effectiveness of these regulations after issuance will be based upon comments received from offices within Treasury and the Internal Revenue Service, other governmental agencies, and the public.

Non-Application of Executive Order 12291

The Treasury Department has determined that this regulation is not subject to review under Executive Order 12291 or the Treasury and OMB implementation of the Order dated April 28, 1982.

Regulatory Flexibility Act

No general notice of proposed rulemaking is required by 5 U.S.C. 553(b) for interpretative regulations. Accordingly, the Regulatory Flexibility Act does not apply and no Regulatory Flexibility Analysis is required for this rule.

Drafting Information

The principal author of this regulation is Susan K. Thompson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both substantively and stylistically.

List of Subjects in 26 CFR Parts 1.61–1–1.281–4

Income taxes, Taxable income, Exemptions, Deductions, Industrial development bonds.

Adoption of Amendments to the Regulations

Accordingly, the proposed amendments to 26 CFR Part 1, as set forth in the notice of proposed rulemaking published in the **Federal Register** on February 24, 1982 (45 FR 8029), are hereby adopted without change.

This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

David G. Glickman,

Deputy Assistant Secretary of the Treasury.

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph (e)(2)(ii) of § 1.103–8 is amended by adding a new subparagraph (*d*) immediately following subparagraph (*c*), and paragraph (e)(4) is amended by removing Example (3) and adding new Examples (3) and (4) in its place. These added provisions read as follows:

§ 1.103–8 Interest on bonds to finance certain exempt facilities.

* * * * *

(e) *Certain transportation facilities.* * * *

(2) *Definitions.* * * *

(ii) * * *

(*d*) A hotel located at or adjacent to an airport satisfies the requirements of paragraph (e)(2)(ii)(*b*), that is, it is of a character and size commensurate with the character and size of the airport at or adjacent to which it is located, if the number of guest rooms in the hotel is reasonable for the size of the airport, taking into account the current and projected passenger usage of the terminal facility. If the hotel contains meeting rooms, the number and size of these rooms must be in reasonable proportion to the number of guest rooms in the hotel. Limited recreational facilities will not prevent the hotel from being of a character and size commensurate with the character and size of the airport.

* * * * *

(4) *Examples.* * * *

Example 3. On June 1, 1982, M Airport Authority, a political subdivision of State O, issues obligations, the proceeds of which are loaned to X Corporation, a nonexempt person. X uses the proceeds to construct a hotel adjacent to the main terminal building at M Airport. X will be unconditionally liable for repayment of the proposed obligations. The hotel will be used to provide temporary and overnight accommodations for airline passengers using M Airport. The number of rooms in the hotel is reasonable for an airport of M's size, taking into account the current and projected passenger usage of the terminal facility. In addition to guest rooms, the hotel will contain a restaurant, small retail stores (such as a gift shop and newstand), and limited recreation facilities (such as a swimming pool). The hotel will also contain several multipurpose rooms suitable for use as meeting rooms. The number and size of these rooms will be in reasonable proportion to the number and size of the guest rooms in the hotel. Use of the guest rooms, restaurant and stores, recreational facilities, and meeting rooms by air passengers arriving at or departing from M Airport will be incidental to the use of the hotel by air passengers for temporary and overnight accommodations. The hotel is of a character and size commensurate with the character and size of M Airport. Consequently, applying the provisions of § 1.103–8(e)(2), the hotel is functionally related and subordinate to M Airport. The obligations are industrial development bonds. Section 103(b)(1) does not apply to the obligations, however, unless the provisions of section 103(b)(10) and § 1.103–11 apply.

Example 4. On June 1, 1982, N Airport Authority, a political subdivision of State P, issues obligations the proceeds of which are loaned to Y Corporation, a nonexempt person. Y uses the proceeds to construct a hotel adjacent to the main terminal building at N Airport. Y Corporation will be unconditionally liable for repayment of the proposed obligations. The hotel will contain extensive recreational facilities, including a large roof-top swimming pool, tennis courts, and a health club. In addition, facilities for conferences consisting of a ballroom-sized meeting room capable of being partitioned by movable panels and several smaller meeting rooms will be constructed. The number of rooms in the hotel will substantially exceed the number which is reasonable based on the current and projected passenger usage of the terminal facility. Because of the presence of extensive recreational and conference facilities, as well as the presence of on excessive number of rooms at the hotel, the hotel fails to be of a character and size commensurate with the character and size of N Airport. The result would be the same if the hotel did not have extensive recreational facilities. Consequently, the hotel is not functionally related and subordinate to N Airport under § 1.103–8(e)(2). The obligations are industrial development bonds and interest thereon is not excluded from gross income by reason of subsection (a)(1) or (b)(4) of section 103.

* * * * *

[FR Doc. 82–31104 Filed 11–10–82; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–049A]

Occupational Exposure to Lead: Respirator Fit Testing

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

ACTION: Final rule.

SUMMARY: OSHA is amending 29 CFR 1910.1025(f)(3) pertaining to the fit testing of respirators for lead-exposed employees. This amendment allows employers to choose between quantitative fit testing or one of three qualitative fit test protocols—isoamyl acetate, saccharin solution aerosol, or irritant fume—to select appropriate and effective negative pressure half-mask respirators for lead-exposed employees. The amendment will permit greater flexibility for employers and employees without sacrificing employee health.

DATE: This amendment is effective on November 12, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, Occupational Safety and Health Administration, Rm. N–3637,

200 Constitution Avenue, NW., Washington, D.C. 20210; telephone 202–523–8151.

SUPPLEMENTARY INFORMATION:

A. Background

On November 14, 1978, the Occupational Safety and Health Administration (OSHA) promulgated a standard regulating occupational exposure to lead (43 FR 52052) pursuant to section 6(b) of the Occupational Safety and Health Act. The standard, 29 CFR 1910.1025, requires employers to provide employees with respirators where engineering and work practice controls do not reduce employee exposures below the permissible exposure limit of 50 $\mu g/m^3$ (micrograms of lead per cubic meter of air). Respirators are a primary means of protecting employees under the rule because the engineering controls and work practice requirement is phased in over periods extending up to ten years.

In order to help assure that respirators will provide employees with the necessary protection, the standard requires employers periodically to perform quantitative fit tests (QNFT) on all users of negative pressure respirators. Briefly, a quantitative fit test is a method for numerically measuring any leakage of the seal between the respirator facepiece and the wearer's face. The fit test is used to determine if the respirator assigned to the employee provides the protection factor specified in the respirator selection table of 29 CFR 1910.1025(f)(2)(i). A qualitative fit test (QLFT) assesses the adequacy of respirator fit by determining whether or not an individual wearing the respirator can detect the odor, taste, or irritation of a contaminant introduced into the vicinity of the wearer's head. If the contaminant is subjectively detected, the respirator fit is considered to be inadequate. The Agency decided to require QNFT rather than QLFT based on its conclusion that the former is more accurate than the latter.

In February, 1980, the Minnesota Mining and Manufacturing Company (3M) petitioned OSHA to reconsider or modify this provision, and to stay its enforcement pending reconsideration. The Agency denied both requests on May 16, 1980. In June, 1980, 3M filed suit in the U.S. Court of Appeals for the District of Columbia Circuit (No. 80–1608) asking the court to review and set aside the OSHA decision of May 16. Subsequently, this court proceeding was held in abeyance pending the resolution of this rulemaking.

Because of new information contained in petitions received by the Agency that improved forms of QLFT may be an effective and less burdensome alternative to QNFT, OSHA decided to propose an interim rule permitting the use of specified forms of qualitative fit testing under the lead standard (46 FR 27358, May 19, 1981). The proposal characterized the rule as "interim" because the Agency is undertaking a complete review of its respirator standard (29 CFR 1910.134).

Interested members of the public were encouraged to submit written comments on this proposal by July 6, 1981. On July 10, 1981 (46 FR 35683), OSHA extended the comment period to August 4, 1981. On August 11, 1981 (46 FR 40704), OSHA announced the scheduling of informal public hearings to receive additional testimony. The hearings were held in Washington, D.C. on September 22–23, 1981, and the hearing participants were allowed until November 9, 1981 to submit additional evidence and December 18, 1981, to submit summary briefs.

On August 20, 1982, OSHA reopened the record to admit additional new data from validation measurements of the saccharin protocol performed by Los Alamos National Laboratory (LANL) and to allow comments on the LANL data as well as other appropriate comments to be made (47 FR 36448). The comment period closed on September 20, 1982. Nine submissions were received.

In this proceeding, OSHA has considered only the narrow issue of whether or not to accept the proposed QLFT methods, or other methods, and the specific protocols associated with them in the context of the lead standard.

B. Effectiveness of QLFT Versus QNFT for Lead-Exposed Employees

The central issue in the proceeding was whether, and under what conditions, specific forms of QLFT can provide the same assurance of employee health protection as QNFT in the fit testing of negative pressure respirators for lead exposed employees. OSHA's evaluation of the evidence submitted in this rulemaking indicates that QLFT can provide the same assurance of employee health protection as QNFT in instances where protection factors up to 10 are required, and when specific protocols are followed for half-mask respirators.

Generally, the use of QLFT received widespread support when used for employees exposed to atmospheric lead concentrations not more than ten times (10x) the PEL (Tr. 17–18, 89, 147, 275, 340). The American National Standards Institute (ANSI), a private, nonprofit federation of standards developing organizations and standards users, has approved a standard entitled "Practices for Respiratory Protection" (ANSI Z88.2–1980) which permits qualitative fit-testing of respirators. This ANSI standard was adopted in 1980, and thus was not available to OSHA in 1978 when the Agency decided to require QNFT for lead-exposed employees. Measurement of fit is a relatively recent development, and was not substantively addressed in the previous ANSI respirator standard which was available when the lead standard was promulgated. ANSI approval of standards is intended to verify that the principles of openness and due process have been followed in the approval procedure, and that a consensus of those directly and materially affected by the standards has been achieved.

Section 6.11 of the ANSI standard states that "the results of qualitative or quantitative respirator-fitting tests shall be used to select specific types, makes, and models of negative-pressure respirators for use by individual respirator wearers." Appendix A5 of the Z88.2 standard contains suggested protocols for QLFT. Included in Appendix A5 are protocols for QLFT using irritant smoke (A5.1) and odorous vapor (A5.2).

Dr. Richard Boggs of Organization Resources Counselors (ORC) noted that "Qualitative fit testing done according to the (proposed) protocol * * * should assure that each employee will receive a respirator that is as comfortable as possible, and gives a high degree of protection" (Tr. 340).

Mr. William Revoir stated that, "OSHA should permit employers to use either qualitative fit testing or quantitative fit testing in selecting specific makes and models of negative pressure type respirators for assignment ot particular employees". "Both methods", he said, "are safe to use provided that they are carefully carried out under proper conditions using procedures that have been validated by comprehensive testing" (Tr. 275).

Dupont also expressed support for allowing qualitative fit testing to be used when protocols are followed to assure adequate fit. As it stated in a written submission, "Since the qualitative protocols achieve the minimum requirements on fit testing specified by the lead standard, OSHA should permit their use, allowing the employer to determine the most cost effective means of compliance" (Ex. 53).

LANL evaluated the saccharin fit testing procedure and also endorsed the use of QLFT with established protocols as an effective substitute for QNFT. Marsh (LANL Ex. 58) stated that, "The

saccharin qualitative fitting test was found to effectively reject half-mask respirators with measured fit factors of less than ten."

In addition, Alan Hack (Ex. 22) testified that he believed that a properly conducted QLFT would assure a protection factor of 10 for half-masks.

Opposing this view, however, were several participants, including the United Steelworkers of America (USW) and the International Brotherhood of Painters and Allied Trades (IBPAT). Mr. Patt of IBPAT testified that, "We maintain that the current proposal represents human experiments with the lead standard, that it's utterly inappropriate to apply improperly tested qualitative fit test methods in a demonstrated high risk situation first" (Tr. 386), and that, "The qualitative fit test validation data presented today is inadequate for an acceptable probability of respirator tests" (Tr. 377). Dr. Hitcho of USW stated that, "Because of the limitation in testing procedures, where the employer does not know the actual concentrations being generated and because a subjective determination by the wearer still must be made as to whether there is any leakage, there is no way to know the actual protection factor with certainty. Therefore, unlike quantitative fit tests, you run a much greater risk of fitting an employee with a respirator that will not provide the proper protection"(Tr. 255–56).

In a later USW submission, although still expressing opposition to QLFT, Mary-Win O'Brien stated (Ex. 61–6), "On the false negative question, as long as any standard sets an upper limit of 5 to 10 on the PF allowed with the QLFT and if a recheck is required if blood lead levels or air leads go up, employees could be protected." The additional rechecking suggested by Ms. O'Brien goes beyond the scope of this rulemaking. However, it has as much relevance to QNFT as to QLFT. Therefore, OSHA understands the latest USW submissions to acknowledge the validity of QLFT as an alternative to QNFT.

IBPAT's principal concerns were that: (1) The qualitative fit test protocols were inadequate as proposed (Tr. 387); (2) the subjective nature of QLFT puts the employee under pressure to select a respirator without sufficient opportunity to test for fit or comfort (Tr. 392); and (3) QNFT is a preferable means of fit testing and does not entail expenses in excess of QLFT sufficient to justify the use of QLFT for lead-exposed employees (Tr. 384).

OSHA partially agrees with IBPAT's first point that the QLFT protocols as proposed are inadequate and has required appropriate improvements in them for this rule. However, OSHA concludes that the evidence in the record does support the safety of QLFT provided that the assigned protection factors are not exceeded and provided the protocols are adhered to. These issues are discussed further in the sections of the preamble specific for each protocol.

Addressing IBPAT's second concern, based on evidence in the record (Tr. 91–92, 107–08, 136, 281–82) OSHA concludes that the problems associated with perceived employer pressure, peer pressure, or false reporting by test subjects should be alleviated by certain changes in the proposed protocols, such as providing a broad selection of respirators and allowing a two-week trial period. Mr. Revoir (Norton Company, ANSI Z88.2 committee) stated that "OSHA should be congratulated for proposing this (employee selection of respirators) provision as part of a respirator fitting protocol. A respirator which is comfortable to wear not only may be likely to provide a good fit on a person, but also * * * will undoubtedly encourage the person to wear the respirator whenever exposed to a harmful atmosphere in the workplace" (Tr. 280–81). Mr. Manley (DuPont) further cited proper training as being an effective means of ensuring employee cooperation for fit testing (Tr. 136).

IBPAT's third concern, the comparative costs of QLFT versus QNFT, is discussed in the Regulatory Impact Assessment section of this preamble. OSHA found that allowing QLFT could result in meaningful cost savings.

The USW was also concerned that respirators in actual use—whether fitted quantitatively or qualitatively—do not provide adequate protection for workers, and asked that OSHA review the respirator provisions of all standards. OSHA recognizes that some problems in the use of respiratory protection against toxic atmospheres do exist, but found in promulgating the 1978 lead standard that full compliance with the PEL through engineering controls alone would not be technologically feasible for a number of industries for periods ranging up to ten years (43 FR 52977–52985, 53008). Recognizing that respirators are currently necessary for compliance, OSHA believes that the problems with in-use leakage are best handled through careful assignment of appropriate fit factors.

After considering all the evidence submitted, OSHA has concluded that QLFT can provide health protection equivalent to QNFT for lead-exposed employees where protection factors of ten or less are required, and where the specific protocols that have been verified through testing are followed. OSHA has based its conclusion primarily upon the specific test data which has been submitted to the record by the Los Alamos National Laboratory, 3M, Dupont, and others. The weight of the evidence supplied by these parties supports the Agency's conclusion. Furthermore, none of the parties objecting to the use of QLFT where protection factors of ten or less are required have submitted specific test data to justify their objections.

C. Qualitative Fit Test Protocols

As stated in the proposal, OSHA believes that QLFT must meet certain requirements in order to provide adequate respiratory protection for employees (46 FR 27359). In the final standard, these requirements have been detailed in specific qualitative fit test protocols for each type of QLFT under consideration. The standardization of these protocols is essential to a successful QLFT. Following specific procedures each time QLFT is done will help control the variables of these sensitive tests, ensure their reproducibility, and thus provide workers with the respiratory protection they need.

Only those protocols specified in the final rule have been adequately tested and therefore verified as being appropriate procedures. At this time, OSHA cannot ensure protection of employees by allowing employers to use other procedures which have not been so validated. All of the participants in the rulemaking have been given the opportunity to comment on the specific protocols or to suggest new ones. The consensus appears to endorse the use of specific protocols as necessary, and that those proposed, with minor modifications, are appropriate. The final standard's provisions reflect this consensus.

OSHA has reviewed the record and, in particular, the data submitted by organizations which had conducted tests on the three protocols under consideration (i.e., saccharin, isoamyl acetate, and irritant smoke). Much of this data was recently collected, and was not available to OSHA during the lead rulemaking. All tests described in the submissions, when conducted according to the protocols required by this rule, produced data showing that respirators with fit factors of less than 10 were invariably detected by all three types of QLFT and that, in most cases, fit factors of less than 100 were detected.

In a statistical analysis of data submitted for all three protocols, NIOSH (Ex. 52) argues that, based on confidence intervals associated with the estimate of the probability that the protocol would pass a respirator with a fit factor of less than 10, the percentage of wearers with unacceptable leakages would be excessive. This argument however, is based on data which show no false passes at fit factors of 10 or below for any of the three protocols. The basic point made by NIOSH is that, even with a most probable value of zero for false passes, the associated 95 percent confidence interval makes possible on unacceptable number of false passes, albeit at lower probability. OSHA recognizes this possibility. However, this situation is due mainly to the large size of the 95 percent confidence interval which, in turn, results from the small size of the data sets. The same situation will exist with QNFT. OSHA believes that there is insufficient information in the record upon which to establish a clear distinction between QNFT and QLFT on the basis of statistical analysis of data. However, it is important to note that such a distinction is irrelevant since the superiority of QNFT over QLFT is not at issue in this rulemaking. What is at issue is whether QLFT can itself provide an adequate level of protection for exposures up to ten times the PEL. In view of the data now in the record, and the arguments accompanying those data, OSHA has determined that QLFT can, in fact, provide the required protection.

Although all of the studies in the record generally support OSHA's conclusion that QLFT can be used to detect fit factors of less than 10 under the lead standard, the Agency only relied upon those which were found to be appropriately designed, with results that can be logically compared to those of other studies. Throughout the following discussion, those studies which the Agency decided not to use as substantiation for OSHA's position are indicated, and the perceived inadequacies in the conduct of the study are described.

The following is a summary of the evidence OSHA reviewed for each QLFT protocol:

Saccharin

The saccharin QLFT protocol relies on a respirator wearer's ability to taste an aerosal of saccharin solution droplets produced by a hand-operated nebulizer. The aerosal is contained in a small enclosure around the head and neck of the respirator wearer. Test subjects are screened by their ability to taste a low level of saccharin aerosal when breathing through the mouth.

Numerous studies and test data were submitted to the record on the saccharin protocol. In each case, the study authors concluded that the saccharin protocol was invariably capable of detecting respirators with a fit factor of less than 10, as determined by QNFT. OSHA finds the evidence submitted to the record to be convincing, and therefore concludes that the saccharin protocol is appropriate for assigning respirators for use in atmospheres up to 10 times the PEL for lead. In other words, the saccharin protocol may be used to assign a protection factor of 10 or less for half-mask respirators.

The following studies were conducted in such a manner that their results and conclusions could be compared with each other. The Los Alamos National Laboratories (LANL) performed validation tests on the saccharin protocol. Although the LANL data were generated using a model 45 nebulizer, the data are usable because LANL submitted detailed particle sizing information which shows the aerosal to be comparable to that produced by a model 40. Whether this is always true has not been demonstrated in the record. LANL ran two series of tests, one with rubber facepiece respirators and one with fabric facepiece respirators. In the first set 50 subjects were used for a total of 144 tests. (Exh. 58, p. 10, LANL). In the second set, on the fabric facepiece respirators, a total of 40 tests were run.

The second data set from 3M Co. involved 174 tests on 87 subjects using respirators with replaceable type high-efficiency filters (Ex. 6–16. Atch 1). The data were generated using conventional oil mist QNFT (Dynatech Frontier equipment) for comparison. The third set submitted by 3M consisted of data generated by Held and Rodrigues under contract to 3M. This set involved 68 subjects each tested once.

A major question which has been raised concerning the saccharin protocol during this rulemaking is whether the particle size of the aerosal is too large to be effective in reliably screening respirators. Those who questioned the use of saccharin protocol QLFT were concerned that saccharin aerosal particles might be larger than the aerosal particles used in QNFT, and that they are sufficiently larger than typical industrial aerosals so that their behavior is different in penetrating faceseal leaks (Ex. 24, 38, 43, 54). Arguments that were raised primarily theoretical in nature and would be compelling if supported by careful measurements appropriate to the respirator application. However, in tests performed by LANL (Ex. 58) to determine the mass median aerodynamic diameter (MMAD) of the aerosal distribution generated by the nebulizer, it was determined that the particle size distribution was within acceptable limits. The author of the LANL report states, "The data obtained in these measurements reveal a consistency which is surprising for an aerosal generated by a simple squeeze bulb nebulizer. As one would expect for a hygroscopic aerosol, there is a tendency toward a larger MMAD as the relative humidity is increased, but even at 99 percent relative humidity, the MMAD is still less than 3 microns (um)." In addition, Dr. Liu, who had expressed concerned on this issue (Ex. 24, 43) after reviewing the LANL results (Ex. 62) stated not only with respect to the aerosol size distribution, but to the saccharin protocol in general, "With regard to the interpretation of the test results and conclusions to be drawn from these results, I am also in agreement with Dr. Marsh that the sodium saccharin aerosol has a stable size distribution and that the sodium saccharin test protocol is capable of rejecting respirators with fit factors less than 10 with a high degree of reliability." On the basis of the test results and Dr. Liu's support, OSHA concludes that aerosol size distribution does not reduce the effectiveness of the saccharin protocol.

Although as stated above all of the data in the record supports the conclusion made by OSHA, the Agency only relied on those studies which are appropriately designed, with results that can be compared to those of other studies. Some of the submissions did not meet these requirements.

The largest data set, submitted by 3M, involving 191 subjects and 382 tests, relied for validation on a comparision of results with quantitative tests based on particle count measurements of the saccharin aerosol (Ex. 6–16 Atch 1). A saccharin mist QNFT using particle counters is a completely novel and unevaluated technique. Validating such a method would directly involve all of the particle size concerns discussed above. Therefore, this attempted validation of QLFT involves comparing one unknown to another unknown and is not useful. These data have not been relied upon in assessing the utility of the saccharin QLFT. Mr. Hack of LANL also concluded that such data were inappropriate (Tr. p. 28).

In an effort to aid analysis of the record prior to the hearing, the OSHA Training Institute performed a small

series of comparison tests. However, the recommended test enclosure was not available and so none was used. Although the performance of the protocol was poor in discriminating higher from lower fit factors, the testing was inaccurate as validation because the test enclosure was not used (Ex. 15).

DuPont Company has also submitted data for the saccharin protocol (Ex. 40). This set of data involved 22 individuals and 68 tests. The results of DuPont's study might not be directly comparable to those of other studies in the record since they used the model 45 nebulizer, rather than the model 40. The difference in nebulizer model may result in variations in particle size and thus could affect the findings of the study. OSHA has therefore decided that the significance of this particular set of data is uncertain, and has not relied upon it in reaching the Agency's conclusions. However, in the DuPont study, of ten wearers with fit factors of 10 or less, none passed the saccharin test. Moreover, of 20 wearers with fit factors less than 100, only one passed and that one had a fit factor of 84. OSHA considers these data to be relevant.

Another data set was submitted by 3M that resulted from tests run on rubber facepieces in which holes had been cut in the front to create large leaks. The geometry of such a cutout is so different from normal mask leakage and the path of travel for the aerosol is so different that OSHA judged these data inappropriate for consideration.

In each of the data sets not excluded for consideration in the above discussion, the saccharin test was able to detect every half-mask respirator which had a fit factor of less than 10. From these studies, OSHA concludes that the saccharin protocol can reliably detect ill-fitted respirators when a fit factor of 10 is required. Tests were not performed on other than half-mask respirators, and therefore QLFT can only be used with half-mask respirators.

Isoamyl Acetate (IAA)

The isoamyl acetate QLFT protocol relies on a respirator wearer's ability to smell the banana-like odor of isoamyl acetate vapor, which is evaporated from a wetted towel hung at the top of a small enclosure about the upper body of the wearer. Test subjects are screened by their ability to smell a low level of isoamyl acetate.

DuPont submitted test data of paired testing by QNFT and by their IAA protocol for QLFT (Ex. 6–38). The data showed a high degree of agreement between the candidate protocol and QNFT. According to Dynatech, this was due in large part to having tested primarily subjects with very well-fitted respirators so that both tests showed good fits most of the time (Ex. 34E, p. 3–4 Dynatech). Therefore the data is of limited usefulness in establishing the ability of the IAA protocol to screen out inadequate fits.

After the hearing DuPont submitted additional testing data that included many more cases where fit factors were less that 100. These data showed that the protocol was successful in rejecting fits that were less than a fit factor of 10 (Ex. 40). A total of 54 tests were run on half masks, and 27 had fit factors less than 10. Of these 27, none passed the QLFT. These data support the conclusion that the isoamyl acetate protocol QLFT can be confidently used to screen out fits resulting in fit factors of less than 10.

Comparison test data were also submitted by National Paint and Coatings Association (NPCA) in three data sets (Ex. 6–59). The first set involved a pooled group of 105 subjects at several member companies. QNFT measurements were only done on those subjects who passed the QLFT, so no information is available concerning the actual fit factors of those who failed. Thus no estimate of the reliability of the protocol can be made from these data.

Both the second and third data sets from NPCA also cannot be used to estimate the reliability of the isoamyl acetate protocol because in neither case were there any fit factors of less than 10. Therefore OSHA feels that these data cannot be used to verify or reject its conclusion regarding respirator protection factors of 10 for half-mask respirators.

Mr. Revoir (then with the Norton Company; ANSI Z88.2 committee) stated that he found two problems with the proposed protocol—olfactory fatigue, and the possibility of the protocol indicating that a respirator has a fit factor greater than is justified. (Ex. 34D, pp. 11–14).

OSHA believes that the provisions of the protocol already adequately address the potential problem of olfactory fatigue, which is the temporary loss of the employee's ability to detect IAA when being repeatedly exposed. Separate rooms and ventilation systems are required for the fit testing and for the odor threshold screening. This is to ensure that employees are not exposed to IAA vapors before their test procedure begins. In addition, exhaust ventilation is required for the fit testing area to reduce ambient contamination levels. Delay periods are built in to the protocol that are designed for (or at least will function to assist) olfactory sensitivity recovery. Also the test subject is required to exit the test enclosure promptly if leakage is detected.

OSHA, however, agrees with Revoir's criticism that the IAA protocol, as proposed, may inflate the actual fit factor, and has modified the IAA protocol in response to this criticism. The probability of the IAA protocol passing respirators with fit factors which are actually too low is dependent on two factors—the sensitivity test IAA concentration (i.e. the concentration used for odor threshold screening), and the IAA challenge concentration within the test chamber (i.e. the concentration the employee is exposed to while testing the respirator). If an individual were tested with the highest sensitivity test concentration and the lowest test chamber concentration, he or she would be less likely to detect a poorly fitting respirator than if the sensitivity test concentration were lower and the test chamber concentration higher. Mr. Manley (Dupont) stated that under the proposed protocol IAA chamber concentrations fluctuated between 75 ppm and 250 ppm (Tr. 99). He further testified that the IAA odor sensitivity test concentration could be as high as 2.4 ppm (Tr. 100).

OSHA has determined that the protocol suggested in the May 19 proposal could be easily modified so as to increase its effectiveness substantially without adding either cost or testing time to the proposed procedure. The modifications consist of: (1) Reducing the sensitivity test concentration by 20% and (2) increasing the average challenge concentration within the hood enclosure. The protocol as adopted in this final rule requires that the jar solution be made with .4cc rather than .5cc of stock solution and that a 50% larger wet towel be used with a proportionate increase in the isoamyl acetate that wets it.

Based on the data submitted by DuPont (Ex. 40), and with the modification of the proposed protocol, OSHA believes that the isoamyl acetate protocol is adequate to detect respirators with fit factors less than 10 and, in almost all cases, less than 100, and that it therefore can be safely used where exposures will not exceed 500 $\mu g/m^3$.

Irritant Smoke

The irritant smoke QLFT involves the introduction of an irritating substance in the vicinity of the respirator faceseal. Test subjects will cough involuntarily if the irritant leaks into the respirators. Although OSHA did not propose a protocol for use of irritant smoke QLFT,

it has decided that the record supports inclusion of such a method in the final standard.

Irritant smoke has been used for many years in a variety of formal and informal protocols as a qualitative fitting test. Alan Hack suggested that irritant smoke QLFT be approved for use under this rulemaking (Ex. 22). He stated that, "This test is used extensively in nuclear installations, is recommended in Z88.2, and was reported on by Hardis, et al. of Livermore, in UCRL–83381. Their results: of 274 tested, for half masks no one had a PF of less than 10 who passed the smoke test, for full facepiece, 7 (less than 3%) had a PF of less than 100 who passed the smoke test. I believe that there is enough experience with the irritant smoke test to permit its use as an approved QLFT."

The irritant nature of the fume has been assumed adequate to ensure a reliable and effective fit test. The American Iron and Steel Institute (AISI), for example, contended that no precise definition of a protocol would be required. However, AISI members conducted tests of their contention, and found that this assumption was unjustified (Ex. 32, 41, p.1, AISI). The data revealed a very high error rate, indicating that two thirds or more of the inadequate fits would never be detected. (Ex. 37, p. 51, NIOSH). As stated by AISI, "The initial pilot study did not establish a rigid or uniform irritant smoke protocol because the intent was to demonstrate that even given poorly controlled testing procedures the irritant smoke is a reliable test for distinguishing half mask respirators that will provide a fit factor of at least ten. A careful analysis and review of the data and methodology used by the three participating companies indicates this hypothesis is wrong. We have since determined that certain specific elements should be incorporated into an irritant smoke qualitative fit test protocol if it is to be effective, reliable, and reproducible." (Ex. 41).

AISI defined a protocol and arranged for additional tests. The new data set consisted of 110 tests in which 15 were at fit factors less than 10 and none of these passed the irritant smoke test (Ex. 41). The use of the defined protocol thus increased the reliability of the irritant smoke test in effectively screening out unacceptable fits.

In addition, LANL initiated a set of validation measurements in order to test an irritant smoke protocol. The protocol used (Ex. 63) differs from that submitted by AISI in that the wearer need only sense the smoke without reacting involuntarily in order to reject the fit. Therefore, the LANL results cannot be used to support the AISI protocol which is part of this rulemaking. However, the LANL data (Ex. 64) show that out of 150 tests of half mask respirators, there were 98 cases of fit factors less than 100 and, of these, only three were not rejected by the LANL protocol. The three false passes had fit factors of 25, 30, and 43. OSHA believes that these results, while not entirely applicable, tend to strengthen confidence in the use of irritant smoke.

The Allied Corporation has also submitted a small data set for consideration. A small number of these tests (5%) were at fit factors less than 100. No information was given on the number of cases that did not pass the irritant smoke test nor was there any indication of the fit factors of those not passing the irritant smoke test. Consequently this data set was not considered usable in evaluating the appropriateness of the irritant smoke protocol.

Data submitted by 3M to OSHA (Hardis, et. al. (Ex. 7–1)) were also considered inappropriate because the method of administering the irritant smoke was too uncontrolled (using a squeeze bulb in open air). Data submitted by DuPont (Ex. 40) were also considered inappropriate because the smoke was administered by a squeeze bulb into a hood in which the respirator wearer's head was situated. OSHA considered this method to be excessively uncomfortable for the wearer. The AISI protocol entered into the record requires a smoke pump to be used in conjunction with an exhaust hood so that the procedure provides control without imposing extreme discomfort on the wearer.

For the foregoing reasons, the irritant smoke decision was made on the basis of the AISI data. Since no respirator with a known fit factor of less than 10 passed the irritant smoke test, OSHA considers the irritant smoke protocol suitable for assuring that half mask negative pressure respirators are safe to use under the lead standard in atmospheres where exposures do not exceed ten times the PEL.

Changes Made in the Proposed Protocols

In this final rule, OSHA has made minor changes to the proposed IAA and saccharin protocols to increase their reliability and to improve confidence in the results of such testing. Two areas of change bear specific mention. OSHA is adding a number of specific steps to the respirator selection process to help assure that the subject can meaningfully assess the comfort of the chosen model, and that he or she will end up with a comfortable respirator. For example, the model chosen as most comfortable must be worn at least 5 minutes before testing; after passing the fit test the subject must be given an opportunity to test another model if the respirator has become uncomfortable during testing; and the employee must be given a further opportunity to select and test another model if, within two weeks of on-the-job wear, the chosen facepiece becomes uncomfortable (IAA B–5, 9, 10).

The rulemaking record contains strong support for these changes. For example, the DuPont Company explained that if a man went out in the workplace and found after a few days that a respirator was not comfortable; he must come back and repeat the testing process with another respirator (Tr. 108). The need to wear the respirator for more than a short time to assess comfort was also stated in the record (Tr. 281–283).

Also, the protocols require that the array of respirators offered to the employee include at least three sizes of elastomeric facepieces and two manufacturers. Providing a wide array of respirators will help assure that most employees can be fitted, and that each employee tested will obtain a comfortable respirator as well. Record support for a wide array was substantial (Tr. 21, 150, 213, 322–23).

OSHA has also increased the time required for each exercise from 30 seconds in the proposal to one minute in the final protocols. This change too has ample record support (Tr. 74, 284, 315).

The specifications for the saccharin protocol have also been altered with respect to the head enclosure to be used. The proposal, as well as 3M's original submission, specified a hood 19 inches high by 19 inches in diameter. By contrast the kit provided by 3M to do the test, and, by all indications, the one used by all parties to run their validations, measures approximately 12 inches in diameter by 14 inches high. Consequently the protocol actually tested is one using the smaller hood, and therefore the smaller hood is specified in the appendix.

Respirator Selection

By specifying a broad assortment of respirators in the panel offered to each employee, OSHA has tried to assure that the vast majority of employees are able to be fitted through the application of the allowable testing protocols. OSHA is aware, however that some employees cannot be fitted with half-mask respirators, or because they are insensitive to the testing agent, cannot be tested using one or more of these protocols. In such cases, the employer

must either offer another kind of fit testing, another kind of respirator, or both. The choice depends on OSHA's requirements and the particular situation which precludes the fitting of an available half-mask respirator by using a particular QLFT protocol. For example, if an employee cannot be fitted with a half-mask respirator, he may be fitted with a full-mask respirator or a powered air-purifying divice (PAPR). In the former case, QNFA is required. In the latter case, no fit test would be required. If an employee cannot detect the testing agent used for that employer's QLFT, the employer may try testing with another approved QLFT, test with QNFT, or assign a PAPR.

Summary

The major consequence of this rule revision which permits QLFT is to place greater reliance on the subjective evaluation of the fit of half-mask respirators. It should be noted that the issue of concern in these discussions is the use of QLFT to establish a protection factor of 10 for half-mask facepieces. All of the studies described used half-masks.

The revision is appropriate because the methods (protocols) themselves have been shown to be effective within given limits. Employees are given an adequate opportunity to understand the whole respirator program through training and an opportunity to exercise their judgment to reject a respirator which appears inadequate. Employee cooperation and candor are vital to the successful and proper implementation of the protocols. The opportunities for refitting and retesting contained in the protocols included in the final standard, as well as the availability of a wide variety of facepieces, are expected to encourage and facilitate employee cooperation. They are, therefore, appropriately included as a part of revisions that place greater reliance on the employee's subjective judgment. In addition, the record clearly shows that respirators selected by employees for comfort will achieve substantially increased average protection factors (Tr. 211–212, Turner).

Very specific protocols are being required in this final rule because the terms "qualitative fit testing" would otherwise be so vague as to be virtually unenforceable, and would be of little help to employers in determining how to comply with the standard. As stated above, with the exception of irritant smoke these protocols were proposed, and other than suggestions for minor modifications, were generally agreed upon by participants in the rulemaking. The testing protocols must be performed exactly as listed in the appendices because it is only these protocols which have had their performance substantiated quantitatively. Failure to use all the steps and employ all the proper test conditions amounts to the use of a different testing protocol with uncertain results and would not comply with the standard. For example, the isoamyl acetate protocol requires two separate rooms that are well ventilated but not on the same recirculating ventilation system. A failure to adhere to these limitations will very likely result in deterioration of the employee's ability to detect isoamyl acetate, which will cause tested employees to be unable to detect masks which do not fit. This in turn would subject them to high lead exposure and its consequent health risk.

D. Regulatory Impact Analysis; Regulatory Flexibility Analysis

In accordance with Executive Order 12291 (46 FR 13193), OSHA hereby states that this rulemaking does not constitute a "major rule" since its effect will not meet any of the definitional elements in s1(b) of the Executive Order. OSHA also certifies that this proposal does not require a regulatory flexibility analysis under the Regulatory Flexibility Act because it will not have a significant economic impact on a substantial number of small entities.

An analysis of evidence submitted to the rulemaking docket indicates that the proposed change allowing use of QLFT or QNFT for half-mask respirators worn by employees exposed to less than 500 $\mu g/m^3$ of airborne lead is cost-effective. Compliance with the revised requirement is less expensive than compliance with the current provision requiring QNFT for all employees wearing negative pressure respirators. This increased flexibility, however, does not increase the risk of employee exposure to airborne lead above 50 $\mu g/m^3$. The upper bound on total annual cost-savings of this regulatory action, which are detailed in the section below, is estimated to be as much as $6,300,000.

OSHA has carefully examined the potential for increasing air lead exposures of employees as a result of allowing the substitution of QLFT for QNFT. OSHA believes that the record supports the conclusion that the protection resulting from providing respirators will prevent employee exposures to lead in excess of 50 $\mu g/m^3$. Furthermore, where air lead levels exceed 500 $\mu g/m^3$ and the assurance of a protection factor of more than ten is therefore necessary, OSHA retains the requirement for QNFT to ensure that workers wearing respirators do not inhale more than 50 $\mu g/m^3$ of airborne lead. These issues are discussed in other sections of this preamble.

Analysis of the cost data in the record shows that both the annual and capital costs of QNFT exceed the costs of QLFT. There are two major factors associated with QNFT that make it more expensive than QLFT. First, employers using QNFT incur capital expenditures for sophisticated equipment, including test boots and instrumentation. Capital costs are about $7,000 per firm (Ex. 6–12), assuming that firms purchase one unit each. Estimates for the capital costs varied, but OSHA believes that $7,000 is a representative figure. To the extent that smaller firms prefer to hire consultants at a daily rate of about $200 and rent the equipment to perform QNFT (Ex. 25), these capital costs are overstated. The record does not contain sufficient evidence to estimate the number of firms likely to use consultants and therefore OSHA cannot estimate the extent to which the capital costs are overstated. Second, evidence in the record suggests that the time required to fit test a respirator wearer for the first time does not differ significantly between QNFT and QLFT. Subsequent fit testing using QNFT appears to be comparable to QLFT. Thus, initial QNFT and QLFT each take about 30 to 40 minutes (Ex. 25, DuPont and Ex. 27, NPCA), and employers using QNFT would incur about 20 minutes of downtime per employee per retest compared with about 20 minutes of downtime per employee per retest for QLFT as required by protocols in this rulemaking. However, set-up time per test day associated with QNFT may be as much as twice as long as QLFT set-up time (Ex. 25).

One important factor increases the costs of QLFT relative to QNFT. The record shows that the rate of false positives resulting from QLFT exceeds the rate of false positives from QNFT (Ex. 48). This means that the QLFT methods reject a greater number of respirators that actually have acceptable fits than the QNFT methods do, and thus result in more retesting of subjects to attain adequate fits. Estimates of the rate of false positives in QLFT range from 36 percent to 90 percent (Ex. 34E). Using available studies in the record (Ex. LANL, Ex. 6–40, Ex. 16, and Ex. 16–A), OSHA calculates an average false positive incidence for QLFT of about 39.5%. The cost implications of this are significant. For instance, on the basis of one study (Ex. 6–38), OSHA found that 149 tests were required to qualitatively fit test 98 employees. Thus, the costs of retesting

employees increased the total costs of QLFT by about 30%. To the extent that the rate of false positives may be even higher in some firms, the resulting cost impact may induce employers to continue using QNFT rather than QLFT.

Annual costs of compliance with the current requirement to perform semiannual QNFT are estimated at nearly $6,800,000. Annual costs for this amended rule which gives employers the flexibility to choose either QNFT or QLFT for employees exposed to less than 500 $\mu g/m^3$ of airborne lead, but maintains the requirement for QNFT for all employees exposed to airborne lead in excess of 500 $\mu g/m^3$ are estimated at about $500,000. Thus, cost-savings resulting from this action are estimated to be as high as $6,300,000 per year. However it should be noted that this is a maximum upper bound in view of the potential for using consultants as described earlier.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Respiratory protection.

PART 1910—[AMENDED]

Accordingly, pursuant to sections 6(b) and 8(g) of the Occupational Safety and Health Act of 1970, 84 Stat. 1593, 1600, 29 U.S.C. 655(b), 657(g); 5 U.S.C. 553; and Secretary of Labor's Order 8–76 (41 FR 25059), 29 CFR Part 1910 is amended as follows:

1. 29 CFR 1910. 1025 is amended by revising paragraph (f)(3) (ii) as follows:

§ 1910.1025 Lead.

* * * * *

(f) Respiratory protection * * *

(3) Respirator usage.* * *

(ii) Employers shall perform either quantitative or qualitative face fit tests at the time of initial fitting and at least every six months thereafter for each employee wearing negative pressure respirators. The qualitative fit tests may be used only for testing the fit of half-mask respirators where they are permitted to be worn, and shall be conducted in accordance with Appendix D. The tests shall be used to select facepieces that provide the required protection as prescribed in table II.

* * * * *

2. In § 1910.1025, the fourth paragraph of Appendix B, Section IV: Respiratory Protection, is amended to read as follows:

Appendix B to Section 1910.1025—Employee Standard Summary

* * * * *

IV. * * *

Your employer must assure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical. Obtaining a proper fit on each employee may require your employer to make available two or three different mask types. In order to assure that your respirator fits properly and that facepiece leakage is minimized, beginning on November 12, 1982, your employer must give you either a qualitative fit test in accordance with Appendix D of the standard or a quantitative fit test if you use a negative pressure respirator. Any respirator which has a filter, cartridge or canister which cleans the work room air before you breathe it and which requires the force of your inhalation to draw air thru the filtering element is a negative pressure respirator. A positive pressure respirator supplies air to you directly. A quantitative fit test uses a sophisticated machine to measure the amount, if any, of test material that leaks into the facepiece of your respirator.

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3. In § 1910.1025, Appendix B, Section XV: For Additional Information, Part A, item 7, is revised and new items 8 and 9 are added as follows:

* * * * *

XV. * * *

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7. Appendices to the standard (Appendices A, B, C), **Federal Register**, Vol. 44, pp. 60980–60995, October 23, 1979.

8. Corrections to appendices, **Federal Register**, Vol. 44, 68828, November 30, 1979.

9. Revision to the standard and additional appendices (Appendices D and E), **Federal Register**, Vol. 47, pp. (pages for this notice), November 12, 1982.

4. In § 1910.1025, a new Appendix D is added to read as follows:

* * * * *

Appendix D to Section 1910.1025—Qualitative Fit Test Protocols

This appendix specifies the only allowable qualitative fit test protocols permissible for compliance with paragraph (f)(3)(ii).

I. Isoamyl Acetate Protocol

A. Odor threshold screening.

1. Three 1–liter glass jars with metal lids (e.g. Mason or Bell jars) are required.

2. Odor-free water (e.g. distilled or spring water) at approximately 25°C shall be used for the solutions.

3. The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1-liter jar and shaking for 30 seconds. This solution shall be prepared new at least weekly.

4. The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but may not be connected to the same recirculating ventilation system.

5. The odor test solution is prepared in a second jar by placing .4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. Shake for 30 seconds and allow to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution may be used for only one day.

6. A test blank is prepared in a third jar by adding 500 cc of odor free water.

7. The odor test and test blank jars shall be labelled 1 and 2 for jar identification. If the labels are put on the lids they can be periodically *dried off* and switched to avoid people thinking the same jar always has the IAA.

8. The following instructions shall be typed on a card and placed on the table in front of the two test jars (i.e. 1 and 2):

"The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

9. The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatique in the subject.

10. If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA QLFT may not be used.

11. If the test subject correctly identifies the jar containing the odor test solution he may proceed to respirator selection and fit testing.

B. Respirator selection.

1. The test subject shall be allowed to select the most comfortable respirator from a large array of various sizes and manufacturers that includes at least three sizes of elastomeric half facepieces and units of at least two manufacturers.

2. The selection process shall be conducted in a room separate from the fit-test chamber to prevent odor fatigue. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to assess an "comfortable" respirator. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This may not constitute his formal training on respirator use, only a review.

3. The test subject should understand that he is being asked to select the respirator which provides the most comfortable fit for him. Each respirator represents a different size and shape and, if fit properly, will provide adequate protection.

4. The test subject holds each facepiece up to his face and eliminates those which are obviously not giving a comfortable fit. Normally, selection will begin with a half-mask and if a fit cannot be found here, the subject will be asked to go to the full facepiece respirators. (A small percentage of users will not be able to wear any half-mask.)

5. The more comfortable facepieces are recorded; the most comfortable mask is donned and *worn at least five minutes* to assess comfort. Assistance in assessing comfort can be given by discussing the points in #6 below. If the test subject is not familiar with using a particular respirator, he shall be directed to don the mask several times and to

adjust the straps each time, so that he becomes adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject:

- Chin properly placed.
- Positioning of mask on nose.
- Strap tension.
- Fit across nose bridge.
- Room for safety glasses.
- Distance from nose to chin.
- Room to talk.
- Tendency to slip.
- Cheeks filled out.
- Self-observation in mirror.
- Adequate time for assessment.

7. The test subject shall conduct the conventional negative and positive-pressure fit checks (e.g. see ANSI Z88.2–1980). Before conducting the negative- or positive-pressure checks, the subject shall be told to "seat" his mask by rapidly moving the head side-to-side and up and down, taking a few deep breaths.

8. The test subject is now ready for fit testing.

9. After passing the fit test, the test subject shall be questioned again regarding the comfort of the respirator. If it has become uncomfortable, another model of respirator shall be tried.

10. The employee shall be given the opportunity to select a different facepiece and be retested if during the first two weeks of on-the-job wear the chosen facepiece becomes unacceptably uncomfortable.

C. Fit test.

1. The fit test chamber shall be substantially similar to a clear 55 gallon drum liner suspended inverted over a 2 foot diameter frame, so that the top of chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

2. Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

3. After selecting, donning, and properly adjusting a respirator himself, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hook, to prevent general room contamination.

4. A copy of the following test exercises and rainbow (or equally effective) passage shall be taped to the inside of the test chamber:

Test Exercises

i. Normal breathing.

ii. Deep breathing. Be certain breaths are *deep* and *regular*.

iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the shoulders. Have the test subject inhale when his head is at either side.

iv. Nodding head up-and-down. Be certain motions are complete and made about every second. Alert the test subject not bump the respirator on the chest. Have the test subject inhale when his head is in the fully up position.

v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

vi. Normal breathing.

5. Each test subject shall wear his respirator for at least 10 minutes before starting the fit test.

6. Upon entering the test chamber, the test subject shall be given a 6 inch by 5 inch piece of paper towel or other porous absorbent single ply material, folded in half and wetted with three-quarters of one cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

7. Allow two minutes for the IAA test concentration to be reached before starting the fit-test exercises. This would be an appropriate time to talk with the test subject, to explain the fit test, the importance of his cooperation, the purpose for the head exercises, or to demonstrate some of the exercises.

8. Each exercise described in No. 4 above shall be performed for at least one minute.

9. If at any time during the test, the subject detects the banana-like odor of IAA, he shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

10. Upon returning to the selection room, the subject shall remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber, etc. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

11. If a person cannot be fitted with the selection of half-mask respirators, include full facepiece models in the selection process. When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having him break the face seal and take a breath before exiting the chamber.

12. When the test subject leaves the chamber he shall remove the saturated towel, returning it to the test conductor. To keep the area from becoming contaminated, the used towels shall be kept in a self-sealing bag. There is no significant IAA concentration buildup in the test chamber from subsequent tests.

13. Persons who have successfully passed this fit test may be assigned the use of the tested respirator in atmospheres with up to 10 times the PEL of airborne lead. In other words this IAA protocol may be used to assign a protection factor no higher than 10.

II. Saccharin Solution Aerosol Protocol

A. Taste threshold screening.

1. Threshold screening as well as fit testing employees shall use an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly of part # FT 14 and FT 15 combined is adequate.

2. The test enclosure shall have a three-quarter inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

3. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

4. The test subject shall don the test enclosure. For the threshold screening test, he shall breath through his open mouth with tongue extended.

5. Using a DeVilbiss Model 40 Inhalation Medication Nebulizer, the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

6. The threshold check solution consists of 0.83 grams of sodium saccharin, USP in water. It can be prepared by putting 1 cc of the test solution (see C6 below) in 100 cc of water.

7. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely then released and allowed to fully expand.

8. Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

9. If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

10. If the second response is negative ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

11. The test conductor will take note of the number of squeezes required to elicit a taste response.

12. If the saccharin is not tasted after 30 squeezes (Step 9), the test subject may not perform the saccharin fit test.

13. If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

14. Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

15. The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

B. Respirator selection.

Respirators shall be selected as described in section IB above, except that each respirator shall be equipped with a particulate filter cartridge.

C. Fit test.

1. The fit test uses the same enclosure described in B1 and B2 above

2. Each test subject shall wear his respirator for at least 10 minutes before starting the fit test.

3. The test subject shall don the enclosure while wearing the respirator selected in section A above. This respirator shall be properly adjusted and equipped with a particulate filter cartridge.

4. The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

5. A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

6. The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

7. As before, the test subject shall breathe through the open mouth with tongue extended.

8. The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure and the fit test solution is sprayed into the enclosure using the same technique as for the taste threshold screening and the same number of squeezes required to elicit a taste response in the screening. (See B 10 above).

9. After generation of the aerosol the test subject shall be instructed to perform the following exercises for one minute each.

i. Normal breathing.

ii. Deep breathing. Be certain breaths are *deep* and *regular*.

iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the shoulders. Have the test subject inhale when his head is at either side.

iv. Nodding head up-and-down. Be certain motions are complete. Alert the test subject not to bump the respirator on the chest. Have the test subject inhale when his head in the fully up position.

v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

10. Every 30 seconds, the aerosol concentration shall be replenished using one-half the number of squeeze as initially (C8).

11. The test subject shall so indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

12. If the saccharin is detected the fit is deemed unsatisfactory and a different respirator shall be tried.

13. Successful completion of the test protocol shall allow the use of the tested respirator in contaminated atmospheres up to 10 times the PEL. In other words this protocol may be used assign protection factors no higher than ten.

III. Irritant Fume Protocol

A. Respirator selection.

Respirators shall be selected as described in section IB above, except that each respirator shall be equipped with high efficiency-acid gas-organic vapor cartridges.

B. Fit test.

1. The test subject shall be allowed to smell a weak concentration of isoamyl acetate and of the irritant smoke to familiarize him with the characteristic odor of each.

2. The test subject shall properly don the respirator selected as above, and wear it for at least 10 minutes before starting the fit test.

3. The test conductor shall review this protocol with the test subject before testing.

4. The test subject shall perform the conventional positive pressure and negative pressure fit checks. Failure of either check shall be cause to select an alternate respirator.

5. A simplified isoamyl acetate based fit test shall be performed using ampules of IAA such as the Norton Respirator Fit Test Ampules or equivalent. Pass the ampule around the perimeter of the respirator at the junction of the facepiece and face. If leakage is detected, readjust the respirator. If leakage persists the respirator is rejected.

6. If no odor of IAA is detected the irritant smoke test shall be administered.

7. Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach a short length of tubing to one end of the smoke tube. Attach the other end of the smoke tube to a low pressure air pump set to deliver 200 milliliters per minute.

8. Advise the test subject that the smoke can be irritating to the eyes and instruct him to keep his eyes closed while the test is performed.

9. The test conductor shall direct the stream of irritant smoke from the tube towards the faceseal area of the test subject. He shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

10. The following exercises shall be performed while the respirator seal is being challenged by the smoke. Each shall be performed for one minute.

i. Normal breathing.

ii. Deep breathing. Be certain breaths are *deep* and *regular*.

iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the shoulders. Have test subject inhale when his head is at either side.

iv. Nodding head up-and-down. Be certain motions are complete. Alert the test subject not to bump the respirator on the chest. Have the test subject inhale when his head is in the fully up position.

v. Talking—slowly and distinctly, count backwards from 100.

vi. Normal breathing.

11. If the irritant smoke produces an involuntary reaction (cough) by the test subject, the test conductor shall stop the test. In this case the tested respirator is rejected and another respirator shall be selected.

12. Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube to determine whether he reacts to the smoke. Failure to evoke a response shall void the fit test.

13. Steps B4, B9, B10 of this protocol shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agents (IAA, irritant smoke).

14. Respirators successfully tested by the protocol may be used in contaminated atmospheres up to ten times the PEL. In other words this protocol may be used to assign protection factors not exceeding ten.

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, D.C. 20210.

(Sec. 6. Pub. L. 91–596, 84 Stat. 1593 (29 U.S.C. 655), 29 CFR 1911: 41 U.S.C. 35, 38; Secretary of Labor's Order No. 8–76 (41 FR 25059))

Signed at Washington, D.C. this 8th day of November 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

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DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Part 401

Seaway Regulations; Miscellaneous Amendments

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Saint Lawrence Seaway Development Corporation and its counterpart agency, the St. Lawrence Seaway Authority of Canada, have completed their periodic review of joint Seaway Regulations and have agreed that several sections are in need of revision. The Seaway Corporation therefore proposes to amend 33 CFR Part 401—Subpart A in order (1) to insure its consistency with actual operating procedures, (2) to clarify several existing regulations, and (3) to complete the conversion of certain measurements to the metric system.

EFFECTIVE DATE: November 12, 1982.