way that employees can understand, the training will not be effective. Therefore, final paragraph (k)(2) requires that training be conducted in a way that is understandable to employees. Employers should develop training programs based upon their employees' educational level and language background. This will ensure that all employees will receive training that will enable them to maximize the effectiveness of the respirators they use. Inclusion of a provision addressing training comprehension was supported in the record (Tr. 166) and is consistent with similar requirements in other recent OSHA rulemakings (Cadmium, 29 CFR 1910.1027; Bloodborne pathogens, 29 CFR 1910.1030; Formaldehyde, 29 CFR 1910.1048).

Final paragraph (k)(3) requires the employer to provide training before the employee uses a respirator in the workplace. This provision was included under proposed paragraph (k)(2) and was widely supported by rulemaking participants (Tr. 1011, Tr. 1986; Exs. 54-91, 54-165, 54-196, 54-234, 54-267, 54-278, 54-298, 54-319, 54-334, 54-361, 54-387, 54-428, 54-455). No comments opposing this requirement were received.

Final paragraph (k)(4) provides that an employer who can demonstrate that a new employee has received training within the last 12 months that addressed the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph (k)(1), the employee can demonstrate knowledge of the element(s). Employers availing themselves of this provision must, however, provide subsequent training no later than 12 months from the date of the previous training, as required by final paragraph (k)(4).

An employee who has been trained in the use of respirators who moves to another job that involves the use of respirators may not need to take all of the initial training prescribed in paragraph (k)(4). Prior training in the topics required by the standard may remain relevant in the new work setting. Thus, OSHA is permitting limited "portability" of training, as noted in the standard. Training in the elements listed in paragraph (k)(1) that has been provided in the past 12 months by a previous employer may be taken into account by the new employer when evaluating the training needs of that new employee.

The employer must demonstrate that the employee has received the prior training and retained the necessary knowledge before the prior training can be accepted as meeting the requirements of paragraph (k). Discussions with the employee and with the previous employer may be used to determine whether the previous training has been sufficient to enable the employee to wear, use, and care for the respirator successfully. If the employer cannot demonstrate that the new employee has been trained in the required elements of the program, and understands these elements, the new employer is obligated to train the employee. In cases where training in some elements is lacking or inadequate, the employer is required by paragraph (k)(4) to provide training in those elements.

Final paragraph (k)(5) requires retraining annually and when certain situations occur. The requirement for annual training was strongly supported by management, labor, and other rulemaking participants as being necessary to ensure the continuing effectiveness of the respirator program (Exs. 15-10, 15-18, 15-19, 15-20, 15-37, 15-44, 15-47, 15-48, 15-50, 15-54, 15-55, 15-71, 54-91, 54-157, 54-165, 54-173, 54-208, 54-222, 54-245, 54-265, 54-292, 54-319, 54-332, 54-361, 54-363, 54-387, 54-424, 54-427, 54-428, 54-442, 54-455, 122, 166; Tr. 187, 443, 547, 614, 1011, 1022, 1226, 1768). For example, the Railway Labor Executive Association testified:

The training requirements as proposed should be mandated on an annual basis . . . Such a training schedule will assure continuous familiarization with the equipment and will serve to negate the inevitable effects of complacency on the part of both the employer and the employee. (Tr. 443)

Exxon stated that "Annual training is good so the employee will feel comfortable with the respirator they will be using in the future" (Tr. 547). James Johnson of Lawrence Livermore National Laboratory testified that annual training is ". . . necessary to ensure a reasonable amount of recall and performance . . ." (Tr. 187). Eastman Chemical Company (Ex. 54-245) commented that "Eastman supports [the] annual training requirement . . . our Company believes this is necessary to adequately train employees." ASARCO and U.S. Steel require that their employees who wear respirators undergo annual training, and ASARCO states in its Respiratory Protection Manual that:

All respirator wearing employees shall be given annual training on routine respirator use. . . . Applicable individuals will also be thoroughly instructed and trained annually in the use of respiratory protection and necessary procedures for non-routine or emergency situations. (Ex. 163)

The Respirator Protection Program training manual for U.S. Steel, submitted by AISI, requires that: "Each respirator wearer should be retrained at least annually. Where necessary, more frequent training should be performed. The required use of respirators should be specified in routine training aids such as Safe Job Procedures." (Ex. 142)

A number of commenters recommended that training should be required less frequently than annually (Exs. 15-41, 54-316, 54-324) or should be required only in response to a change in the respirator program (Exs. 54-168, 54-172, 54-178, 54-187, 54-213, 54-234, 54-267, 54-273, 54-275, 54-278, 54-297, 54-307, 54-316, 54-324, 54-334, 54-352, 54-389, 54-408, 54-434). Other commenters recommended more frequent (than annual) training for employees required to use SCBAs, or for employees who may be required to use respirators in emergency situations (Exs. 54-210, 54-290, 54-363, 54-410, 54-424).

OSHA believes that annual training is necessary and appropriate to ensure that employees know about the respiratory protection program and that they cooperate and actively participate in the program. Further, as specifically noted by several witnesses at the hearing, annual training is necessary so that employees will be confident when using respirators (Tr. 547, Tr. 595). Annual training will also eliminate complacency on the part of both the employer and employees with respect to respirator use (Tr. 443), and annual training will ensure a reasonable amount of recall and performance on the part of the respirator user (Tr. 187). In addition, periodic training provides an opportunity for the employee to interact with trained professionals who can provide instruction and understanding in the correct use of the respirator (Tr. 186), which will serve to overcome employee resistance to proper respirator use (Tr. 1021). OSHA also believes that employee interaction with respirator instructors on at least an annual basis will reinforce employee knowledge about the correct use of respirators and other pertinent elements of the respiratory protection program.

Commenters requesting that training be required less frequently than annually provided no substantive data demonstrating that training every two years, for example, would be sufficient for respirator users to retain information critical to the successful use of respirators on a continuing basis (Exs. 54-316, 54-324). Less frequent periodic training would tend to diminish employee attention to proper respirator use and may result in a long period of poor respirator practice before problems are identified and corrected. OSHA notes that both the ANSI Z88.2-1980 and Z88.2-1992 respiratory protection standards provide for annual retraining. Further, annual periodic training of workers with respect to the use of respirators is required in other OSHA standards (i.e., 29 CFR 1910.1001, Asbestos; 29 CFR 1910.1017, Vinyl chloride; 29 CFR 1910.1018, Arsenic; 29 CFR 1910.1025, Lead; 29 CFR 1910.1029, Coke oven emissions; 29 CFR

1910.1043, Cotton dust; 29 CFR 1910.1044, Dibromochloropropane (DBCP); 29 CFR 1910.1045, Acrylonitrile; 29 CFR 1910.1047, Ethylene oxide; and 29 CFR 1910.1048, Formaldehyde). In addition, OSHA's compliance experience has demonstrated that inadequate respirator training is a common problem (Ex. 33-5), and is often associated with respirator program deficiencies that could lead to employee exposures to workplace contaminants. Adherence to annual training will minimize respirator misuse. Thus, the Agency's experience under other rulemakings, as well as its compliance experience with the previous respiratory protection standard, serve, in part, as the basis for concluding that annual training for respirator users under this final standard is reasonable and appropriate.

As noted above, a number of commenters argued that training should be required only to inform employees about changes in the respirator program. This view suggests that regular, periodic training in the use of respirators is not necessary to ensure the success of a respirator program. However, as discussed above, evidence provided by management, labor, and other participants in this and other rulemaking records demonstrates the importance of reinforcing an employee's knowledge with respect to the use of respirators on a regular basis to ensure the successful use of respirators. Accordingly, the final standard in paragraph (k)(5) includes the requirement for annual training for respirator users. This provision ensures the successful implementation of the respiratory protection program by keeping employees thoroughly and accurately informed on a regular basis regarding the current status of the program.

Several commenters recommended that training be provided more frequently than annually to users of SCBAs and to employees who are required to use respirators during emergency situations (Exs. 54-210, 54-290, 54-363, 54-410, 54-424). OSHA agrees that retraining more frequently than annually may be appropriate for some users of SCBAs and emergency responders. This concern is addressed in final paragraph (k)(5), which contemplates such additional training in circumstances in which the employer has reason to believe that a previously trained employee does not have the understanding and skill required to use the respirator properly on a continuing basis. Although this provision is performance oriented, it requires that more frequent (than annual) periodic training be provided if necessary (e.g., because of the complexity of the respirator or exposure conditions). If respirator users must be trained more frequently than annually to retain the knowledge necessary to ensure proper use of the respirator, then the employer must provide the additional training.

Final paragraphs (k)(5)(i)-(iii) require additional training when changes in the workplace (process change, increase in exposure, new hazards) or in the type of respirator used by the employee render previous training obsolete, when the employee has not retained the requisite understanding or skill to use the respirator properly, or when any other situation arises in which retraining appears necessary. These provisions recognize circumstances that require supplemental training in addition to full annual training. For example, retraining with respect to the nature of the hazard may be necessary because of an increase in the workplace level of a hazardous substance. Retraining would also be required when an employee does not sufficiently understand any program element (Ex. 54-387). OSHA believes that the regulatory burden imposed on employers by final paragraph (k)(5) will be minimal because this paragraph only requires element-specific retraining on an as-needed basis to supplement annual training.

Final paragraph (k)(6) provides very basic protection for employees who use respirators voluntarily. As discussed, in connection with paragraph (c)(2), such employees are only covered by those provisions of this standard that are necessary to ensure that respirator use does not present a health hazard to these employees. Respirator use can create health and safety problems. For example, an employee who has chronic obstructive lung disease and who is given a negative pressure air-purifying respirator to wear may be at risk of hypertension, overexertion, and dizziness. Employees who voluntarily use some types of

respirators (e.g., air-purifying respirators) are potentially exposed to the hazards associated with respirator use. Consequently, in paragraph (k)(6), OSHA requires employers to provide employees who voluntarily use some types of respirators (e.g., air purifying respirators) with the informational material in Appendix D so that the employee will be familiar with basic respirator use procedures.

### Paragraph (l) -- Program Evaluation

Paragraph (l) requires employers to perform evaluations to determine whether the respiratory protection program is functioning effectively. Problems with protection, irritation, breathing resistance, comfort, and other respirator-related factors occasionally arise in most respiratory protection programs. Although it is not possible to eliminate all problems associated with respirator use, the employer must eliminate as many problems as possible to improve respiratory protection and encourage employee acceptance and safe use of respirators. Eliminating problems is accomplished most effectively when the respiratory protection program is evaluated thoroughly and revised as necessary. Although the previous respiratory protection standard requires that the employer perform regular checks of the effectiveness of the respiratory protection program, it provided little guidance regarding how these evaluations are to be done. The final rule, like the proposal, describes the required program evaluation with greater specificity than OSHA's previous respiratory protection standard did.

Final paragraph (c) of the respirator standard requires the employer to establish a written respiratory protection program. The program must include procedures for evaluating the effectiveness of the respirator program and must designate a program administrator who is to monitor conditions in the workplace on a regular basis to ensure that the provisions of the written respiratory protection program are being properly implemented. Final paragraph (l) specifies certain steps the employer must take as part of his/her regular evaluation of the respiratory protection program.

Paragraph (l) requires the employer to consult employees who use respirators to ascertain whether they perceive any problems with the equipment and to obtain their views on program effectiveness. This assessment must evaluate such factors as difficulty breathing or fatigue during respirator use, whether the respirator interferes with hearing and vision, communication, or job performance or restricts movement, whether the respirator causes discomfort, and whether the employee has confidence in the respirator's effectiveness. The employer must correct any problems that are revealed by the evaluation.

The record supports the need to review and evaluate workplace respirator use to ensure the continuous effectiveness of the respirator program (Exs. 54-91, 54-153, 54-181, 54-213, 54-219, 54-234, 54-244, 54-252, 54-263, 54-265, 54-54-286, 54-297, 54-330, 54-352, 54-387, 54-424, 54-428, 54-455, Tr. 387, 1012, 1714, 1733, 1998). Based on the record, however, the final program evaluation provisions were modified, as discussed below, from those proposed.

Final paragraph (l)(1) requires the employer to conduct regular evaluations of the workplace to ensure that the provisions of the written program are being properly implemented for all employees required to use respirators, and to ensure the continued effectiveness of the program. Proposed paragraph (l)(1) required the employer to review the written respiratory protection program at least annually and to conduct frequent random inspections of the workplace to ensure that the provisions of the program are being properly implemented for all employees. The review of the written program was to include an assessment of each written program element specified under proposed paragraph (c)(1) of the standard.

The final standard under paragraph (l) has deleted the proposed provisions for annual written program review of each element and "frequent random" workplace evaluations in favor of more

performance-oriented requirements. Although a number of commenters supported annual written program review (Exs. 54-91, 54-153, 54-181, 54-213, 54-244, 54-265, 54-361, 54-387, 54-424, 54-428), others asserted that program review was necessary but should only be required on an as-needed, rather than annual, basis as necessitated by workplace or user conditions or characteristics (Exs. 54-177, 54-234, 54-263, 54-286, 54-297, 54-330, 54-352, 54-402, Tr. 1733). The Chemical Manufacturers Association (CMA) (Ex. 54-263), for example, stated:

For simple programs such as a single air purifying respirator in use with a single contaminant, assessments might be necessary once every 3-5 years. For programs with numerous hazards that change repeatedly such as batch processes, reviews may be needed more frequently.

The CMA (Ex. 54-263) and Mobil Corporation (Ex. 54-234) support adoption of the ANSI Z88.2 (1992) recommendation that reads "The program shall be periodically audited to ensure that it is implemented and reflects the written procedures." Consumer Power (Ex. 54-297) argued that program review and revision should be required "as necessary to reflect changes in respirator used, training, fit test methods, and storage or maintenance of the respirator in use at the facility."

OSHA agrees with commenters that a more performance-oriented approach with respect to written program review is appropriate in lieu of an annual requirement. The Agency believes that the final standard will ensure the maintenance of an up-to-date written respirator program without imposing an arbitrary review schedule. Final paragraph (c)(1) states, in part, that the program shall be updated as necessary to reflect changes in workplace conditions and respirator use. This provision requires employers to review the written program and to revise, as necessary, the written program elements specified in paragraph (c)(1) when workplace conditions affecting the use of respirators change.

Accordingly, the final standard does not contain the proposed requirement for an annual written program review but instead requires program review and revision as necessary based on workplace changes. Evaluation frequency to ensure the continued effectiveness of the program is to be based on program complexity and on factors such as the nature and extent of workplace hazards, types of respirators in use, variability of workplace processes and operations, number of respirator users, and worker experience in the use of respirators. In other words, the employer must audit respirator use in the workplace with sufficient frequency to ensure that continuous, successful implementation of all written respirator program elements prescribed under paragraph (c) is being achieved.

As noted previously, the proposed requirement for "frequent random" workplace evaluations has been deleted in favor of a requirement for evaluations conducted on an as-necessary basis. OSHA agrees with commenters' assertions that the meaning of the term "frequent random" was unclear (Exs. 54-181, 54-334), especially with respect to conditions of infrequent or brief respirator use (Exs. 54-166, 54-177). In such instances, the commenters indicated that evaluations would have to be scheduled based on when respirators are used. The Agency believes that the final standard's evaluation procedures incorporate a flexible and reasonable approach that will meet the needs of different workplaces while ensuring continued, effective implementation of the respirator program. OSHA emphasizes that the change in language in the final standard is not intended to deemphasize the importance of conducting evaluations.

Final paragraph (l)(2) requires the employer to consult regularly with employees who wear respirators to obtain their views on the effectiveness of the program and to correct any problems that are identified. This assessment must determine if the respirators are properly fitted. It must also evaluate whether employees are able to wear the respirators without interfering with effective workplace performance, whether respirators are correctly selected for the hazards encountered, whether respirators are being worn when

necessary, and whether respirators are being maintained properly. Many commenters (Exs. 54-91, 54-153, 54-181, 54-213, 54-265, 54-361, 54-387, 54-424, 54-488) supported the proposed requirement for the employer periodically to consult with employees.

This requirement is essentially unchanged from the proposed provision. Some commenters (Exs. 54-187, 54-278) argued that the employer's obligations to consult with employees should be limited to those employees required by OSHA to wear respirators. However, as explained in detail in the Summary and Explanation for paragraphs (a) and (c), OSHA believes that all employees who are required to wear respirators should be covered by the program, regardless of whether their respirator use is required by OSHA or their employer.

Thus, final paragraph (l)(2) requires the employer to consult with employees who wear respirators when auditing the effectiveness of the respirator program. As discussed above in connection with paragraph (c), OSHA has consistently required employers who provide their employees with respirators to ensure that those respirators do not pose a health hazard (e.g., do not increase the work-of-breathing in a way that threatens health, do not impair vision or hearing). In general, assessments conducted to comply with paragraph (l) will involve a technical evaluation of whether respirators are being used properly. If respirators are not being used properly, the employer is required to correct any problems found during the assessment. The areas to be reevaluated include whether the respirator program is providing employees with properly fitting respirators and whether the appropriate respirators are being selected, used, and maintained properly.

Proposed paragraph (l)(2)(i), which would have required the employer to assess whether the program was "preventing the occurrence of illness," has been deleted from the final rule. Commenters noted that the individual performing the program evaluation under this paragraph is not likely to be a health care professional with sufficient expertise to identify illnesses caused by improper respirator use, other than skin/eye irritation, which can readily be observed by the program administrator, supervisor, employer, or employee. Commenters argued that medical determinations and evaluations are part of the review of an employee's medical status required by paragraph (e) of this section (Exs. 54-187, 54-237). OSHA agrees and, accordingly, has omitted this proposed requirement from final paragraph (l)(2). However, identification of respirator-related medical conditions, such as skin irritation, would properly be part of the program evaluation. Employees identified during the evaluation as having skin irritation can either be referred to the PLHCP or be advised by the program administrator about the need to leave the respirator use area as necessary to wash the face and facepiece, as permitted by paragraph (g). It should be noted that final paragraph (e)(7)(iii) requires medical evaluation if observations made during the program evaluation indicate that such evaluation is necessary.

#### Paragraph (m) -- Recordkeeping

The final standard requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program. The final provisions addressing these records differ in some respects from the proposed requirements. In the proposed rule, paragraph (c) contained recordkeeping provisions for the written respiratory program, paragraph (m) required retention of medical evaluation records, and fit testing records were required to be maintained under Appendix A. In the final rule, however, all recordkeeping requirements have been consolidated in paragraph (m), in response to those commenters who suggested that placing all recordkeeping provisions in one paragraph will improve understanding of the rule's recordkeeping obligations (Exs. 54-267, 54-286).

Paragraph (m)(1) of the final standard requires the employer to retain a medical evaluation record for each

employee subject to medical evaluation under final paragraph (e). Such records are to be kept and made available as required by 29 CFR 1910.1020, OSHA's Access to Employee Exposure and Medical Records rule. The record is to include the result of the medical questionnaire and, if applicable, a copy of the PLHCP's written opinion and recommendations, including the results of relevant medical examinations and tests. It is standard medical practice to make and retain written records of medical examinations and evaluations. Retention of such records will enable PLHCPs in subsequent evaluations to determine whether the employee's health has deteriorated, and will enable employees to obtain copies for their personal physician or other licensed health care professional to review as necessary.

Although the format of final paragraph (m)(1) has been simplified from that of the proposed rule, the substance of the medical evaluation records to be retained is similar. Several proposed paragraphs referred specifically to provisions in 29 CFR 1910.1020 that address the maintenance, availability, and transfer of the medical evaluation records. As recommended by several commenters, however, only one reference to 29 CFR 1910.1020 is needed for this purpose, and the final respiratory protection rule has been revised accordingly (Exs. 54-220, 54-350, 54-362, 54-455, Tr. 1054).

Final paragraph (m)(2) addresses the retention of respirator fit-testing records. The provisions of this paragraph remain basically unchanged from the requirements of Appendix A, section II. 12 of the proposal. The records specified in final paragraphs (m)(2)(i)(A) -- (E) consist of the name or identification of the person tested; the type of fit test performed (QLFT, QNFT -- irritant smoke, saccharin, etc.); the make, model, and size of the respirator fitted; the date of the fit test; pass/fail results if a QLFT is used; or the fit factor and strip chart recording or other record of the test results if quantitative fit testing was performed.

Under final paragraph (m)(2)(ii), the fit test record must be maintained until the next fit test is administered. If the employee's use of a respirator is discontinued (e.g., because of a change of duties or successful implementation of engineering controls), fit test records need not be retained for the employee. Fit test records must be maintained to determine whether annual fit testing has been done, and whether the employee who was tested passed the QLFT or passed the QNFT with a fit factor that was appropriate for the type of respirator being used. OSHA agrees with commenters (Exs. 36-6, 36-17, 36-34, 36-46, 54-165, 54-210) who stated that fit testing records must be maintained to ensure that all respirator users have received a fit test, the respirator selected by fit testing is being used, and retesting is being performed annually.

Some commenters argued that the employer should only be required to certify that fit testing has been completed, and that retaining the other proposed information would provide little additional benefit (Exs. 54-222, 54-310). OSHA disagrees with this position. The Agency believes it is essential that fit test records identify the respirator and employee being fit tested. As noted in the preceding paragraph, other commenters stated that the information in this record would be the only means of determining whether the appropriate respirator was being used by the employee. OSHA believes that the effectiveness of the respiratory protection program will be substantially improved if these records are kept. Similar recordkeeping requirements are found in many OSHA standards: 29 CFR 1910.1027, Cadmium; 29 CFR 1910.1028, Benzene; 29 CFR 1910.1048, Formaldehyde; 29 CFR 1910.1050, Methylenedianiline.

Final paragraph (m)(3) specifically requires employers to maintain a written copy of the current respiratory protection program prescribed by final paragraph (c). As discussed under paragraph (c), a written program is necessary to assure the appropriate use of respirators and the on-going effectiveness of the program.

Final paragraph (m)(4) provides that written materials required to be maintained under final paragraph (m) must be made available, upon request, to employees and to the Assistant Secretary for examination and copying. This final paragraph replaces, but is consistent with, the record availability requirement of proposed paragraph (m)(2). Employee access to these records is necessary to ensure that employees can assess and verify information describing their exposure to respiratory hazards in the workplace and the effectiveness of the respirator program in protecting them from those hazards. Access to these records by the Assistant Secretary or his or her designees is necessary to allow OSHA to monitor compliance with the standard and its effectiveness.

The access provisions in final paragraph (m)(4) are consistent with provisions found in other OSHA standards: 29 CFR 1910.1001, Asbestos; 29 CFR 1910.1027, Cadmium; 29 CFR 1910.1028, Benzene; 29 CFR 1910.1047, Ethylene Oxide; 29 CFR 1910.1048, Formaldehyde; and 20 CFR 1910.1050, Methylenedianiline.

#### Paragraph (n) -- Dates

The final Respiratory Protection standard will become effective on April 8, 1998. For most requirements of the standard, however, compliance need not be achieved until the start-up dates specified in paragraph (n) of the final rule. Unless a different start-up date is specified for a particular requirement, compliance must be achieved by the effective date.

The proposal would have required compliance with all provisions of the standard 90 days after publication of the final standard in the **Federal Register**. The Air Conditioning Contractors of America (Ex. 54-248) stated that a 90-day compliance period should be sufficient if OSHA plans to disseminate information to employers in a "user-friendly" format, but that additional time would be required if industry organizations had to analyze and distribute information on the final standard by themselves. Several commenters recommended a 6-12 month effective date for implementing the final standard (Exs. 54-248, 54-271, 54-283, 54-293, 54-309). The U.S. Enrichment Corporation (Ex. 54-283) wanted the standard phased in over a 12-month period to allow additional time for the employer to obtain respiratory protection equipment from manufacturers and to perform fit testing. The American Subcontractors Association (Ex. 54-293) stated that small contractors rely on their organization and others for education and training regarding new standards, and that a 90-day period is too short a period for transition to a new program. They specifically mentioned training, updating written programs, changing written standard operating procedures (SOPs), and medical examinations as provisions in the standard that may be difficult to comply with in a short time period. The Associated Building Contractors (Ex. 54-309) also wanted the final standard to be phased in over 12 months to allow for revising written SOPs and programs, training, and medical evaluation of respirator users. Exxon (Ex. 54-266) and the American Petroleum Institute (Ex. 54-330) stated that employers could not fit test every employee within the specified 90-day effective date and recommended that employees be fit tested within one year of the effective date of the standard.

Based on many of these comments, OSHA concludes that additional time is required for employers to comply with certain provisions of the final standard. The Agency has therefore included extended start-up dates for some of the program elements. OSHA does intend, however, to disseminate information on this standard in a "user friendly" format.

Within 150 days of the effective date of the standard, employers must determine whether respirator use is required under paragraph (a). This period will afford employers sufficient time to become familiar with the final standard and to evaluate whether respirator use is required in their workplaces.

Employers must comply with all the remaining requirements of the respirator standard no later than 180 days after the effective date of the standard. OSHA concludes that with the start-up dates provided, all employers will have adequate time to comply. Paragraph (n)(3) states that if there is an administrative or judicial delay of the standard, the respiratory protection provisions of the previous standards (i.e., 29 CFR 1910.134 and 29 CFR 1926.103) will remain in effect and will be enforced until the issues have been resolved. Many employers already have an established respiratory protection program that includes specific program elements (e.g., fit testing, annual training, medical evaluations of respirator users, and program evaluation) that comply with the requirements of the Agency's prior respirator standards. Program elements that were implemented to meet the prior respirator standards' requirements may also meet the requirements of this final respiratory protection standard. Paragraph (n)(4) states that if, in the 12 month period preceding the effective date of the revised standard, the employer has conducted annual respirator training, fit testing, respirator program evaluation, or medical evaluations, the employer may use the results of these activities to comply with the corresponding provisions of this section, provided that these activities were conducted in a manner that meets the requirements of the revised standard. For example, if the employer has an existing fit testing program in place on the effective date of the final standard, the employer may continue that fit testing program if it meets the fit testing requirements of the final standard. In such cases, employees would be retested within one year of their last fit test date. Employers, therefore, can incorporate annual fit testing, training, and program evaluation into their existing respiratory protection programs if the appropriate program elements comply with the provisions of the final standard. This approach should help reduce the impact of the final rule on employers with effective existing respirator programs.

#### Paragraph (o) -- Appendices

The final paragraph of the standard identifies four appendices that supplement the requirements specified in the regulatory text. Appendices A (Fit Testing Procedures), B-1 (User Seal Check Procedures), B-2 (Cleaning Procedures), and C (Medical Questionnaire) are mandatory, and contain requirements for performing fit testing, user seal checks, cleaning, and medical evaluations that supplement the regulatory requirements in paragraphs (e), (f), (g), and (h) of the final standard.

Appendix D (Information for Employees Using Respirators When Not Required Under The Standard) is nonmandatory.

The four appendices are discussed in detail under the Summary and Explanation sections of the corresponding paragraphs of the final standard: Appendix A in paragraph (f), "Fit Testing"; Appendix B-1 in paragraph (g), "Use of respirators"; Appendix B-2 in paragraph (h), "Maintenance and care of respirators"; Appendix C in paragraph (e), "Medical evaluation"; Appendix D in paragraph (c), "Written program" and paragraph (a), "Permissible practice."

#### Paragraph (p) -- Revisions to Specific OSHA Standards

A number of OSHA standards regulating exposure to toxic substance and harmful physical agents incorporate certain provisions of 29 CFR 1910.134. OSHA proposed to revise these provisions to simplify compliance for employers by consolidating many of the Agency's respirator requirements, removing inconsistencies, and deleting duplicative requirements. The purpose of revising the respirator-related provisions of OSHA's existing standards was to conform these standards, to the extent possible, to each other and to revised 29 CFR 1910.134 in general. These standards will be improved by this process, because they will now refer to the revised respiratory protection standard, which is based on current respirator use and technology. For example, revising the respirator-approval references in these standards

from MSHA/NIOSH, Bureau of Mines, and ANSI Z88.2-1969 to the recently published NIOSH regulation at 42 CFR Part 84 updates these respiratory protection provisions. The Agency concludes, therefore, that updating these standards is consistent with the proposed goal of bringing uniformity to OSHA's respiratory protection requirements. OSHA believes that regulatory consistency will improve compliance with the respiratory protection provisions, reduce the compliance burden on the regulated community, and, consequently, enhance the protection provided to employees who use respirators. OSHA's review of the rulemaking record shows that no commenters objected to updating the provisions of these standards to conform with the requirements of revised 29 CFR 1910.134.

The Agency also notes that 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. To the extent possible, therefore, future standards that regulate respirator use in controlling employee exposure to toxic substances and harmful physical agents will refer to provisions of the final respiratory protection standard at 29 CFR 1910.134 instead of containing their own respirator requirements. (However, these standards will continue to have any respirator requirements, *e.g.*, canister/cartridge change schedules, that are specific to the substance or agent being regulated.)

In developing the final revision, OSHA also revised the wording and/or location of some paragraphs to improve the comprehensibility and uniformity of the requirements; however, the substantive requirements of the standards addressing respirators have not been revised. Additionally, the tables in the substance-specific standards specifying parameters for respirator selection have not been republished because these tables will remain unchanged and, thus, will continue to be part of the substance-specific standards until resolution of the reserved portions of this final standard.

OSHA found that the existing substance-specific standards were especially in need of revision. 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 revisions to 29 CFR 1910.134 are sufficiently comprehensive to allow deletion of those provisions in the substance-specific standards that duplicated provisions of revised 29 CFR 1910.134. 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, therefore, that deletion of duplicative provisions from the substance-specific standards will reduce confusion among members of the regulated community and decrease the burden of compliance. It will thereby enhance compliance with the respiratory protection requirements and, consequently, improve the protection afforded to employees who use respirators to control exposure to the toxic substances and harmful physical agents regulated by these standards. The proposed revisions to the substance-specific standards were widely supported by rulemaking participants (Exs. 54-187, 54-208, 54-219, 54-220, 54-233, 54-234, 54-261, 54-263, 54-266, 54-267, 54-273, 54-283, 54-289, 54-327, 54-333, 54-363, 54-424.)

In general, for the substance-specific standards, the incorporated provisions of revised 29 CFR 1910.134 cover the following requirements: definitions (paragraph (b)); respiratory protection program (paragraph (c)); selection of respirators (paragraph (d)); fit testing (paragraph (f)); use of respirators (paragraph (g)); maintenance and care of respirators (paragraph (h)); breathing air quality and use (paragraph (i)); identification of filters, cartridges, and canisters (paragraph (j)); training and information (paragraph (k)); program evaluation (paragraph (l)); and recordkeeping (paragraph (m)). Each of these requirements was

addressed by paragraphs (b), (c), (d), (e), and (f) of the prior respiratory protection standard.

OSHA did not propose to conform the respirator provisions of its Cadmium, Benzene, Formaldehyde, 1,3-Butadiene, and Methylene chloride standards with the corresponding requirements of revised 29 CFR 1910.134. Rulemaking participants recommended that the respirator provisions of the existing Cadmium, Benzene, and Formaldehyde standards be revised to conform with those provisions of 29 CFR 1910.134 to improve regulatory consistency and uniformity (Exs. 54-194, 54-195, 54-208, 54-218, 54-275, 54-294, 54-337, 54-350, 54-387, 54-434). In view of these comments, the Agency assumes that a consensus exists among the regulated community to bring these standards (as well as the 1,3-Butadiene and Methylene chloride standards, which were issued after the close of the comment period for the respirator rulemaking) into conformity with the revised respiratory protection standard. Accordingly, these standards have been revised in the same manner as the other substance-specific standards for which OSHA proposed revisions.

In revising the fit-testing provisions (paragraph (f)) of the substance-specific standards, the frequency of respirator fit testing was revised from semiannually to annually for the Asbestos (29 CFR 1910.1001 and 1926.1101), Arsenic (29 CFR 1910.1018), Lead (29 CFR 1910.1025 and 1926.62) and Acrylonitrile (29 CFR 1910.1045) standards. The Agency believes that this revision will not diminish the effectiveness of respiratory protection provided by these standards. OSHA's experience in recent rulemakings (Cadmium, 1992; Methylenedianiline, 1992; Formaldehyde, 1992; Methylene chloride, 1997) has led the Agency to conclude that annual respirator fit testing, which is provided for in the recent standards, protects employees appropriately, and that semi-annual fit testing is not necessary for employee protection. The basis for adopting a semiannual fit-testing requirement is not discussed in the preambles to any of the standards that contain that requirement. For example, there is no discussion in the preambles of those standards that semiannual fit testing was adopted because of the toxic properties of the regulated substances or the particular characteristics of the respirators to be used.

Recent rulemakings, including proposed revisions to the respiratory protection standard, have provided the Agency with much more scientific and experiential information on fit testing than was available when the affected standards were adopted. A number of commenters in the current rulemaking asserted that provisions for semiannual fit testing in the existing Asbestos, Arsenic, Lead, and Acrylonitrile standards should be revised to conform to the annual fit testing requirements of the recently-adopted standards (Exs. 54-5, 54-179, 54-186, 54-208, 54-218, 54-219, 54-222, 54-242, 54-289, 54-326, 54-330, 54-348, 54-410, 54-424, 54-439, 54-443.) The Agency, therefore, concludes that it is reasonable and appropriate, for the purpose of regulatory consistency and uniformity, to require only annual respirator fit testing in its substance-specific standards.

While the proposal did not incorporate revised paragraph (m) (recordkeeping) into the existing substance-specific standards, OSHA incorporated this paragraph in the final rulemaking in the belief that such action: (1) Will make recordkeeping requirements consistent and uniform for employers who use respirators to control employee exposures to the airborne contaminants regulated by the substance-specific standards; (2) will reduce the regulatory burden on employers because they are currently required under 29 CFR 1910.1020 to maintain exposure and medical records; and, (3) it is a prevailing business and industrial-hygiene practice to retain fit-testing records to demonstrate that protection was provided to exposed employees.

For the 13 carcinogens addressed by existing 29 CFR 1910.1003 (the "13 Carcinogens standard"), the provision requiring employers to ensure that employees use respirators "in accordance with 29 CFR 1910.134" was amended to require compliance with paragraphs (b), (c), (d) (except (d)(1) (iii), (iv), and

(d)(3)), and (e)-(m) of the final standard. While the proposal did not incorporate revised paragraph (e) (medical evaluation) into the 13 Carcinogens standard, OSHA did so in the final rulemaking because such incorporation is consistent with the requirements of existing 29 CFR 1910.134, conforms to accepted industry practice, and improves comprehension of, and compliance with, the respiratory protection requirements of the 13 Carcinogens standard.

Unlike 29 CFR 1910.1003, each of the existing substance-specific OSHA standards includes unique medical-evaluation requirements for employees who use respirators. OSHA believes that the medical-evaluation requirements for respirator use established under its existing substance-specific standards provide a high degree of medical protection to employees who are required to use respirators to control their exposures to the airborne substances regulated by the substance-specific standards. In addition, the medical-evaluation requirements for respirator use in the substance-specific standards are part of a comprehensive, integrated medical-surveillance program designed to evaluate employees for conditions and risks associated with exposure to the regulated substances; consequently, OSHA believes that any revision to the frequency or content of medical evaluations for respirator use would unnecessarily disrupt ongoing medical-surveillance programs and, therefore, jeopardize the health of employees who must use respirators to prevent exposure to hazardous workplace substances.

Paragraph (d)(1)(iii) of the revised respiratory protection standard, which requires employers to estimate exposure levels in selecting appropriate respirators, has not been incorporated into OSHA's substance-specific standards in the final rulemaking. The existing substance-specific standards, except the 13 Carcinogens standard, already include exposure assessment provisions that are more specific than the general exposure-assessment requirement in the final respiratory protection standard. With respect to the 13 Carcinogens standard, no PELs or other exposure criteria are specified in that standard that would be relevant to respirator selection. In the 13 Carcinogens standard, exposure estimates for the substances regulated by the standard are not necessary for respirator selection because appropriate respirators have been identified for specific work activities that occur during employee exposure to each of the 13 carcinogenic substances.

OSHA excepted substance-specific standards that already contain requirements for cartridge- and canister-change schedules (Vinyl chloride, Benzene, Acrylonitrile, Formaldehyde, and 1,3-Butadiene) from paragraphs (d)(3)(iii)(B) (1) and (2) of the revised respiratory protection standard, which also addresses change schedules, to preclude regulatory conflict. The Agency finds that information obtained during the rulemakings for these substance-specific standards resulted in the development of change schedules that were especially tailored to the chemistry of the specific substance, documented the exposure conditions requiring these schedules, and determined the types of respirators required for employee protection. Consequently, the Agency concludes that the change schedules adopted during these rulemakings must not be replaced by the generic change-schedule requirements of revised 29 CFR 1910.134.

As proposed, the Agency also removed a number of appendices from the substance-specific standards that addressed fit-testing requirements, replacing them with references to Appendix A of revised 29 CFR 1910.134. In this regard, the Agency proposed to update Section IV of Appendix B of 29 CFR 1910.1025 (the Lead standard) by citing Appendix A of 29 CFR 1910.134 as the reference for fit-testing procedures; the proposed revision has been made in the final rulemaking. While not proposed, the Agency revised the same information in Appendix B of 29 CFR 1926.62 (the Lead standard for Construction), removed the sixth paragraph from Section IV of Appendix B of 29 CFR 1910.1025 and 1926.62 as being outdated, and revised references for respirator approval in Section IV of Appendix B of 29 CFR 1910.1025, Section IV

of Appendix A to 29 CFR 1910.1045 (the Acrylonitrile standard), Section IV of Appendix A to 29 CFR 1910.1047 (the Ethylene Oxide standard), Section III of Appendix A to 29 CFR 1910.1050 (the 4,4'-Methylenedianiline standard), and Section IV of Appendix B to 29 CFR 1926.62, Lead in Construction. The Agency believes that these revisions will conform the affected standards with the provisions of the revised respiratory protection standard; the resulting consistency will, therefore, reduce confusion and ease compliance.

The following provisions, addressing fit-testing, respirator selection, and respirator use, have been deleted from OSHA's substance-specific standards because they duplicate requirements specified in revised 29 CFR 1910.134:

(1) ***Fit Testing***

This requirement is specified in paragraph (f) of the revised respiratory protection standard, allowing for the removal of the following paragraphs:

(a) 29 CFR 1910.1001 Asbestos.

(g)(4) and Appendix C

(b) 29 CFR 1910.1018 Inorganic arsenic.

(h)(3) (i), (ii), and (iii)

(c) 29 CFR 1910.1025 Lead.

(f)(3) (i) and (ii), and Appendix D; Section IV of Appendix B, revised in part

(d) 29 CFR 1910.1027 Cadmium.

(g)(4) and Appendix C

(e) 29 CFR 1910.1028 Benzene.

(g)(5) and Appendix E

(f) 29 CFR 1910.1045 Acrylonitrile.

(h)(3)(iii)

(g) 1910.1048 Formaldehyde.

(g)(3)(ii) and Appendix E

(h) 29 CFR 1910.1050 Methylenedianiline.

(h)(5) and Appendix E

(i) 29 CFR 1910.1051 1,3-Butadiene.

(h)(5) and Appendix E

(j) 29 CFR 1910.1052 Methylene chloride.

(g)(7)

(k) 29 CFR 1926.60 Methylenedianiline.

(i)(5) and Appendix E

(l) 29 CFR 1926.62 Lead.

(f)(3) (i) and (ii), and Appendix D; Section IV of Appendix B

revised in part

(m) 29 CFR 1926.1101 Asbestos.

(h)(4) and Appendix C

(n) 29 CFR 1926.1127 Cadmium.

(g)(4) and Appendix C

***(2) Respirator-Approval Requirements that Reference MSHA or NIOSH 30 CFR Part 11***

The requirement to select respirators approved by NIOSH in 42 CFR part 84 is specified in paragraph (d)(1)(ii) of the revised respiratory protection standard. This requirement updates the existing respirator-approval requirement in the substance-specific standards to select respirators approved by MSHA or NIOSH under 30 CFR part 11, allowing for removal of the following paragraphs:

(a) 29 CFR 1910.1001 Asbestos.

(g)(2)(i) [part]

(b) 29 CFR 1910.1017 Vinyl chloride.

(g)(2)

(c) 29 CFR 1910.1018 Inorganic arsenic.

(h)(2)(iii)

(d) 29 CFR 1910.1025 Lead.

(f)(2)(iii); Section IV of Appendix B revised in part

(e) 29 CFR 1910.1027 Cadmium.

(g)(2)(i) [part]

(f) 29 CFR 1910.1028 Benzene

(g)(2)(ii)

(g) 29 CFR 1910.1029 Coke oven emissions.

(g)(2)(iii)

(h) 29 CFR 1910.1044 1,2-Dibromo-3-chloropropane.

(h)(2)(ii)

(i) 29 CFR 1910.1045 Acrylonitrile.

(h)(2)(ii); Section IV of Appendix A revised in part

(j) 29 CFR 1910.1047 Ethylene oxide.

(g)(2)(ii); Section IV of Appendix A revised in part

(k) 29 CFR 1910.1048 Formaldehyde.

(g)(2)(i) [part]

(l) 29 CFR 1910.1050 Methylenedianiline.

(h)(2)(ii); Section III of Appendix A revised in part

(m) 29 CFR 1910.1051 1,3-Butadiene.

(h)(2)(ii) [part]

(n) 29 CFR 1910.1052 Methylene chloride.

(g)(3) [part]

(o) 29 CFR 1926.60 Methylenedianiline.

(i)(2)(ii)

(p) 29 CFR 1926.62 Lead.

(f)(2)(iii); Section IV of Appendix B revised in part

(q) 29 CFR 1926.1101 Asbestos.

(h)(2)(ii)

(r) 29 CFR 1926.1127 Cadmium.

(g)(2)(i) [part]

### (3) *Respirator Use*

Paragraph (g) of the revised respiratory protection standard addresses, in part, facepiece seal protection (paragraph (g)(1)), and employees leaving the work area to wash their faces and respirator facepieces (paragraph (g)(2)(ii)(A)) and to change filter elements (paragraph (g)(2)(ii) (B) and (C)), allowing removal of the following paragraphs:

(a) 29 CFR 1910.1001 Asbestos.

(g)(3) (ii) and (iii)

(b) 29 CFR 1910.1018 Inorganic arsenic.

(h)(4) (ii) and (iii)

(c) 29 CFR 1910.1025 Lead.

(f)(4) (ii) and (iii)

(d) 29 CFR 1910.1027 Cadmium.

(g)(3) (ii) and (iii)

(e) 29 CFR 1910.1028 Benzene.

(g)(4)(iii)

(f) 29 CFR 1910.1029 Coke oven emissions.

(g)(4)

(g) 29 CFR 1910.1043 Cotton dust.

(f)(4)

(h) 29 CFR 1910.1044 1,2-Dibromo-3-chloropropane.

(h)(3)(ii)

(i) 29 CFR 1910.1045 Acrylonitrile.

(h)(3)(iv)

(j) 29 CFR 1910.1048 Formaldehyde.

(g)(3)(v)

(k) 29 CFR 1910.1050 Methylene dianiline.

(h)(4)(ii)

(l) 29 CFR 1910.1051 1,3-Butadiene.

(h)(4)(v)

(m) 29 CFR 1910.1052 Methylene chloride.

(g)(5)

(n) 29 CFR 1926.60 Methylene dianiline.

(i)(4)(ii)

(o) 29 CFR 1926.62 Lead.

(f)(4) (ii) and (iii)

(p) 1926.1101 Asbestos.

(h)(3) (ii) and (iii)

(q) 29 CFR 19126.1127 Cadmium.

(g)(3) (ii) and (iii)

The full text, after deletions and revisions, of the paragraphs dealing with respirators that remain in each of OSHA's existing substance specific standards has been published in Section XI of this preamble.

The provisions of the respiratory protection standard found in 29 CFR part 1926 (Construction), specifically 29 CFR 1926.103, are now identical to the new 29 CFR 1910.134. Following its policy of not repeating identical health provisions in order to reduce paperwork burden and to avoid regulatory confusion, OSHA is deleting the duplicate text in 29 CFR 1926.103 and cross-referencing the text in 29 CFR 1910.134. To implement this action, the title of this section remains, but a Note is added to read: "Note: The requirements applicable to construction work under this section are identical to those set forth at 29 CFR 1910.134 of this chapter." For the convenience of the Construction industry, OSHA makes available an indexed manual that includes the full text of all regulations applicable to construction, including OSHA's respirator requirements.

OSHA is also revising or removing a number of provisions in addition to safety and health standards, other than the substance-specific standards, that duplicate provisions now found in the revised respiratory protection standard. These standards and their revisions include:

(1) 29 CFR 1910.94 Ventilation.

(a)(1)(i) -- Removed the phrase "continuous flow" from the definition of abrasive-blasting respirator consistent with the proposed requirement to select respirators in accordance with 29 CFR 1910.134.

(a)(5)(i) -- Revised the reference from "30 CFR part 11" to "42 CFR Part 84."

(a)(5)(iii) -- Provided the reference "42 CFR Part 84."

(a)(5)(iv) -- Revised the reference from "Sec. 1910.134 (a) and (b)" to "Sec. 1910.134."

(a)(6) -- Revised the air-requirement reference for abrasive-blasting respirators from "ANSI Z9.2-1960" to "29 CFR 1910.134(i)."

(c)(6)(iii)(a) -- Revised the reference from "MSHA/NIOSH/ANSI Z-88.2-1969" to "NIOSH under 42 CFR Part 84."

(d)(9)(vi) -- Revised the reference from "MSHA/NIOSH" to "NIOSH under 42 CFR Part 84."

(2) 29 CFR 1910.111 Storage and handling of anhydrous ammonia.

(a)(2)(x) -- Revised the reference from "MSHA" to "the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84."

(b)(10)(ii) -- Revised the reference from "Bureau of Mines" to "NIOSH under 42 CFR Part 84."

(3) 29 CFR 1910.156 Fire brigades.

(f)(1)(i) and (v) -- Revised the reference from "MSHA/NIOSH" to "NIOSH under 42 CFR Part 84."

(4) 29 CFR 1910.252 General requirements.

(c)(4)(ii) and (iii), (c)(7)(iii), (c)(9)(i), and (c)(10) -- Revised the references from "MSHA/NIOSH" to "National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84" and "NIOSH under 42 CFR Part 84."

(5) 29 CFR 1910.261 Pulp, paper, and paperboard mills.

(b)(2) and (g)(10) -- Revised the reference from "ANSI Z88.2-1969" to "29 CFR 1910.134."

(h)(2)(iii) and (iv) -- Revised the reference from "ANSI Z-88.2-1969 and K-13.1-1967" to "29 CFR 1910.134."

(6) 29 CFR 1926.57 Ventilation.

(f)(1)(ii) -- Removed the phrase "continuous flow" from the definition of abrasive-blasting respirator consistent with the proposed requirement to select respirators in accordance with 29 CFR 1910.134.

(f)(5)(i) -- Revised the reference from "30 CFR Part 11" to "42 CFR Part 84."

(f)(5)(iii) -- Provided the reference "42 CFR Part 84."

(f)(6) -- Revised the air-requirement reference for abrasive-blasting respirators from "ANSI Z9.2-1960" to "29 CFR 1910.134(i)."

(h)(6)(iii)(A) -- Revised the reference from "MSHA/NIOSH/ANSI Z-88.2-1969" to "NIOSH under 42 CFR Part 84."

(i)(9)(vi) -- Revised the reference from "MSHA/NIOSH" to "NIOSH under 42 CFR Part 84."

(7) 29 CFR 1926.103 Respiratory protection.

Removed paragraphs (a) through (i) and replaced them with a note to read as follows:

**Note:** The requirements applicable to construction work under this section are identical to those set forth at Sec. 1910.134 of this chapter.

(8) 29 CFR 1926.800 Underground construction.

(g)(2) -- Revised the reference from "MSHA/NIOSH" to "the National Institute for Occupational Safety and Health under 42 CFR Part 84," and from "Sec. 1926.103 (b) and (c)" to "29 CFR 1926.103."

## Appendices

The four appendices are discussed in detail under the Summary and Explanation sections for the following paragraphs of the final standard: Appendix A in paragraph (f), "Fit Testing"; Appendix B-1 in paragraph (g), "Use of respirators"; Appendix B-2 in paragraph (h), "Maintenance and care of respirators"; Appendix C in paragraph (e), "Medical evaluation"; Appendix D in paragraphs (c), "Written program" and paragraph (a), "Permissible practice."

[63 FR 1152, January 8, 1998]

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