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 ILDH 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 showin 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 µm, 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 µm, 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, 54–154, 54–197, 54–205, 54–206, 54–208, 54–209, 54–213, 54–14, 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 requirement 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° F (23° C) and 104° F (40° 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 NIOSH 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, § 1910.1027; 1–3 Butadiene, § 1910.1051; Methylene Chloride, § 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 (Methylenedianaline); 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 smaoke 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 reseat 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 reseats itself. If the respirator fails to reseat 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, § 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 § 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.