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Department of Health and Human Services

Public Health Service

42 CFR Part 84

National Institute for Occupational Safety and Health; Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices Used in Mines and Mining; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 84

National Institute for Occupational Safety and Health (NIOSH) Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices Used in Mines and Mining

AGENCIES: National Institute for Occupational Safety and Health, Centers for Disease Control (CDC), Public Health Service, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This Notice proposes regulations at Part 84 of Title 42 of the Code of Federal Regulations (42 CFR Part 84) for certifying respirators. Upon promulgation, 42 CFR Part 84 will replace Part 11 of Title 30 of the Code of Federal Regulations (30 CFR Part 11). 30 CFR Part 11 is the existing regulation under which the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) test and certify respirators for use in mines and mining. Elsewhere in this issue of the **Federal Register**, MSHA is proposing to revoke 30 CFR Part 11. NIOSH is proposing extensive changes in the requirements and tests for certifying respirators which were originally promulgated in 1972 and periodically amended since that date. The revisions are in accordance with the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 842(h), 844 and 957).

Requirements and tests are included for new types of respirators used in mines and mining; new and revised requirements and tests are incorporated which more completely address mine and mining conditions and their effects on respirators; and administrative changes are included which will generally improve the respirator testing and certification program.

Interested parties are invited to participate in this proposed rulemaking by submitting such written views or arguments as they may desire. All communications received before the specific closing date will be considered before taking action on the proposed rule. All comments received will be available for examination in the Office of the Director, Division of Safety Research, NIOSH. The proposal contained in this notice may be changed in light of the comments received.

DATE: Comments must be received on or before October 26, 1987.

ADDRESSES: Send comments on the proposal in triplicate to: Director, Division of Safety Research, NIOSH, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

FOR FURTHER INFORMATION CONTACT: John Moran, Director, Division of Safety Research, NIOSH, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505, telephone (304) 291–4595.

SUPPLEMENTARY INFORMATION: Following promulgation of 30 CFR Part 11 in 1972, NIOSH began conducting research in several areas of respiratory protection. Concurrently, NIOSH began to receive public input concerning the respirator certification program.

In December 1977, NIOSH conducted a public meeting to obtain comments on changes needed in 30 CFR Part 11. In 1979, a group of outside consultants conducted a thorough review of the program. The report received from those consultants was published by NIOSH for further consideration by other interested persons, and a public meeting was held in July 1980, to obtain their comments on the program. In December 1981, the American National Standards Institute Z88 Committee on Respiratory Protection commented on 30 CFR Part 11. In January 1982, the Mine Health Research Advisory Committee transmitted its recommendations to NIOSH for further changes in the program. Since 1982, NIOSH has solicited and investigated reports of problems with NIOSH/MSHA-certified respirators, with the purpose of obtaining direct public input into the certification program.

Investigations, research, comments, and analyses were considered by NIOSH in preparation of this proposed revision that was transmitted to MSHA in September 1983. After meeting with MSHA and considering MSHA comments, the present revision was prepared and is published as a Notice of Proposed Rulemaking. In accordance with the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 842(h), 844 and 957) which has been enacted for the purpose, in part, of developing and promulgating improved mandatory health or safety standards to protect the health and safety of the Nation's coal or other miners, the issuance of certificates of approval for respirators is limited to only those respirators used in coal or other mines.

This revision includes new requirements and tests and changes in existing requirements and tests which NIOSH has determined will provide greater safety and reliability for respirators used in mines and mining.

The most significant of the new requirements in the proposed 42 CFR Part 84 is the proposed requirement for workplace or simulated workplace tests (§ 84.32) to be performed before certification of a respirator. These tests, which would be performed in real or simulated use environments, are designed and intended to resolve a major problem which exists under the present requirements of 30 CFR Part 11. NIOSH has repeatedly observed and been advised by mining personnel and others, of hazardous problems existing in the design and/or performance of respirators that have been certified for approval by MSHA and NIOSH, but have not been used under field conditions. These problems, which the performance requirements of the present 30 CFR Part 11 often cannot identify, may become apparent only after the certified respirator is put into actual use in strenuous mine and other operations. NIOSH believes that earlier recognition and correction of such problems are necessary, and NIOSH has included a requirement that the manufacturer perform a workplace or simulated workplace trial test, as specified in this revision, prior to issuance of a certificate of approval by NIOSH.

Workplace or simulated workplace test requirements are included to provide for certification of respirators to either a minimum performance level or to a higher performance level.

NIOSH has detailed protocols for the conduct of laboratory tests. These protocols have been made available to all certification applicants and, indeed, serve as the basis for correlation between such tests conducted by the manufacturer/applicant and the NIOSH certification tests. The NIOSH laboratory serves not only as the testing authority but as the test procedure reference laboratory. Under the proposed revisions, NIOSH will similarly provide detailed model laboratory test protocols to applicants upon request and will continue to serve as the reference laboratory for quality assurance and laboratory correlation purposes.

In these proposed regulations, NIOSH requires the conduct of workplace or simulated workplace testing. NIOSH and others have conducted such "field" studies to determine the performance of respirators in the workplace setting. NIOSH has experience in and is expanding workplace testing of respirators and has begun to develop model protocols for performing such tests in a proven and reliable manner. These field test protocols establish the criteria for the conduct of such tests to

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self-contained breathing apparatus are exposed to in mining use.

Section 84.248–17. Flammability tests are included to simulate the exposure of self-contained breathing apparatus to heat and flames during mine use.

Section 84.248–18. A regulator over-pressurization test is included to simulate use of self-contained breathing apparatus in mines and mining.

Subpart U. New requirements are included for certification of powered air-purifying respirators, updating and revising the present requirements where necessary.

Subpart V. To provide a more severe test of respirator efficiency, the tests against various particulate matter, such as silica and lead, are replaced with a test against sodium chloride aerosol. Aerosol experts have assured NIOSH that the sodium chloride test, which provides efficiency data throughout the test as well as providing an aerosol more difficult to filter out, is superior to the present silica and lead aerosol tests.

Subpart W. Changes in the humidity and air flow of canister and cartridge tests are included to provide test conditions more nearly like those encountered in mines and mining.

NIOSH invites public comment on the appropriateness of continuing the use of carbon tetrachloride as a challenge vapor for evaluating and certifying organic vapor canister/chemical cartridge respirators. If appropriate, commenters should recommend a replacement or replacement vapor(s) and provide any available data to support their recommendation.

The classifications of air-purifying respirators which may be certified are changed to make their selection by wearers more realistic and easier. For example, instead of classifying dust respirators according to the toxicity of the materials they are designed to protect against, they are classified in this revision according to their relative efficiencies against any particulate matter.

To reflect MSHA's experience with issues of miner safety and health, the proposed rule provides for the two Agencies to consult on approval applications for respirators designed for mine rescue or other mine emergencies. MSHA would review these applications to determine the suitability of the respirators for the mining environment. Under the proposal, any use limitation related to miner safety or health would be included as a condition for approval of the respirators. The proposal would not affect MSHA's testing of electrical components of respirators in potentially explosive atmospheres (intrinsic safety) under the existing requirements of 30 CFR Part 18.

In implementing the proposed revisions, NIOSH and MSHA plan to develop a new Memorandum of Understanding which would, among other things, define the consultative role for MSHA in respirator approvals.

Both MSHA and NIOSH intend that the proposed certification program improve the quality and reliability of respirator performance in the workplace. These improvements will lead to better protective equipment against exposures from toxic substances and other airborne health hazards.

Regulatory Impact Analysis

The Secretary has determined, in accordance with Executive Order 12291, that this rule will not constitute a "major" rule, in that it is not likely to: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U. S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The proposed rule will not have significant impact on small businesses; therefore, preparation of a regulatory flexibility analysis is not required.

Paperwork Reduction Act

Sections of this proposed rule contain information collections which are subject to review by the Office of Management and Budget (OMB) under section 3504(h) of the Paperwork Reduction Act of 1980. We have submitted a copy of this proposed rule to OMB for its review of these information collections. Other organizations and individuals desiring to submit comments on the information collections should direct them to the agency official designated for this purpose whose name appear in this preamble, and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building (Room 3208), Washington, DC 20503, ATTN: Desk Officer for HHS/PHS/CDC/NIOSH.

List of Subjects in 42 CFR Part 84

Mine safety and health, Occupational safety and health respirators, Miners, Personal protective equipment.

For the reasons set out in the preamble, Part 84 of Chapter 1 of Title 42 of the Code of Federal Regulations is proposed to be added as set forth below.

Dated: July 10, 1987.

Robert E. Windom,

Assistant Secretary for Health.

Approved: July 29, 1987.

Otis R. Brown,

Secretary.

Subchapter G—Occupational Safety and Health Research and Related Activities

PART 84—RESPIRATORY PROTECTIVE DEVICES; TESTS FOR PERMISSIBILITY

Subpart A—General Provisions

Sec.

Subpart B—Application Procedure

Subpart C—Quality Assurance

Subpart D—Respirator Testing by Applicant

Subpart E—NIOSH Certification Label

Subpart F—Maintenance, Informational and Instructional Materials

Subpart G—Modification of Certified Respirators

Authority: 30 U.S.C. 842(h), 844 and 957, [Pub. L. 91–173 as amended by Pub. L. 95–164].

Subpart A—General Provisions

§ 84.1 Purpose.

The purpose of this part is to prescribe procedures and requirements for the certification of respirators for use in mines and mining.

§ 84.2 Certified respirators.

(a) A respirator is certified if the respirator meets the requirements set forth in this part. NIOSH will determine if a respirator meets these requirements by reviewing the test reports described in §§ 84.30, 84.32, and 84.33.

(b) *Expiration of manufacturers' certificates and recertification.* (1) Manufacturers' certificates granted prior to the effective date of this part by NIOSH, MSHA and the Bureau of Mines for respirators certified as meeting previous performance requirements shall expire five years from the effective date of these regulations unless certification is withdrawn prior to that time pursuant to the provisions of Subpart H of this part.

(2) A manufacturer may obtain certification of a respirator with an expired manufacturers' certificate by submission of a new application for certification as specified in § 84.10.

(3) A respirator submitted to NIOSH for an original certification or a

respirator with an expired manufacturers' certificate which is submitted to NIOSH for recertification shall meet all relevant performance requirements in effect on the date of application.

(4) A certification granted by NIOSH after the effective date of these regulations shall remain in effect for the time period specified in the subsequent revision of the performance requirement applicable to that type or class of respirator unless certification is withdrawn prior to that time pursuant to the provisions of Subpart H of this part.

§ 84.3 Definitions.

"Applicant" means an individual, partnership, company, corporation, association or other organization which manufactures, assembles, or controls the assembly of a complete respirator and who applies to NIOSH for certification of such respirator or for certification of a modification of a certified respirator.

"Major Modification" is a modification or set of modifications not listed or otherwise provided for in the certified respirator specifications that (1) might appreciably affect the weight, balance, structural strength, performance, or other qualities affecting respirator use, or (2) is not done according to accepted practices or cannot be done by elementary operations.

"Manufacturer" means an individual, partnership, company, corporation, association or other organization which manufactures, assembles, or controls the assembly of a complete respirator and has been granted a NIOSH certification for such respirator.

"Minor Modification" is other than a major modification.

"MSHA" means the Mine Safety and Health Administration, U.S. Department of Labor.

"NIOSH" means the National Institute for Occupational Safety and Health, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services.

"NIOSH certification label" is a label described in Subpart E of this part.

"Respirator" means any device worn by an individual engaged in mining and designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.

"Simulated workplace" means a simulated environment that is a reasonable representation of mines or mining work sites with regard to contaminant exposures for which a respirator is intended to protect.

"Workplace" means any mine or mining work site with regard to contaminant exposures for which a respirator is intended to provide protection.

Subpart B—Application Procedure

§ 84.10 Submission of an application.

(a) An application to NIOSH for certification of a respirator or certification of a major modification of a certified respirator shall be submitted in writing to: Division of Safety Research, NIOSH, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

(b) An application to MSHA for certification of an electrical component of a respirator that is required to be permissible, shall be tested in accordance with Part 18 of this chapter and shall be submitted in writing to: Approval and Certification Center, Box 251, Industrial Park Road, Triadelphia, West Virginia 26059.

§ 84.11 Required contents of an application to NIOSH for certification.

An application to NIOSH for certification of a respirator or certification of a major modification of a certified respirator shall be written in English and shall contain:

(a) A letter of transmittal from the applicant to NIOSH requesting certification of a respirator or certification of a major modification of a certified respirator;

(b) A test report as described in § 84.30;

(c) Written assurance that the applicant will, prior to commencement of production, implement, and thereafter maintain, a program to assure the continued quality of certified respirators which will meet both the minimum requirements and the objectives set forth in § 84.20;

(d) A minimum of two respirators which are made on regular production tooling with no operation included which was not included on the respirators tested by the applicant or his agent and which will not be incorporated in regular production processing;

(e) A copy of the applicant's proposed user maintenance, informational and instructional materials and a sample of the packaging materials;

(f) Engineering drawings of the respirator for which certification is sought;

(g) A complete parts list, including all components or parts which may be replaced during the useful life of the respirator;

(h) Marking of all documents submitted under paragraphs (f) and (g) of this section indicating their confidential or trade secret nature;

(i) A required fee of $200 to cover the cost of NIOSH documentation review, plus any additional costs to cover verification testing, determined in accordance with the provisions in Subpart J;

(j) Written assurance that the applicant will, during any testing required by these regulations which involves human subjects, comply with the requirements in 45 CFR Part 46, Subpart A-Basic HHS Policy for Protection of Human Research Subjects.

§ 84.12 Withdrawal of an application for certification.

(a) An applicant may, by written notification to NIOSH, withdraw its application for certification of a respirator.

(b) Upon request, NIOSH will return to the applicant the respirators submitted for certification. The return of the respirator shall be at the applicant's expense.

(c) Any balance of the paid fee will be refunded to the applicant.

§ 84.13 Evaluation of an application for certification.

If NIOSH determines that the applicant has failed to satisfy the requirements set forth in § 84.11 of this part, NIOSH will so inform the applicant and describe the basis for the NIOSH determination. No additional application fee will be charged.

Subpart C—Quality Assurance

§ 84.20 Quality assurance.

Applicants granted a certification under this part shall—

(a) Inspect or test, or both, the critical characteristics identified in the appropriate subpart of this part;

(b) Calibrate instruments used for the inspection and testing of critical characteristics at least as frequently as, and according to, the instrument manufacturer's specifications, using calibration standards traceable to those set by the National Bureau of Standards, U.S. Department of Commerce or other nationally recognized standards;

(c) Control drawings and specifications so that the product is manufactured as certified;

(d) Report to NIOSH any knowledge of a product distributed with critical characteristics not in accordance with the certification specifications;

(e) Permit a representative(s) of NIOSH to conduct an in-plant audit of the inspection and tests, instrument calibration, and drawing and specification control, if NIOSH has reason to believe a certified respirator is

in nonconformance with the requirements of the part;

(f) Make certified products available for audit, upon request by NIOSH but not more than once a year except for cause, at no cost and at a mutually agreeable site and time.

§ 84.21 Discovery of defect or failure of compliance by manufacturer; notice requirements.

Any manufacturer who discovers that any respirator produced or assembled by him fails to comply with an applicable requirement contained in this part shall:

(a) In accordance with § 84.22, notify NIOSH within one work day of discovery of the failure to comply, if such failure poses an immediate and significant threat of serious injury or death, or

(b) If such failure to comply does not pose an immediate and significant threat of serious injury or death, notify NIOSH within a reasonable time after discovery in accordance with § 84.22, and

(c) Furnish notification if so directed by NIOSH, in accordance with § 84.23, to the following persons:

(1) The dealers or distributors to whom such respirator was delivered by the manufacturer; and

(2) The purchaser of such respirator and any subsequent transferee of such respirator (where known to the manufacturer or where the manufacturer upon inquiry to dealers, distributors, or purchasers can identify the present user).

§ 84.22 Notification by the manufacturer to NIOSH.

The notification to NIOSH required by § 84.21 shall be by telephone or telegram which shall be confirmed in writing by letter, and shall include the following information:

(a) Identification of the respirator or respirators involved;

(b) The total number of such respirators so produced, and the approximate number of such respirators which have left the place of manufacture;

(c) The expected usage for the respirator if known to the manufacturer;

(d) A description of the defect in the respirator or the manner in which the respirator fails to comply with any applicable requirement contained in this part;

(e) An evaluation of the hazards reasonably related to the defect or the failure to comply with the applicable requirement;

(f) The date and circumstances under which the defect or noncompliance was discovered; and

(g) The identification of any trade secret information which the manufacturer desires kept confidential; and

(h) Any other relevant information which NIOSH may require.

§ 84.23 Notification by the manufacturer to affected persons.

(a) The notification by the manufacturer to the persons specified in § 84.21 (c) shall be made within 14 days from the receipt of such directive from NIOSH and shall include the following:

(1) In clear and nontechnical terms, the information prescribed in § 84.22, paragraphs (a), (d), (e), and (h) and instructions with respect to use of the respirator pending the correction of the defect; and;

(2) The following statement:

The manufacturer will remedy the defect or bring the respirator into compliance with each applicable requirement contained in respirator certification regulations in accordance with a plan to be approved by NIOSH, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, NIOSH has approved a plan for the repair, replacement or refund of the respirator, the notification may include the details of the approved plan in lieu of the above statement.

(b) The notification shall be sent—

(1) By certified mail to purchasers of the respirator and to subsequent transferees; and

(2) By certified mail or other more expeditious means to dealers and distributors.

§ 84.24 Copies of communications sent to purchasers, dealers, or distributors.

(a) Every manufacturer of respirators shall furnish to NIOSH a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of respirators of such manufacturer regarding any defect in such respirator or any failure of such respirator to comply with an applicable requirement contained in this part; and

(b) In the event NIOSH deems the content of such notices to be insufficient to protect the public health and safety, NIOSH may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means it deems appropriate.

§ 84.25 Determination by NIOSH that a respirator fails to comply or has a defect.

(a) If NIOSH, through testing, inspection, research, or examination of reports or other data, determines that any respirator does not comply with an applicable requirement contained in this part, NIOSH shall within one work day notify the manufacturer of the respirator in writing specifying:

(1) The respirator or respirators involved;

(2) The defect in the respirator or the manner in which the respirator fails to comply with the applicable requirements contained in this part;

(3) NIOSH's findings, with reference to the tests, inspections, studies, or reports upon which such findings are based; and

(4) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to health or safety of the user of the respirator.

(b) Every manufacturer who receives a notice under paragraph (a) of this section shall reply to NIOSH in writing in accordance with § 84.22 of this part, paragraphs (b), (c), (e), and (g). If such failure appears to pose an immediate and significant threat of serious injury or death, reply shall be made within 24 hours. If such failure to comply does not pose an immediate and significant threat of serious injury or death, the reply shall be made to NIOSH within a reasonable time.

(c) If, after the expiration of the period of time contained in the notice, from NIOSH specified in paragraph (a) of this section, NIOSH determines that the respirator does not comply with an applicable requirement contained in this part, NIOSH shall direct the manufacturer to furnish the notification to the persons specified in § 84.21(b) in the manner specified in § 84.23. The manufacturer shall furnish the required notification within 14 days from the date of receipt of such directive.

Subpart D—Respirator Testing by Applicant

§ 84.30 Laboratory testing by applicant and interim certification.

(a) The applicant shall conduct the laboratory tests necessary to determine if the applicant's respirator meets the relevant performance standards set forth in Subparts O through Z of this part. In addition, the applicant shall test the respirator to determine if the respirator performs as expected and is free from characteristics or defects which may make it unsafe for its anticipated use.

(b) The applicant shall submit a written laboratory test report to NIOSH which shall include:

(1) The results of the tests described in paragraph (a) of this section;

(2) A detailed description of the test procedures employed in producing the test results;

(3) A detailed description of the data and method of data analysis used in obtaining the test results.

(c) NIOSH may, at its discretion, undertake its own testing and/or evaluation of applicant's respirator for the purpose of verifying the test results or conclusions included in applicant's test report.

(d) In addition to the requirements of this part, NIOSH may require, as a further condition of certification, additional tests reasonably necessary to evaluate the quality, effectiveness, or safety of the respirator submitted to NIOSH for certification. NIOSH will notify the applicant in writing of these additional requirements, stating generally the reasons for such requirements.

(e) NIOSH will review the applicant's laboratory test report to determine if the report provides substantial evidence that the applicant's respirator:

(1) Meets the relevant performance requirements set forth in Subparts O through Z of this part;

(2) Performs as expected;

(3) Is free from defects or characteristics that may make it unsafe for its anticipated use.

(f) Within 90 days of the acceptance by NIOSH of the applicant's laboratory test report, NIOSH will issue a notification letter to the applicant indicating whether the laboratory test report provides substantial evidence that the applicant's respirator complies with the requirements of paragraph (e) of this section.

(1) If NIOSH concludes that the applicant's report does provide sufficient evidence of such compliance, the notification letter will constitute an interim certification of the respirator pending a decision by NIOSH on final certification which is contingent upon satisfactory results from workplace or simulated workplace testing.

(2) If NIOSH concludes that the applicant's report does not provide sufficient evidence of such compliance, NIOSH will inform the applicant in writing of its intention to deny interim certification. The letter shall inform the applicant of the basis for the denial and of the applicant's right to appeal the denial in accordance with the provisions in Subpart I.

§ 84.31 Guidelines for workplace or simulated workplace testing.

In conducting workplace or simulated workplace testing the applicant shall conform to the following general guidelines:

(a) The applicant shall utilize a methodology and research design which can be expected to adequately determine if the respirator will perform as required by this part and is free from defects or characteristics which may make it unsafe for its anticipated use;

(b) The applicant shall provide for testing of the applicant's respirator in actual and/or simulated workplace conditions that are reasonably representative of those in which the applicant anticipates the respirator will be used;

(c) The applicant shall provide for testing of applicant's respirator by experts qualified by training and experience to evaluate the effectiveness and safety of the respirator.

§ 84.32 Workplace or simulated workplace testing by applicant; Certification of minimum performance level.

(a) *Workplace or simulated workplace test report.* The applicant shall provide NIOSH with a test report that provides substantial evidence that the applicant's respirator will provide a workplace or simulated workplace protection factor at least equal to that assigned to that category of respirators in paragraph (b) of this section. In addition, the applicant's test report shall provide:

(1) Substantial evidence that the applicant's respirator performs as is expected and is free from defects or characteristics which may make it unsafe for its anticipated use; and

(2) An explanation of the method of observation and recording results, including the variables measured, quantitative assessment of subject response and steps to be taken to minimize bias on the part of the subject and the observer.

(b) Workplace or simulated workplace evaluation of respirator performance shall be conducted so as to determine the distribution of workplace protection factors or simulated workplace protection factors that are measured in workplaces or in simulated workplaces and in work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used.

(1) The workplace protection factor, WPF, or simulated workplace protection factor, SPF, is a measure of the effectiveness of a respirator that is being properly worn and used during normal work activities by a person who has been properly fitted. The WPF or SPF as appropriate can be determined by: WPF or $SPF = C_o/C_i$ where C_o is the time-weighted average (TWA) contaminant concentration outside the facepiece which would be inhaled if the respirator were not used, and C_i is TWA contaminant concentration inside the respirator facepiece which is inhaled by the respirator wearer.

(2) The assigned protection factor is that above which 95 percent of the workplace protection factors would be expected to exceed at a confidence level of 95 percent. The assigned protection factor, PF_a, can be calculated by the following general formula as explained by Natrella[2] for one-sided tolerance limits: $PF_a = PF_a(\lambda, P)$, where $\lambda = 0.95$ and $P = 0.95$. For example, a class of respirators with a $PF_a = 50$ would be expected to provide workplace protection factors or simulated workplace protection factors in excess of 50 for at least 95 percent of users.

Minimum Assigned Protection Factors

Respirator Class	Minimum PFa
Air Purifying	
negative pressure	
full facepiece	50
half or quarter facepiece	10
with low efficiency filter	5
powered	
tight fitting facepiece	50
loose fitting helmet	25
Atmosphere Supplying	
self-contained (SCBA)	
negative pressure	50
positive pressure	10,000
air-line	
negative pressure	
full facepiece	50
half facepiece	10
positive pressure	
full facepiece	2,000
half facepiece	1,000
continuous flow	
half facepiece	50
full facepiece	50
hood or helmet	25
combination positive pressure SCBA with air-line	
half facepiece	1,000
full facepiece	10,000

(c) At the conclusion of the workplace or simulated workplace tests, the applicant shall report the workplace or simulated workplace test results to NIOSH.

(1) If, after completing its review, NIOSH is satisfied that the respirator meets the minimum assigned protection factor requirements of this section and is free from defects or characteristics which may make it unsafe for its anticipated use, NIOSH will issue the applicant a certificate indicating NIOSH certification of the respirator.

(2) If applicant's workplace or simulated workplace test results do not provide substantial evidence that the respirator meets the aforementioned requirements, NIOSH will inform the applicant in writing of its intention to deny certification. The letter shall inform the applicant of the basis for the denial and of the applicant's right to appeal the denial in accordance with the provisions in Subpart I.

(d) NIOSH will issue a certificate to the applicant or send a notification of denial to the applicant within 90 days of acceptance by NIOSH of the applicant's workplace or simulated workplace test results.

§ 84.33 Workplace or simulated workplace testing by applicant; Certification of higher performance level.

In lieu of conformance to the requirements of § 84.32 of this part, the applicant may perform workplace or simulated workplace testing, designed to demonstrate a higher level of performance, i.e. protection factor, than those specified in § 84.32.

(a) Where an applicant intends to submit for certification at a higher level of performance than those specified in § 84.32, the applicant shall advise NIOSH of that intent, prior to initiation of the workplace or simulated workplace testing. NIOSH reserves the right to review the statistical protocol for the study and to observe the conduct of the workplace or simulated workplace tests.

(b) Workplace or simulated workplace evaluation of respirator performance shall be conducted so as to determine the distribution of workplace protection factors or simulated workplace protection factors that are measured in workplaces or in simulated workplaces and in work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used.

(c) The workplace protection factor, WPF, or simulated workplace protection factor, SPF, is a measure of the effectiveness of a respirator that is being properly worn and used during normal work activities by a person who has been properly fitted. The WPF or SPF as appropriate can be determined by: WPF or $SPF = C_o/C_i$ where C_o is the time-weighted average (TWA) contaminant concentration outside the facepiece which would be inhaled if the respirator were not used, and C_i is TWA

contaminant concentration inside the respirator facepiece which is inhaled by the respirator wearer.

(d) The applicant shall provide NIOSH with a test report that provides substantial evidence that the applicant's respirator will provide an assigned protection factor greater than that assigned to that category of respirators in paragraph (c) of § 84.32. The applicant's test report shall provide:

(1) Data that statistically demonstrates that 95 percent of the workplace protection factors would be expected to exceed the higher protection factor at a confidence level of 95 percent. The higher assigned protection factor, PF_a, can be calculated by the following general formula as explained by Natrella[2]: $PF_a = PF_a(\lambda, P)$, where $\lambda = 0.95$ and $P = 0.95$;

(2) Evidence that the respirator is free from defects or characteristics which may make it unsafe for its anticipated use; and

(3) An explanation of the method of observation and recording results, including the variables measured, quantitative assessment of subject response and steps to be taken to minimize bias on the part of the subject and the observer.

(e) If NIOSH finds that the data support the assignment of a higher protection factor than the minimum level of protection factor specified in § 84.32(c), NIOSH will certify the higher protection factor as part of the respirator certification. If NIOSH determines that the data do not support the higher protection factor, NIOSH may require further testing and/or may choose to conduct validation testing of the applicant's respirator or may deny the application. NIOSH will inform the applicant in writing of its intention to deny certification. The letter shall inform the applicant of the basis for the denial and of the applicant's right to appeal the denial in accordance with the provisions in Subpart I.

§ 84.34 Availability of respirator test results and protocols.

NIOSH will make available, for public review, all laboratory and workplace or simulated workplace test results and test protocols utilized in tests conducted under the provisions of this part.

Subpart E.—NIOSH Certification Label

§ 84.40 Required contents of a certification label.

(a) A NIOSH certification label shall contain:

(1) The name and address of the manufacturer;

(2) The name and letters or numbers by which the respirator or respirator component is designated for trade purposes;

(3) The lot number or other appropriate designation of date of manufacture;

(4) The NIOSH logo and the words, "Certified by the U.S. Government";

(5) The certification number assigned by NIOSH;

(6) The effective date of the NIOSH performance standard against which the respirator was tested and certified;

(7) Any conditions or limitations specified by NIOSH; and

(8) The following statement:

Complaints concerning the performance of this respirator should be forwarded to the manufacturer and a copy should be sent to Division of Safety Research, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505

(9) Manufacturers shall have the completely assembled and fully charged weight and completely assembled and fully discharged weight permanently and legibly marked on all self-contained breathing apparatus.

(b) In addition to the requirements set forth in paragraph (a) of this section, the certification labels for mine rescue and emergency respirators as defined in Subpart K shall contain the MSHA logo and any conditions or limitations specified by MSHA.

§ 84.41 General label and marking requirements.

(a) Legible reproductions or abbreviated forms of the certification label acceptable to NIOSH for use on each respirator or respirator component shall be attached to or printed on the following locations:

Respirator Type	Label Type	Location
Self-contained breathing apparatus	Entire	Harness assembly and canister (where applicable).
Gas and vapor air purifying canister respirator	Entire	Respirator container and canister.
Air-line respirator	Entire	Respirator container or instruction card.
Particulate air purifying respirator	Entire	Respirator container and filter container.
	Abbreviated	Filters.
Gas and vapor air purifying cartridge respirator	Entire	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated	Cartridges and filters

(b) Each respirator, major respirator component, and respirator container shall be labeled distinctly to show the name of the manufacturer, the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or date of manufacture.

(c) Pursuant to a request from the manufacturer of a certified respirator, NIOSH will provide prior review of the contents of a proposed certification label.

Subpart F—Maintenance, Informational and Instructional Materials

§ 84.50 Operation and maintenance manuals.

(a) Operation and maintenance manuals shall be provided with each respirator and shall contain the following as minimum requirements:

(1) Operation manuals shall include principles of operation, procedures for fitting to the wearer, a description of parts, operation and use, limitations of use, operation testing, trouble-shooting guidance, and hazards.

(2) Maintenance manuals shall include preventive maintenance procedures, routine repair procedures, test procedures, suggested spare parts, parts lists, and storage recommendations.

(b) The applicant's operation and maintenance manuals shall be written so as to be easily comprehensible to the user.

Subpart G—Modification of Certified Respirators

§ 84.60 Major modification of certified respirators.

(a) Manufacturers of respirators certified by NIOSH who wish to make major modifications to such respirators shall submit applications for certification of such major modifications to NIOSH as set forth in Subpart B of this part.

(b) If an applicant submits to NIOSH a proposed major modification of a respirator which holds a current NIOSH/MSHA certification, the proposed major modification shall meet the performance standards in effect on the date of the original certification of the respirator. NIOSH, at its discretion, may test or evaluate the respirator and verify the applicant's data.

(c) If the respirator as modified fails to meet the relevant NIOSH performance standards in effect on the date of the original certification, NIOSH will inform the applicant in writing of its intention to deny certification of the modified respirator. The letter shall inform the applicant of the basis for the denial and of the applicant's right to appeal the denial in accordance with the provisions of Subpart L.

§ 84.61 Minor modification of certified respirators.

(a) Manufacturers of respirators certified by NIOSH who make minor modifications to such respirators, shall maintain a record of such minor modifications for the duration of the certification.

(b) The record of such minor modifications shall be made available to NIOSH, upon request, within 1 week. The record of such minor modifications shall be made available for inspection by NIOSH personnel during the in-plant audit prescribed in § 84.20(e).

Subpart H—Withdrawal of Certification

§ 84.70 Withdrawal of certification for cause.

NIOSH may withdraw its certification of a respirator for cause. Cause includes, but is not limited to:

(a) Failure of a manufacturer to consistently and effectively implement a quality assurance program which meets the objectives and requirements set forth in § 84.20;

(b) Failure of a manufacturer to promptly allow NIOSH to contact or enter its facility for the purpose of verifying the manufacturer's quality assurance program as provided for in § 84.20(e);

(c) Failure of a manufacturer to provide the notifications required in §§ 84.21 through 84.25;

(d) Placement by a manufacturer on a certified respirator of a NIOSH label not as prescribed in § 84.40;

(e) Failure of a manufacturer to maintain the records required in § 84.61 and/or to provide them to NIOSH in a timely fashion upon request;

(f) The subjection by a manufacturer of a respirator certified by NIOSH to major modification and the selling or advertising for sale of such modified respirator as NIOSH certified without having obtained NIOSH certification of the modification;

(g) Failure of a manufacturer to consistently produce a respirator that is reliable and free from defects or characteristics which may make it unsafe for its anticipated use;

(h) A determination by NIOSH that a test upon which certification depends does not provide reasonable protection to the user of a respirator which has been certified based entirely or in part upon satisfactory performance during such test;

(i) A determination by NIOSH that a certified respirator is so defective as to be dangerous to the health or safety of the user; and

(j) Failure of a manufacturer to permit NIOSH to select a reasonable number of respirators for audit testing as provided for in § 84.20(f).

§ 84.71 Procedure for withdrawal of certification for cause and manufacturer's right to appeal.

(a) If NIOSH determines that cause exists to warrant withdrawal of NIOSH certification of a respirator, NIOSH will notify the manufacturer of the NIOSH intent to withdraw certification, and inform the manufacturer of the reasons for the proposed withdrawal of certification and of the manufacturer's right to appeal the proposed withdrawal of certification.

(b) The manufacturer shall have 30 working days from the date of receipt from NIOSH of the notice of proposed withdrawal of certification to file a written notice of appeal with the Director of NIOSH.

(c) If, within 30 working days, the manufacturer fails to notify the Director of NIOSH of the manufacturer's intent to appeal the proposed withdrawal or certification, the Director of NIOSH shall notify the manufacturer that certification is withdrawn.

(d) If, within 30 working days, the manufacturer notifies the Director of NIOSH of the manufacturer's intent to appeal the proposed withdrawal of certification, the manufacturer will be granted a hearing as provided for in Subpart I of this part.

Subpart I—Appeals

§ 84.80 Appeal procedure.

Appeals by an applicant or manufacturer shall be to the Director of NIOSH. Upon receipt of a notice of appeal, the Director of NIOSH will refer the matter to an Administrative Law Judge who shall hear the appeal. The Administrative Law Judge will make a recommendation to the Director of NIOSH based upon relevant material and reliable evidence of record. Within 30 days of the rendering of the recommendation by the Administrative Law Judge, the Director of NIOSH will revise, reverse or affirm the original NIOSH determination.

Subpart J—Fee Determination

§ 84.90 Fees.

(a) In addition to the application fee prescribed in § 84.11(i), NIOSH will charge fees for services it provides in testing and evaluating products for which certification or related action is requested.

(b) NIOSH will compute fees on the basis of cost to the government to provide these services using the following methodology. For each service provided for a group of related products, NIOSH will determine a flat fee to cover the direct and indirect costs. Products are grouped based on function, construction or technology in accordance with certification requirements applicable to the product. Direct costs are based on current compensation costs for technical and support personnel, allocated according to the staff time spent in the previous fiscal year for each service for a product group. Indirect costs include a proportionate share of management personnel compensation costs, other administrative support costs and facility costs for the previous fiscal year, and depreciation of buildings and equipment. For product groups with insufficient data upon which to calculate a fee, NIOSH will charge an hourly rate based on the actual technical and support staff time spent on the action plus an appropriate share of indirect costs. Costs related to travel and transportation for certification of products tested or evaluated at the manufacturing or installation site are in addition to these flat or hourly fees and will be charged on an actual cost basis.

(c) NIOSH will publish a notice in the Federal Register announcing the availability of the current fee schedule by January of each year.

Subpart K—Mine Rescue and Emergency Respirators

§ 84.100 MSHA Review.

NIOSH will consult with the Mine Safety and Health Administration (MSHA) when an application for approval is submitted for a respirator designed for mine rescue or other mine emergencies. MSHA will review the application to determine the suitability of the respirator for the mining environment. Any use limitation related to mine safety or health shall be included as a condition for respirator approval. No respirator intended for emergency use in mines shall be approved without concurrence by MSHA.

Subparts L–N [Reserved]

Subpart O—Technical Definitions

§ 84.200 Definitions as used in this part.

"Adequate Oxygen" means an atmosphere which contains at least an oxygen partial pressure of 148 millimeters of mercury (19.5 percent oxygen by volume at sea level).

"Air-Purifying Respirator" means a respirator which protects the wearer by removing contaminants from the ambient air.

"Atmosphere Supplying Respirator" means a respirator which provides the wearer with air or oxygen from a source independent of the ambient atmosphere

"Breathing Tube" means a tube at or near ambient pressure through which respirable air is intended to be supplied to the wearer's breathing zone.

"Canister" or "Cartridge" means the active element of a gas and vapor air-purifying respirator which contains the sorbent and/or catalyst which removes specific contaminants from the air drawn through it.

"Compressed Breathing Gas" means oxygen or air stored in a compressed state and supplied to the wearer in gaseous form.

"Contaminant" means a harmful material in the normal respirable atmosphere.

"dBA" means sound pressure levels in decibels, as measured with the A-weighted network of a standard sound level meter using slow response.

"End-of-Service-Life Indicator" means an indicator or warning device on a respirator which warns the wearer that the end of the service life of the device is approaching.

"Exhalation Valve" means a one-way valve that allows exhaled air to exhaust from the respirator and prevents outside air from entering.

"Eyepiece" means a gas-tight, transparent window in a facepiece through which the wearer may see.

"Facepiece" means a respirator component that serves to interface the respirator and the wearer and includes tight fitting facepieces, loose fitting facepieces, and mouthpieces.

"Face Seal Leakage" means the inward leakage that occurs at the interface of the wearer and the respirator plus all other sources of inward leakage except leakage due to air purifying element penetration. When there is no air purifying element penetration, face seal leakage is given by C_i/C_o where C_i is the inhaled concentration and where C_o is the concentration of challenge aerosol outside the facepiece. It may also be expressed as a percentage, if so indicated.

"Filter" means a media component used in respirators to remove solid and/or liquid particles from the inspired air.

"Filter Efficiency" means $1-(C_p/C_o)$, where C_o is the concentration of challenge aerosol and where C_p is the concentration of aerosol penetrating the filter. It may also be expressed as a percentage, if so indicated.

"Filter Penetration" means C_p/C_o where C_o is the concentration of challenge aerosol and where C_p is the concentration of aerosol penetrating the filter. It may also be expressed as a percentage, if so indicated.

"Gas" means an aeriform fluid which is in a gaseous state at standard temperature and pressure.

"Gas and Vapor Respirator" means an air-purifying respirator which provides air to the wearer by removing specific gases and vapors from the ambient air.

"Head Harness" means a device for holding the facepiece securely in place on the wearer's face.

A "Hood" or "Helmet" is a respirator component which covers the wearer's head, and possibly also the neck and shoulders, and is supplied with incoming respirable air for the wearer to breathe. It may include a head harness and connection for a breathing tube.

"Immediately Dangerous to Life or Health" (IDLH): Respiratory exposures which:

(1) Pose an immediate threat of loss of life or of irreversible or delayed effects on health or;

(2) Eye exposures which would prevent an escape from such an atmosphere.

"Liquefied Breathing Gas" means oxygen or air stored in liquid form and supplied to the wearer in a gaseous form.

"Loose Fitting Facepiece" means a facepiece which is not designed to provide a gas-tight seal with the wearer's face, but which prevents the inward contamination of the breathing zone by an outward flow of air.

"Mouthpiece" is that portion of a respirator that is designed to provide a gas tight seal with the wearer's lips when the mouthpiece is inserted into the mouth.

"Negative Pressure Respirator" means any respirator which relies on negative pressure in the facepiece due to wearer's inspiration to provide respirable air.

"Non-Powered Air-Purifying Respirator" means an air-purifying respirator which relies on negative pressure in the facepiece due to the wearer's inspiration to draw air through the air-purifying element.

"Noseclamp" is a device which provides a gas-tight seal of the nostrils.

"Oxygen Deficient Atmosphere" means an atmosphere which contains an oxygen partial pressure of less than 148 millimeters of mercury (19.5 percent by volume at sea level).

"Particulate Respirator" means an air-purifying respirator which removes solid and liquid particulates from the ambient air.

"Positive Pressure Respirator" means any atmosphere supplying respirator which maintains a positive facepiece pressure at work rates less than or equal to those specified in this part.

"Powered Air-Purifying Respirator" means an air-purifying respirator which uses a blower to deliver air through the air purifying element to the wearer's breathing zone at the flow rates specified in this part.

"Resistance" means opposition to the flow of gas, as through a cartridge, canister, filter, orifice or valve.

"Self-Contained Breathing Apparatus" means an atmosphere supplying respirator in which the source of air or oxygen is contained within the respirator independent of any other source.

"Service Time (Service Life)" is the period of time that a respirator provides protection to the wearer, such as the period of time that an air-purifying device is effective for removing a harmful substance from inhaled air.

"Tight Fitting Facepiece" means a facepiece which is designed to provide a gas tight seal with the wearer's face.

"Vapor" means the gaseous state of a substance that is solid or liquid at ordinary temperature and pressure.

Subpart P—Classification

§ 84.210 Classification of certified respirators.

Respirators certified under the provisions of this part are first classified as either air-purifying respirators or atmosphere supplying respirators.

(a) Air-purifying respirators are further classified as either gas and vapor respirators or particulate respirators.

(1) Gas and vapor respirators are further classified as cartridge respirators or canister respirators.

(i) Cartridge respirators are further classified as either non-powered cartridge respirators or powered cartridge respirators. Both are further classified according to the specific gas or vapor or class of gas and vapor for which the respirator is certified.

(ii) Canister respirators are further classified as either low capacity non-powered canister or low capacity powered canister respirators or high capacity non-powered canister or high capacity powered canister respirators depending on the capacity of the sorbent or catalyst.

(2) Particulate respirators are classified as either non-powered particulate respirators or powered particulate respirators. Particulate respirators are further classified in terms of the efficiency of their filter elements as either high efficiency, medium efficiency or low efficiency.

(b) Atmosphere supplying respirators are classified as either self-contained breathing apparatus or air-line respirators.

(1) Self-contained breathing apparatus are classified as either open-circuit self-contained breathing apparatus or closed-circuit self-contained breathing apparatus.

(i) Open-circuit self-contained breathing apparatus are further classified as either positive pressure open-circuit self-contained breathing apparatus (P) or negative pressure open-circuit self-contained breathing apparatus (N).

(ii) Closed-circuit self-contained breathing apparatus are further classified as either positive pressure closed-circuit self-contained breathing

apparatus (P) or negative pressure closed-circuit self-contained breathing apparatus (N).

(iii) All classifications of self-contained breathing apparatus are further classified as "escape only" (Es) or "entry and escape" (En).

(iv) All classifications of self-contained breathing apparatus are further classified in terms of service life as either 3 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or other service times as may be prescribed by NIOSH.

(2) Air-line respirators are further classified in terms of the regulator type as either positive pressure air-line respirators, negative pressure air-line respirators, or continuous flow air-line respirators.

(c) The classification described above in this section is indicated schematically as follows:

Air-Purifying Respirators

Gas and Vapor Respirators

Cartridge Respirator
- Powered Cartridge
- Non-Powered Cartridge

Canister Respirators
- Non-Powered Low Capacity Canister
- Powered Low Capacity Canister
- Non-Powered High Capacity Canister
- Powered High Capacity Canister

Particulate Respirators

Non-Powered Particulate
- Low Efficiency
- Medium Efficiency
- High Efficiency

Powered Particulate
- Medium Efficiency
- High Efficiency

Atmosphere Supplying Respirators

Self-Contained Breathing Apparatus
- Open Circuit SCBA (P or N) (Es or En)
- Closed Circuit SCBA (P or N) (Es or En)

Air-line Respirators
- Positive Pressure Air-line
- Negative Pressure Air-line
- Continuous Flow Air-line

§ 84.211 Combination respirators.

Respirators which are combinations of any two or more of the basic classifications described in § 84.210 may be certified under the provisions of this part. Unless specifically indicated otherwise in this part, such combination respirators shall comply with the requirements of each basic respirator classification of which it is composed. For example, a combination particulate respirator and cartridge respirator shall meet the requirements for a particulate respirator and the requirements for a cartridge respirator.

Subpart Q—General Construction and Performance Requirements

§ 84.220 General construction requirements.

(a) Respirators shall be designed and constructed to ensure against creation of any hazard to the wearer.

(b) Respirators shall be constructed of materials which are durable and cannot be damaged by normal handling.

(c) Respirators and components thereof, except those not intended to be reused, shall be constructed of materials which will withstand repeated cleaning and disinfection as recommended by the manufacturer as part of the instructions for use and maintenance.

(d) Respirators shall be designed, constructed, and assembled to permit easy access for inspection, cleaning, and repair or replacement of functional parts without adversely affecting the performance of the respirator.

(e) All respirators incorporating an eyepiece(s) or window(s), such as a full facepiece respirator or a helmeted powered air-purifying respirator, shall provide impact and penetration resistance equal to or greater than that specified in paragraphs 5.2.8.1 and 5.2.8.2 of the ANSI Z87.1–1979 standard.

(f) All respirators shall permit the wearer adequate vision and be designed to permit the wearing of safety glasses meeting the requirements of the ANSI Z87.1–1979 standard without adversely affecting the performance of the respirator. Temple bars of such safety glasses may be removed for use in full facepieces.

(g) Respirators with mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal at the nostrils.

(h) Facepieces, hoods, and helmets shall be designed and constructed to minimize integral eyepiece, spectacle, and window(s) fogging.

(i) Respirators shall be resistant to corrosion and deterioration from chemical and physical agents to which they are likely to be exposed in the workplace.

(j) Respirator components which come into contact with the wearer's skin shall be made of materials which are non-irritating to skin of normal sensitivity.

(k) The components of each respirator for use in mines where permissibility is required shall meet the requirements for permissibility and intrinsic safety set forth in Title 30, Code of Federal Regulations, Part 18, Schedule 2G.

§ 84.221 Test requirements; General.

Where a combination respirator is assembled from two or more types of respirators, as described in § 84.211, each of the individual respirator types which have been combined shall, as applicable, meet the minimum requirements for such respirators set forth in this part.

§ 84.222 Breathing tubes.

Breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(a) Restriction of free head movement;

(b) Disturbance of the fit of facepieces, mouthpieces/noseclamps, hoods, or helmets;

(c) Interference with the wearer's activities; and

(d) Shutoff of airflow due to kinking, or from body, chin or arm pressure.

§ 84.223 Body harnesses.

(a) If a respirator is equipped with a body harness such harness shall be designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Body harnesses shall be designed and constructed to permit easy donning and removal of the respirator, to hold the respirator securely in place during use, to permit easy removal and replacement of respirator parts, and, where applicable, to provide for holding a full facepiece in the ready position when not in use.

(c) Body harnesses for self-contained breathing apparatus shall not melt when exposed to temperatures of 400 °F for 30 minutes.

§ 84.224 Respirator containers.

(a) Respirators shall be packaged for shipment and sale in a durable container bearing markings which show the manufacturer's name, the type and commercial designation of the respirator it contains, and all appropriate labels.

(b) Containers may provide for storage of more than one respirator; however, such containers shall prevent contamination of respirators which are not removed, and prevent damage to respirators during transit.

(c) Containers for gas and vapor air-purifying canister respirators and self-contained breathing apparatus shall permit rapid removal of the respirator.

(d) Containers supplied by the applicant for carrying or storing self-contained breathing apparatus will be inspected, examined, and tested as components of the respirator for which certification is sought.

§ 84.225 Head harnesses.

(a) Tight fitting facepieces shall be equipped with head harnesses designed and constructed to provide adequate tension during use and an even

distribution of pressure over the entire area in contact with the face.

(b) Mouthpiece/noseclamps shall be equipped, where applicable, with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place.

(c) Facepiece head harnesses shall be adjustable and, where applicable, replaceable.

§ 84.226 Inhalation and exhalation valves.

(a) Inhalation and exhalation valves shall be protected against distortion.

(b) If air-purifying respirators are equipped with inhalation valves, such valves shall prevent exhaled air from entering and adversely affecting cartridges, canisters, and filters.

(c) If a respirator is equipped with an exhalation valve, such valve shall be:

(1) Protected against damage and external influence; and

(2) Designed and constructed to prevent inward leakage of contaminated air.

§ 84.227 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats shall be subjected to a suction of 25 mm water-column height while in a normal operating position.

(b) Leakage between the valve and valve seat shall not exceed 30 ml per minute.

§ 84.228 Air velocity and noise levels; Hoods and helmets.

Noise levels generated by the respirator, except as indicated below, shall be measured inside the hood or helmet at maximum obtainable airflow and within pressure and hose length requirements and shall not exceed 80 dBA when worn in accordance with the manufacturer's instructions. Where the respirator is an escape self-contained breathing apparatus with a hood or helmet, and the rated service time does not exceed 10 minutes, the noise level shall not exceed 100 dBA when the apparatus is worn in accordance with the manufacturer's instructions.

§ 84.229 Procedure for sequential analysis of performance test results using one-sided tolerance limits.

(a) Unless otherwise specified in this part, all performance tests which produce quantitative results shall at a minimum be analyzed for compliance with the relevant performance specification using one-sided normal tolerance limits at the 95 percent confidence level for 95 percent of the target population represented by the tested samples.

(b) For a performance specification that represents an upper acceptable limit for some measured performance characteristic, a one-sided upper tolerance limit (UTL) will be calculated, which must equal or lie below the performance specification for the samples to demonstrate acceptable performance.

(c) For a performance specification that represents a lower acceptable limit for some measured performance characteristic, a one-sided lower tolerance limit (LTL) will be calculated, which must equal or exceed the performance specification for the samples to demonstrate acceptable performance.

(d) The performance of three (3) samples shall first be measured by procedures of the relevant performance test. Calculate either a UTL or LTL using: $UTL=(m+Ks)$ and $LTL=(m-Ks)$, where (m) is the sample arithmetic mean, (s) is the sample standard deviation (with an (n−1) divisor), and (K) is the tolerance limit factor 6.158. If the three (3) samples demonstrate acceptable performance at the 95 percent confidence level, the performance test may be terminated.

(e) If the initial sample of three (3) fails to demonstrate performance at the required level of confidence, three (3) additional samples shall be tested and m, s, and UTL or LTL shall be recalculated for the total sample of six (6) using a K of 3.006. If the six (6) samples fail to demonstrate acceptable performance at the 95 percent confidence level, the respirator under evaluation shall be considered unacceptable.

Subpart R—Face Seal Leakage

§ 84.230 Applicability.

All respirators shall be tested and evaluated for face seal leakage in accordance with the provisions of this subpart. The term "face seal leakage" refers to the inward leakage that occurs at the interface between the wearer and the respirator even though for some respirators the sealing may not actually occur on the wearer's face.

§ 84.231 General.

(a) In this subpart it is assumed that the only two sources of inward leakage of contaminant into the respirator wearer's breathing zone are face seal leakage and, where applicable, filter penetration. That is, it is assumed that for a well designed respirator all other sources of leakage (such as hose couplings, exhalation valves, lens seals, etc.) are negligible. If these other sources are not negligible, the tests of this subpart are intended to include them as if they were face seal leakage. Subtracting the effect of these additional sources shall not be permitted in the analysis of data.

(b) Face seal leakage and filter penetration are measured separately and limitations are placed on each separately in this part. Face seal leakage is addressed in this subpart while filter penetration is addressed in other subparts. Accordingly, this subpart defines face seal leakage to include all sources of leakage except filter penetration. Therefore, when air-purifying respirators are tested for face seal leakage, the highest efficiency particulate filters compatible with the respirator shall be fitted. If the use of the highest efficiency filter available does not reduce the effects of filter penetration to negligible levels, the effect of filter penetration on the face fit test may be eliminated analytically in the analysis of data.

(c) Gas and vapor respirators shall be evaluated for face seal leakage with high efficiency particulate filters in place.

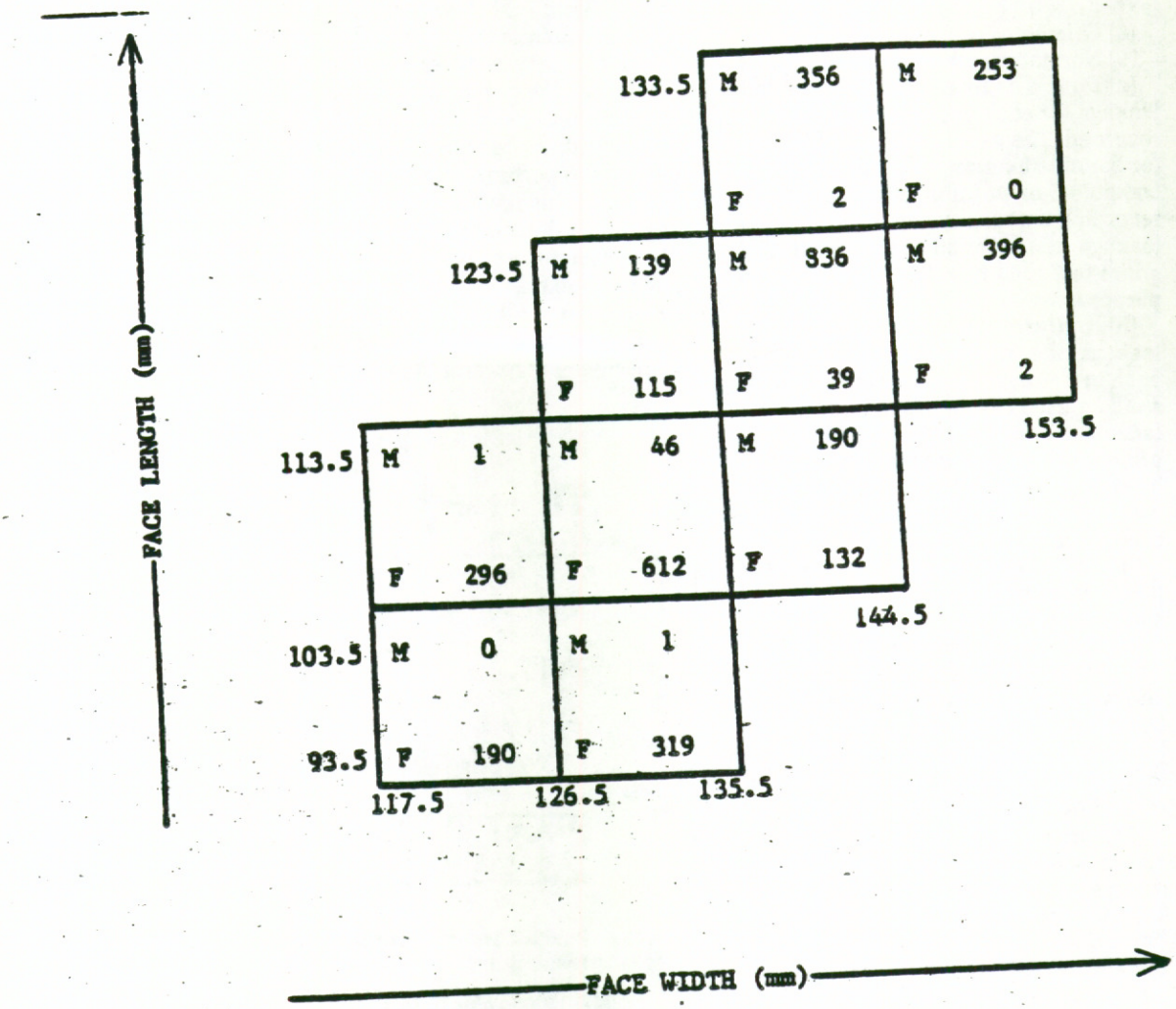
§ 84.232 Negative pressure respirators, either air-purifying or atmosphere supplying respirators.

(a) *Sizing.* The manufacturer shall specify to NIOSH as part of its application the range of facial sizes which the respirator is intended to fit. Such size specifications shall be in terms of face length (Menton-Nasal Root Depression Length) and face width (Bizygomatic Breadth). The applicant shall specify one or more contiguous cells of the Los Alamos panel structure shown in Figure 1.[1] The tests outlined in this subpart are intended to verify the ability of the respirator to accommodate the variety of facial shapes within the specified size range by panel testing.

(b) *Panel Selection.* Each facepiece shall be tested on a panel of 25 adult individuals having facial dimensions within the range of dimensions specified by the applicant. The distribution of facial sizes within a panel so constructed shall approximate the distribution of facial sizes of the general adult population having facial dimensions within the specified range. To achieve this end, the number of individuals in each panel cell shall be in approximate proportion to the distribution of the Los Alamos panel. Individuals having unshaven facial hair, deep scars, unusually deep wrinkles, or unusual facial deformity that would be positioned between the facepiece and the wearer's face, shall not be included in the panel.

[1] Hack, A., et al., Selection of Respirator Test Panel Representative of U.S. Adult Facial Sizes. Los Alamos Report No. LA-5488, issued March, 1974.

Figure 1



(c) *Pretest Fitting.* Each test subject shall be asked to follow the written donning and fitting instructions recommended by the applicant and included as part of the application. The test supervisor shall monitor the fitting activities to ensure—

(1) that the instructions are adequate and clear, and

(2) that the test subject follows the written instructions of the applicant.

If, in the judgment of the test supervisor, the fitting procedures have not been followed, the test supervisor shall intervene and assist in fitting the respirator in accordance with the applicant's written instructions. The test subject shall then wear the respirator for at least 15 minutes prior to beginning face seal leakage tests. During that waiting period the test subject may readjust the respirator to improve comfort or stability if the readjustments are provided for by the applicant's written instructions. The waiting period may be reduced or eliminated for short duration respirators.

(d) *Spectacles.* To ensure that respirators are compatible with the use of industrial safety spectacles, all half- and quarter-facepiece respirators shall be evaluated with the test subject properly fitted with safety spectacles that comply with requirements of ANSI Z87.1-1979 standard.

(e) *Test Hardware.* Facepieces shall be leak tested on each panel member using an appropriate aerosol of low toxicity such as crystalline sodium chloride or oil mist. The aerosol shall have a mass median aerodynamic diameter of 0.6±0.2 micrometers with a geometric standard deviation less than 2.2. The challenge aerosol concentration should not vary more than ±5 percent as a function of spatial position in the vicinity of the respirator being tested. The challenge aerosol concentration should not vary as a function of time more than ±10 percent. The aerosol detector shall be linear within 10 percent throughout its range of operation. All facepieces shall be probed or modified to obtain aerosol samples which can be used to determine the inhaled aerosol concentration.

(f) *Exercise Regimen.* During the quantitative leak testing, the test subject shall perform each of the following exercises for a minimum period of one minute in the following sequence:

(1) Normal breathing.

(2) Deep breathing.

(3) Turning head from side to side.

(4) Nodding head up and down.

(5) Repeatedly raising arms upward and simultaneously looking upward.

(6) Bending forward at waist and simultaneously extending arms downward toward toes.

(7) Talking, reading from prepared text.

(8) Grimacing or frowning, and

(9) Normal breathing.

(g) *Data.* The time averaged face seal leakage for each exercise shall be recorded. The average face seal leakage for the nine exercises, L, will be computed. In addition, a strip chart recording that shows the instantaneous leakage as a function of time for the entire test shall be retained for reference purposes.

(h) *Analysis.* Once the face seal leakage rate, L, has been determined for each test subject, the following analysis shall be used to determine if the facepiece under evaluation has a high probability of providing the required level of protection to that portion of the user population designated by the facial size range specified by the applicant.

(1) The analysis begins by tabulating the average face seal leakage, L, for each test subject.

(2) The inward leakage ratio $R=(1/L)-1$ is calculated for each value of L and tabulated. The leakage ratio, R, can be shown to correspond to the ratio between the volumetric flow rate through the face seal leak and the flow rate through the respirator filter.

(3) Assume that the values of log R are normally distributed and compute the mean and standard deviation.

(4) Compute the one sided tolerance limit, $X_L=X-ks$, the value above which there is 95 percent confidence that 95 percent of the values of log R will lie,[2] where X and s are the mean and standard deviation computed above and $k=1.838$.

(5) Compute the upper leakage limit, L_u, the value of L corresponding to X_L.

$L_u=1/(1+10^{X_L})$

As a result of this analysis it can be inferred with 95 percent confidence that 95 percent of the population represented by the test panel can achieve leakage values that are less than the upper leakage limit, L_u.

(i) *Marking.* Each facepiece shall be marked to indicate the range of facial sizes for which it is intended. The marking scheme shall be based on the panel structure of § 84.232(a).

(j) *Performance Criteria.* If the upper leakage limit, L_u, is less than the maximum face seal leakage allowed for the particular type of respirator under evaluation, the performance of the facepiece is considered acceptable. If it is greater than the maximum allowed leakage the performance of the facepiece is unacceptable. The maximum allowed face seal leakage for all full-facepiece respirators is 0.01 (or 1 percent, if expressed as a percentage). The maximum allowed face seal leakage for half- and quarter-facepieces on an air-purifying respirator is determined by which of the three filter classes is incorporated in the respirator. Filter elements are classified as low efficiency, medium efficiency and high efficiency filters, that is, having efficiencies of 95 percent, 99 percent and 99.97 percent, respectively. Half- and quarter-facepiece respirators employing low efficiency filters will have a maximum allowed face seal leakage of 0.05. Half- and quarter-facepieces having medium or high efficiency filters will have a maximum allowed face seal leakage of 0.02. The maximum allowed face seal leakage for half- and quarter-facepieces incorporated into atmosphere supplying respirators and gas and vapor respirators is 0.02. These performance criteria are summarized below:

Facepiece Type	Maximum Allowed Face Seal Leakage for Particulate Respirators		
	Low Efficiency	Medium Efficiency	High[a] Efficiency
Quarter	0.05	0.02	0.02
Half	0.05	0.02	0.02
Full/ Mouthpiece	0.01	0.01	0.01

[a] Applies also to atmosphere supplying and gas and vapor respirators.

§ 84.233 Positive pressure atmosphere supplying respirators.

(a) Facepieces used in positive pressure atmosphere supplying respirators shall be tested in both a negative pressure mode and a positive pressure mode. The negative pressure test may be eliminated if the facepiece is also incorporated into a negative pressure respirator which has been successfully tested under the provisions of this Subpart and found to have an upper leakage limit less than 0.01 for full-facepieces or less than 0.02 for half- and quarter-facepieces. The negative pressure test shall not be eliminated when the facepiece weight or balance has been significantly changed in the conversion from a negative pressure to a positive pressure respirator.

(b) If testing in the negative mode is necessary, such testing shall be conducted on the full panel of test subjects in accordance with the provision of § 84.232. The maximum allowable leakage will be 0.01 for full

[2] Natrella, M.G., Experimental Statistics, National Bureau of Standards Handbook 91, Issued August 1, 1963.

facepieces and 0.02 for half- and quarter-facepieces.

(c) Testing in the positive pressure mode shall be conducted for the purpose of evaluating total respirator performance. Three complete respirators shall each be evaluated. Each shall be tested in accordance with the provisions of § 84.232 (c) through (g) to evaluate applicants donning and use instruction and to determine that there is no unacceptable inward leakage. Inward leakage greater than 0.0001 in any of the three respirators is unacceptable. The statistical analysis prescribed in § 84.229 shall not apply.

§ 84.234 Continuous flow atmosphere supplying respirators.

Continuous flow atmosphere supplying respirators shall be tested in their normal operating mode (at the lowest specified flow rate) by the full 25 member panel in accordance with the procedures of § 84.232 (a) through (h). The maximum allowable face seal leakage shall be 0.0003.

§ 84.235 Powered air-purifying respirators.

Powered air-purifying respirators shall be tested in their normal operating mode by the full 25 member panel in accordance with the procedures outlined in § 84.232 (a) through (h). The maximum allowable face seal leakage shall be 0.0003 for powered particulate respirators equipped with high efficiency filters and powered gas and vapor respirators. The maximum allowable face seal leakage shall be 0.01 for powered particulate respirators equipped with either medium or low efficiency filters.

§ 84.236 Mouthpiece respirators.

Respirators having a mouthpiece/noseclamp shall be tested as appropriate for the particular respirator under evaluation, to demonstrate that the total inboard leakage is either not significantly above that permitted for filter penetration, where applicable.

§ 84.237 Reduced panel size.

For respirators designed to fit only the extreme facial sizes, it may be quite difficult to construct the full 25 member panel. In those cases, it may be judged that a reduced panel size is appropriate. The number of panel members may be reduced to as low as 10 provided the method of data analysis is adjusted accordingly. For example, if the panel is reduced to 10 members, the value of k used in § 84.232(h)(4) must be adjusted to k=2.355.

§ 84.238 Regulator preconditioning.

All open circuit self-contained breathing apparatus shall be preconditioned with the regulator overpressurization procedure of § 84.248–18 prior to conducting the face fit testing of this subpart.

Subpart S—Self-Contained Breathing Apparatus

§ 84.240 Self-contained breathing apparatus; Description.

(a) Self-contained breathing apparatus, as used herein, are distinguished by a supply of breathing air, oxygen, or oxygen generating material, that is contained in the apparatus for providing breathing air or oxygen, depending on design. This apparatus may be configured as either an open or closed-circuit system that will provide either positive or negative facepiece pressure relative to the ambient environment. Self-contained breathing apparatus may be configured and so designated as follows:

(1) *Closed-circuit apparatus.* A recirculation breathing apparatus in which exhaled carbon dioxide has been removed from the exhalation and the oxygen content within the system has been replenished from sources composed of:

(i) Compressed oxygen;

(ii) Chemical oxygen; or

(iii) Liquid oxygen.

(2) *Open-circuit apparatus.* A breathing apparatus in which the exhalation is exhausted to the atmosphere without recirculation and the oxygen content within the system has been replenished from sources composed of:

(i) Compressed air; or

(ii) Liquid air.

(3) *Positive pressure or negative pressure apparatus.* A self-contained breathing apparatus may be designed such that open-circuit or closed-circuit apparatus may operate with positive or negative pressure within the facepiece relative to the ambient environment. Self-contained breathing apparatus may be certified for use in the following categories:

(i) Closed-circuit, negative pressure;

(ii) Closed-circuit, positive pressure;

(iii) Open-circuit, negative pressure; or

(iv) Open-circuit, positive pressure.

§ 84.241 Reserved.

§ 84.242 Interchangeability of oxygen and air prohibited; use of 100 percent oxygen in open flames and high heat.

(a) Certifications shall not be issued for any respirator which permits the interchangeable use of oxygen and air.

(b) Certifications may be issued for use of self-contained breathing apparatus using oxygen as described in Informational Appendix A paragraph (j) of this part. Use of such apparatus near open flames or high heat is not recommended.

§ 84.243 Compressed breathing gas and liquefied breathing gas containers.

(a) Compressed breathing gas and liquefied breathing gas containers shall meet the minimum requirements of the Department of Transportation for Interstate shipment of such containers when fully charged as specified in Title 49, Code of Federal Regulations, Parts 100 through 178.

(b) Such containers shall be permanently and legibly marked to identify their contents; e.g., compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen.

(c) Containers normally removed from apparatus for refilling shall be equipped with an indicating gauge which shows the pressure in the container.

(d) Compressed breathing gas container valves or a separate charging system or adapter provided with each apparatus shall be equipped with outlet threads specified for the service by the American National Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections, ANSI B57.1–1965 standard, obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

§ 84.244 Pressure indicators.

(a) Gas pressure gauges employed on compressed breathing gas containers shall be marked in force per unit area.

(b) Liquid-level gauges shall be marked in fractions of total container capacity, or in units of liquid volume.

(c) Gas pressure gauges other than those specified in paragraphs (a) and (b) of this section shall be marked in:

(1) Force per unit area,

(2) Fractions of total container capacity, or

(3) Both in force per unit area and fractions of total container capacity.

(d) (1) Dial-indicating gauges shall be reliable to within ±5 percent of full scale when tested both up and down the scale at each of 5 equal intervals.

(2) The full scale graduation of dial-indicating gauges shall not exceed 150 percent of the maximum rated cylinder pressures specified for the container in applicable Department of Transportation specifications or permits or 150 percent of the maximum pressure specified by the manufacturer's instructions, whichever is less.

(e) (1) Stem-type gauges shall be readable by sight and by touch and shall have a stem travel distance of not less

than one-fourth inch between each graduation.

(2) A minimum of five graduations shall be engraved on the stem of each gauge and these graduations shall include readings for empty, one-quarter, one-half, three-quarters, and full.

(3) Stem gauge readings shall not vary from true readings by more than one-sixteenth inch per inch of stem travel.

(f) Where the apparatus is equipped with a manual shut-off valve between the high pressure outlet and the pressure gauge, the loss of breathing gas through the broken gauge or severed gauge connection shall not exceed 70 liters per minute when the cylinder pressure is 6,900 kN/m² (1,000 pounds per square inch) gauge or when the liquid level is at one-half.

(g) Where the apparatus is of open-circuit design and is not equipped with a manual or automatic shut-off valve, the volume of breathing gas escaping through the broken gauge or severed gauge connection shall not exceed 5 percent of the full rated breathing gas volume, when measured at 25 percent of the service pressure to the end of the rated service time of the apparatus. Where the apparatus is of closed-circuit design and is not equipped with a manual or automatic shut-off valve, the total volume of breathing gas (Z) permitted to escape through the broken gauge or severed gauge connection shall not exceed the following, where X equals the total volume of breathing gas, in liters, in the cylinder at full pressure and Y equals the duration of the apparatus in minutes:

$$Z = \frac{X}{t} - 1.75Y$$

Z shall be measured at 20 percent of the service pressure to the end of the rated service time of the apparatus.

(h) Oxygen pressure gauges shall have the words, "Oxygen" and "Use No Oil," marked prominently on the gauge.

(i) (1) Apparatus using compressed breathing gas, except apparatus classified for escape only, shall be equipped with gauges visible to the wearer which indicate the amount of gas content remaining in the container.

(2) Apparatus using liquefied breathing gas, except apparatus classified for escape only, shall be equipped with gauges visible to the wearer which indicate the remaining liquid content in the container; however, where the liquid content cannot be rapidly vented, and the service time of the device begins immediately after filling, a timer shall be provided in place of a visible gauge.

§ 84.245 Timers; Elapsed time indicators; Remaining service life indicators.

(a) Elapsed time indicators shall be provided for apparatus with a chemical oxygen source, except:

(1) Apparatus classified for escape only; or,

(2) Liquefied breathing gas apparatus equipped with gauges visible to the wearer which indicate the remaining liquid content in the container.

(b) The timer or other indicator shall be accurately calibrated to indicate remaining service life.

(c) Timers shall be readable by sight and by touch during use by the wearer.

(d) Timers shall be equipped with automatically preset alarms which will warn the wearer for a period of 7 seconds or more after the preset time has elapsed.

(e) Remaining service-life indicators or warning devices shall be provided in addition to a pressure gauge on compressed gas self-contained breathing apparatus, except apparatus used for escape only, and shall operate automatically without preadjustment by the wearer.

(f) Each remaining service life indicator or warning device shall give an alarm before the remaining service life or cylinder pressure of the apparatus is reduced to between 20–30 percent of the rated service time or full cylinder pressure. There shall be no degrading of performance at 20–30 percent of full cylinder pressure.

(g) If a manual shutoff is not used for a remote gage, then the alarm should activate at 20–30 percent of rated service pressure or time.

(h) Remaining service life indicators shall be clearly and distinctly detectable by a wearer having normal hearing in the presence of a noise background of 100 dBA of "pink noise," a noise spectrum which is composed of equal sound pressure levels for all octave bands.

(i) Remaining service life indicators or warning devices must warn the wearer for a period of seven seconds or more after the alarm is initiated.

§ 84.246 Hand-operated valves.

(a) Hand-operated valves shall be designed and constructed to prevent removal of the stem from the valve body during normal usage to ensure against a sudden release of the full pressure of the container when the valve is opened.

(b) Valves shall be designed or positioned to prevent accidental opening and closing and damage from external forces.

(c) Valves operated during use of the apparatus shall be installed in locations where they can be readily adjusted by the wearer.

(d) Main-line valves, designed and constructed to conserve gas in the event of a regulator or demand valve failure, shall be provided in addition to gas container valves, except when such failure will not affect performance.

(e) Hand-operated bypass systems designed and constructed to permit the wearer to breathe and to conserve his gas supply in the event of a regulator or demand valve failure, shall be provided where necessary.

(f) Valves installed on apparatus shall be clearly distinguishable from one another by sight and touch.

(g) The manually operated bypass system valve control shall be colored red. For closed circuit apparatus, the bypass valve shall be designed to close automatically if not being held open by the wearer.

(h) A main-line or bypass valve or system will not be required on apparatus for escape only.

(i) Safety relief valves or systems, designed and constructed to release excess pressure in the breathing circuit, shall be provided on closed-circuit apparatus, and shall meet the following requirements:

(1) The relief valve or system shall operate automatically when the pressure in the facepiece or mouthpiece reaches 13 mm±5 mm (one-half inch water-column height) of pressure above the minimum pressure required to fill the breathing bag, within the breathing resistance requirements for the apparatus. With the mask or mouthpiece attached in a normal manner to the breathing machine, and operated as described in § 84.248–3, the mask or mouthpiece pressure shall not exceed 540 mm (21 inches water-column height) when tested in each of the following modes:

Mode 1—With the regulator in a "failed open" mode; i.e., with the pneumatic system subjected to the pressure of a fully charged bottle;

Mode 2—With the bypass valve in a locked open position; and

Mode 3—With the demand valve, if any, in a locked open position.

(2) The relief valve or system shall be designed to prevent external atmospheres from entering the breathing circuit.

(3) The relief valve or system shall be designed to permit overriding for test purposes and in the event of a failure in the valve or system, except for escape only.

§ 84.247 Breathing bags.

(a) Breathing bags shall have sufficient volume to prevent gas waste during exhalation and to provide an adequate reserve for inhalation.

(b) Breathing bags shall be constructed of materials which are flexible and resistant to gasoline vapors.

(c) Breathing bags shall be installed in a location which will protect them from damage or collapse by external forces, except on apparatus classified for escape only.

§ 84.248 Self-contained breathing apparatus; Performance requirements; General.

Self-contained breathing apparatus and the individual components of each such device shall as applicable meet the requirements specified in §§ 84.248–1 through 84.248–18.

§ 84.248–1 Component parts exposed to oxygen pressures.

Each applicant shall certify that the materials employed in the construction of component parts exposed to oxygen pressures above atmospheric pressure are safe and compatible for their intended use.

§ 84.248–2 Compressed gas filters.

All self-contained breathing apparatus using compressed gas shall have a filter downstream of the gas source to effectively remove particles from the gas stream.

§ 84.248–3 Breathing bag test.

(a) Breathing bags shall be tested in an air atmosphere saturated with gasoline vapor at room temperature (24–30 °C) for a continuous period of twice the rated time of the apparatus (except for apparatus for escape only where the test period shall be the rated time of the apparatus).

(b) The bag shall be operated during this test by a breathing machine with 24 respirations per minute and a minute-volume of 40 liters.

(c) A breathing machine cam with a work rate of 100 watts (622 kp-m/min)[1] shall be used.

(d) The air within the bag(s) shall not contain more than 100 parts per million of gasoline vapor at the end of the test.

§ 84.248–4 Weight markings.

All self-contained breathing apparatus shall have the completely assembled and fully charged weight and the completely assembled and fully discharged weight permanently and legibly marked on the apparatus.

§ 84.248–5 Breathing resistance test.

(a) *Inhalation resistance.* (1) Resistance to inhalation airflow shall be measured in the facepiece or mouthpiece while the apparatus is operated by a breathing machine at a work rate of 100 watts (622 kp-m/min).[3]

(2) The face mask pressure of positive pressure closed circuit equipment shall remain positive during the entire inhalation cycle, while the breathing apparatus is operated in the breathing machine as described in § 84.248–3.

(3) Inhalation resistance for open or closed circuit apparatus with positive or negative pressure shall comply with the requirements as specified in the chart in § 84.248–5(c).

(b) *Exhalation resistance.* (1) For open-circuit apparatus, resistance to exhalation airflow shall be measured in the facepiece or mouthpiece with air flowing at a continuous rate of 85 liters per minute.

(2) For closed-circuit apparatus, resistance to exhalation air flow shall be measured in the facepiece or mouthpiece with a breathing machine at a work rate of 100 watts (622 kp-m/min).

(3) Exhalation resistance for open or closed circuit apparatus with positive or negative pressure shall comply with the requirement as specified in the chart in § 84.248–5(c).

(c) Breathing resistance performance requirement chart.

[3] Silverman, L., G. Lee, T. Plotkin, L. Amory, and A.R. Yancey, Fundamental Factors in Design of Protective Equipment, O.S.R.D. Report No. 5732, issued Apr. 1, 1945. The dimensions of the breathing machine cam are available from MSHA upon request.

Apparatus is:	Maximum Allowable Breathing Resistance: Inhalation (mm of water column height)	Exhalation (mm of water column height)
Open circuit		
Negative pressure	32	25
Positive pressure (above static)	≥0	51
Positive pressure (including static pressure)	>0	89[b]
Static pressure (no flow)	NA	38
Closed circuit		
Negative pressure	100 - MER[a]	64[b]
Positive pressure	≥0	89[b]

[a] MER - Measured exhalation resistance in mm of water column height.
[b] Including the pressure required to fully open the relief valve, if applicable.

§ 84.248–6 Gas flow test.

(a) *Open-circuit apparatus.* (1) A static-flow test shall be performed on all open-circuit apparatus.

(2) The flow from the apparatus shall be greater than 300 liters per minute when the pressure in the facepiece of negative pressure apparatus is lowered by 51 mm (2 inches) water column height when full container pressure is applied.

(3) Where positive pressure apparatus are tested, the flow shall be measured at zero gauge pressure in the facepiece and shall be greater than 300 liters per minute.

(4) Where apparatus with compressed breathing gas containers are tested, the flow test shall also be made with 25 percent of full container pressure.

(b) *Closed-circuit apparatus.* Oxygen concentrations measured in the facepiece during machine or human subjects testing shall be maintained above 19.5 percent. This may be accomplished by various methods. Where a strictly mechanical flow method is used, the following requirements must be achieved:

(1) For constant flow devices, the rate of flow shall be at least three liters per minute for the entire rated service time of the apparatus.

(2) All negative pressure devices shall provide at least 60 liters of breathing gas per minute when the regulator (admission valve) is in the fully open position at 4 inches of water column height.

(3) All positive pressure devices shall provide at least 30 liters of breathing gas per minute when the regulator (admission valve) is in the fully open position and shall maintain equal to or greater than ambient pressure.

(4) When constant flow is used in conjunction with negative pressure flow, the constant flow shall be greater than 1.5 liters per minute for the entire rated service time. For positive pressure apparatus, the constant flow shall be greater than 1 liter per minute for the entire rated service time.

§ 84.248–7 Bypass gas flow test.

(a) *Open-circuit apparatus.* (1) The bypass gas flow test shall be performed on two samples of each open-circuit apparatus equipped with a bypass valve as prescribed in § 84.246 of this part.

(2) The apparatus breathing gas container shall be fully pressurized to the service pressure, the facepiece of the apparatus shall be attached to an anthropometric head form, and the bypass valve shall be fully opened.

(3) The breathing gas container valve shall be fully opened and the airflow shall be measured at 500 psig decreasing increments until 25 percent of the service pressure remains.

(4) Except as prescribed in paragraph (e) of this section, at any pressure, an adjustable bypass valve shall provide a minimum flowrate of 85 Lpm and a maximum flowrate not greater than 130 Lpm.

(5) Any bypass valve on a self-contained breathing apparatus for escape only shall provide a minimum flowrate of 85 Lpm.

(6) Any constant flow bypass valve shall provide a minimum flow rate of 85 Lpm and a maximum flow rate of 130 Lpm.

(b) *Closed-circuit apparatus.* (1) The bypass gas flow test shall be performed on two samples of each closed-circuit apparatus equipped with a bypass valve as prescribed in § 84.246 of this part.

(2) The apparatus breathing gas container shall be fully pressurized to the service pressure, the facepiece of the apparatus shall be attached to an anthropometric head form, the bypass valve shall be fully opened, and the pressure relief valve shall be overridden as prescribed by the manufacturer.

(3) The breathing gas container valve shall be fully opened and the oxygen flow shall be measured at 500 psig decreasing increments until 25 percent of the service pressure remains.

(4) At any pressure, the bypass valve shall provide a minimum airflow of 30 Lpm.

§ 84.248–8 Service time test; Open-circuit apparatus.

(a) Service time shall be measured with a breathing machine operated as described in § 84.248–3.

(b) The open-circuit apparatus shall be classified according to the length of time it supplies air or oxygen to the breathing machine.

(c) The service time obtained on this test shall be used to classify the open-circuit apparatus in accordance with the provisions of Subpart P.

§ 84.248–9 Service time test; Closed-circuit apparatus.

(a) The closed-circuit apparatus shall be classified according to the length of time it supplies adequate breathing gas to the wearer during use test No. 4 described in Table 4 in § 84.248–14.

(b) The service time obtained on use test No. 4 shall be used to classify the closed-circuit apparatus in accordance with the provisions of Subpart P.

§ 84.248–10 Test for carbon dioxide in inspired gas; Open- and closed-circuit apparatus; Maximum allowable limits.

(a) The concentration of carbon dioxide in inspired gas in open-circuit apparatus shall be measured at the mouth while the apparatus mounted on a dummy head is operated by a breathing machine.[4]

(1) The breathing rate shall be 14.5 respirations per minute with a minute-volume of 10.5 liters.

(2) A sedentary breathing machine cam shall be used.

(3) The apparatus shall be tested at a temperature of 27±2° C.

(4) A concentration of 5 percent carbon dioxide in air shall be exhaled into the facepiece.

(b) The concentration of carbon dioxide in inspired gas in closed-circuit apparatus shall be measured at the mouth while the parts of the apparatus contributing to dead-air space are mounted on a dummy head and operated by the breathing machine as described in paragraphs (a) (1) through (4) of this section.

(c) During the testing required by paragraphs (a) and (b) of this section, the concentration of carbon dioxide in inspired gas at the mouth shall be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

[4] Kloos, E.J., and J. Lamonica. A Machine-Test Method for Measuring Carbon Dioxide in the Inspired Air of Self-Contained Breathing Apparatus. Bureau of Mines Report of Investigations 6865. 1966. 11 pp.

Where the service time is	Maximum allowable average concentration of carbon dioxide in inspired air percent by volume
Not more than 30 minutes	2.5
1 hour	2.0
2 hours	1.5
3 hours	1.0
4 hours	1.0

(d) In addition to the test requirements for closed-circuit apparatus set forth in paragraph (b) of this section, gas samples shall be taken during the course of the use tests described in Tables 1, 2, 3, and 4 in § 84.248–14. These gas samples shall be taken from the closed-circuit apparatus at a point downstream of the carbon dioxide sorbent, and they shall not contain more than 0.5 percent carbon dioxide at any time, except on apparatus for escape only, using a mouthpiece only, the sample shall not contain more than 1.5 percent carbon dioxide at any time.

§ 84.248–11 Tests during low temperature operation.

(a) The manufacturer shall specify the minimum temperature for safe operation and two persons shall perform the tests described in paragraphs (c) and (d) of this section, wearing the apparatus according to applicant's directions. At the specified temperature, the apparatus shall meet all the requirements described in paragraph (e) of this section.

(b) The apparatus shall be cold soaked at the applicant's specified minimum temperature for 16 hours.

(c) The apparatus shall be worn in the low temperature chamber for 30 minutes, or for the service time of the apparatus, whichever is less.

(d) During the test period, alternate 1-minute periods of exercise and rest shall be required with the exercise periods consisting of stepping onto and off a box of 21.5 cm (8½ inches) high at a rate of 30 cycles per minute.

(e) *Requirements.* (1) The apparatus shall function satisfactorily at the specified minimum temperature on duplicate tests.

(2) The wearer shall have sufficient unobscured vision to perform the work.

(3) The wearer shall not experience undue discomfort because of airflow restriction or other physical or chemical changes in the operation of the apparatus.

(4) For evaluating the escape apparatus portion of air-line supplied respirators, the air-line shall be briefly connected to determine proper functioning, then disconnected.

(f) Auxiliary low-temperature parts which are commercially available to the user may be used on the apparatus to meet the requirements described in paragraph (e) of this section.

§ 84.248–12 Shock and vibration tests.

Shock and vibration tests shall be conducted prior to the use tests described in §§ 84.248–13 through 84.248–16.

(a) A vibration test shall be conducted in accordance with the Military Standard MIL–STD 810C test for equipment installed on rubber tire vehicles. The device shall be machine tested at 60 liters/minute and must maintain a positive facepiece pressure. The low air-supply warning device shall function within 10 percent of the normal range. Apparatus shall be secured to the vibration table or confined in an insecure fashion consistent with manufacturers' recommendations to users for storage. The apparatus shall be independently monitored for vibration during the test to ensure the test equipment was functioning properly.

(b) A shock test shall also be performed on the apparatus subjected to vibration testing. The shock shall consist of a 1-meter free drop to a concrete floor on each axis.

(c) For apparatus sealed against moisture, the leak test recommended by the manufacturer shall be performed following the vibration and shock tests.

(d) These tests shall be performed on four apparatus. One apparatus shall be disassembled and inspected for significant damage which is likely to cause the apparatus to fail to provide the required protection to the user. The other apparatus shall be tested on human subjects according to the use tests described in §§ 84.248–13 through 84.248–16, if no serious damage was noted upon disassembly.

§ 84.248–13 Use tests; Purpose and requirements; General.

(a) The use tests described in Tables 1, 2, 3, and 4 in § 84.248–14 are designed to represent the workload performed in the mining, mineral, or allied industries by a person wearing the apparatus tested.

(b) The apparatus tested shall be worn by personnel trained in the use of self-contained breathing apparatus.

(c) Breathing resistance shall be measured within the facepiece or mouthpiece and the wearer's pulse and respiration rate shall be recorded during each 2-minute sample period prescribed in tests 1, 2, 3, and 4.

(d) Use tests 1, 2, 3, 4, and 5 shall be conducted on each of three respirators.

Each respirator shall be worn by a different subject.

§ 84.248–14 Use tests 1, 2, 3, 4, and 5; Purpose.

(a) *Use tests 1, 2, 3, and 4; Purpose.* Use tests 1, 2, 3, and 4, set forth in Tables 1, 2, 3, and 4, respectively, prescribe the duration and sequence of specific activities. These tests shall be conducted to:

(1) Familiarize the wearer with the apparatus during use;

(2) Provide for a gradual increase in activity;

(3) Evaluate the apparatus under different types of work and physical orientation; and

(4) Provide information on the operating and breathing characteristics of the apparatus during actual use.

(b) *Use test 5; Purpose and description.* (1) Use test 5 shall be conducted with respect to liquefied breathing gas apparatus only.

(2) This test shall be conducted to evaluate operation of the apparatus in other than vertical positions.

(3) The wearer shall lie face downward for one-fourth the service life of the apparatus with a full charge of liquefied breathing gas, and then a one-quarter full charge of liquefied breathing gas.

(4) The test shall be repeated with the wearer lying on each side and on his back.

(5) The oxygen content of the gas supplied to the wearer by the apparatus shall be continuously measured.

§ 84.248–15 Use transfer test.

(a) Three test subjects shall perform the use transfer test five times each, using not less than two combination respirators.

(b) Each test subject shall don the complete combination respirator after reading the manufacturer's instructions for use of the combination respirator, and shall operate the combination respirator in the supplied-air mode from the external air supply.

(c) The external air supply shall be turned off by an observer, without warning to the test subject, and the test subject shall operate the combination respirator until reduction or loss of external air supply alerts the test subject that the external air supply has been terminated.

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TABLE 1--DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 1, IN MINUTES

(42 CFR Part 84, Subpart S, 84.248-14, et. seq.)

Activity	Service Time in Minutes[a]						
	3	5	10	15	30	45	60
Sampling and readings				2	2	2	2
Walks at 4.8 km. (3 miles) per hour	3	5	3	4	8	12	18
Sampling and readings			2	2	2	2	2
Walks at 4.8 km. (3 miles) per hour			3	5	8	12	18
Sampling and readings			2	2	2	2	2
Walks at 4.8 km. (3 miles) per hour					6	13	16
Sampling and readings					2	2	2

[a] Repeat 1 hour test for 2, 3, and 4 hour service times.

TABLE 2--DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 2, IN MINUTES

(42 CFR Part 84, Subpart S, 84.148-14, et. seq.)

Activity	Service time in Minutes							
	3	5	10 minutes	15 minutes	30 minutes	45 minutes	60 minutes	2, 3, and 4 hours[a]
Sampling and readings				2	2	2	2	2
Walks at 4.8 km. (3 miles) per hour			1	1	3	4	6	10
Carries 23 kg. (50 pound) mass over overcast			1 time in 2 minutes	1 time in 2 minutes	2 times in 4 minutes	3 times in 6 minutes	4 times in 8 minutes	5 times in 10 minutes
Walks at 4.8 km. (3 miles) per hour				1	3	3	3	5
Climbs vertical treadmill [b] or equivalent)	1	1	1	1	1	1	1	1
Walks at 4.8 (3 miles) km. per hour	1		1			2	3	5
Climbs vertical treadmill (or equivalent)	1					1	1	1
Sampling and readings					2	2	2	2
Walks at 4.8 km. (3 miles) per hour				2	2	3	5	11
Climbs vertical treadmill (or equivalent)				1	1	1	1	1
Carries 23 kg. (50 pound) mass over overcast				1 time in 2 minutes	3 times in 6 minutes	4 times in 8 minutes	5 times in 10 minutes	5 times in 10 minutes
Sampling and readings			2			2	2	2
Walks at 4.8 km. (3 miles) per hour				1	3	3	3	
Climbs vertical treadmill (or equivalent)			1		1	1	1	Then repeat above activities once
Walks at 4.8 (3 miles) km per hour			2			2	3	
Climbs vertical treadmill (or equivalent)						1	1	
Carries 20 kg. (45 pound) mass and walks at 4.8 (3 miles) km. per hour	1						2	
Walks at 4.8 (3 miles) km. per hour	1	2				1	4	
Sampling and readings				2	2	2	2	

[a] Total test time for Test 2 for 2-hour, 3-hour, and 4-hour apparatus is 2 hours.
[b] Treadmill shall be inclined 15° from vertical and operated at a speed of 1 foot per second.

TABLE 3--DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 3, IN MINUTES

(42 CFR Part 84, Subpart S, 84.248-14, et. seq.)

Activity	Service time-- 3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3, and 4 hours
Sampling and readings				2	2	2	2	(a)
Walks at 4.8 km. (3 miles) per hour			1	1	2	2	3	
Runs at 9.7 km. (6 miles) per hour	1	1	1	1	1	1	1	
Pulls 20 kg. (45 pounds) mass to 5 feet		15 times in 1 minute		30 times in 2 minutes	30 times in 2 minutes	30 times in 2 minutes	60 times in 6 minutes	
Lies on side	1/2	1	1	2	3	4	5	
Lies on back	1/2	1	1	2	2	3	3	
Crawls on hands and knees	1	1	1	2	2	2	2	
Sampling and readings			2		2	2	2	
Runs at 9.7 km. (6 miles) per hour				1	1	1	1	
Walks at 4.8 km. (3 miles) per hour					2	8	10	
Pulls 20 kg. (45 pounds) mass to 5 feet			30 times in 2 minutes		60 times in 6 minutes	60 times in 6 minutes	60 times in 6 minutes	
Sampling and readings				2		2	2	
Walks at 4.8 km. (3 miles) per hour			1		3	4	10	
Lies on side						2	4	
Lies on back						2	1	
Sampling and readings					2	2	2	

[a] For two-hour, 3-hour, and 4-hour apparatus, perform test No. 3 for 1-hour apparatus, then test No. 1 for 1-hour apparatus (total test time is 2 hours).

TABLE 4--DURATION AND SEQUENCE OF SPECIFIC ACTIVITIES FOR TEST 4, IN MINUTES

(42 CFR Part 84, Subpart S, 84.148-14, et. seq.)

Activity	Service time--									
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2 hours	3 hours	4 hours
Sampling and readings				2	2	2	2	(b)	(c)	(d)
Walks at 4.8 km. (3 miles) per hour				1	2	2	2			
Climbs vertical treadmill[a] or equivalent	1	1	1	1	1	1	1			
Walks at 4.8 km. (3 miles) per hour		1	1	1	2	2	2			
Pulls 20 kg. (45 pound) mass to 5 feet		30 times in 2 minutes	30 times in 2 minutes	30 times in 2 minutes	60 times in 5 minutes	60 times in 5 minutes	60 times in 5 minutes			
Walks at 4.8 km. (3 miles) per hour			1	1	1	2	3			
Carries 23 kg. (50 pound) mass over overcast				1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 8 minutes			
Sampling and readings			2		2	2	2			
Walks at 4.8 km. (3 miles) per hour				1	3	3	4			
Runs at 9.7 km. (6 miles) per hour		1	1	1	1	1	1			
Carries 23 kg. (50 pound) mass over overcast			1 time in 1 minute	1 time in 1 minute	2 times in 3 minutes	4 times in 6 minutes	6 times in 9 minutes			
Pulls 20 kg. mass to 5 feet	5 times in 1 minute			15 times in 1 minute	60 times in 5 minutes	30 times in 2 minutes	36 times in 3 minutes			
Sampling and readings				2	2	2	2			
Walks at 4.8 km. (3 miles) per hour	1		1			2	6			
Pulls 20 kg. (45 pound) mass to 5 feet						60 times in 5 minutes	60 times in 5 minutes			
Carries 20 kg. (45 pound) mass and walks at 4.8 km. (3 miles) per hour						3	3			
Sampling and readings						2	2			

[a]Treadmill shall be inclined 15° from vertical and operated at a speed of 30 cm. (1 foot) per second.
[b]Perform Test No. 1 for 30-minute apparatus; then perform Test No. 4 for 1-hour apparatus; then perform Test No. 1 for 30-minute apparatus.
[c]Perform Test No. 1 for 1-hour apparatus; then perform Test No. 4 for 1-hour apparatus; then perform Test No. 1 for 1-hour apparatus.
[d]Perform Test No. 1 for 1-hour apparatus; then perform Test No. 4 for 1-hour apparatus; then perform Test No. 1 for 1-hour apparatus twice (i.e., two one-hour tests).

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(d) When the test subject becomes aware that the external air supply is terminated, the test subject shall so advise the observer and the observer shall start a timer.

(e) The test subject shall then proceed to transfer to the self-contained air supply, using whatever procedure is specified by the manufacturer, and shall disconnect the respirator from the external air supply.

(f) Transfer shall be effected when air is supplied to the combination respirator from the self-contained air supply and the respirator is disconnected from the external air supply. The observer shall stop the timer when transfer is effected.

(g) Transfer shall be effected in not more than 15 seconds.

§ 84.248-16 Use tests; Requirements.

(a) The apparatus shall satisfy the respiratory requirements of the wearer for the classified service time.

(b) Fogging of the eyepiece shall not obscure the wearer's vision, and the wearer shall not experience undue discomfort because of fit or other characteristics of the apparatus.

(c) When the ambient temperature during testing is 24±6 °C, the maximum temperature of inspired air recorded during use tests shall not exceed the following, after correction for deviation from 24 °C:

Where service life of apparatus is --	Where percent relative humidity of inspired air is --	Maximum permissible temperature of inspired air shall not exceed	
		°F	°C
1/4 hour or less	0 - 100	135	57
1/2 hour to 3/4 hour	0 - 50	125	52
	50 - 100	110[a]	43[a]
1 to 2 hours	0 - 50	115	46
	50 - 100	105[a]	41[a]
3 hours	0 - 50	110	43
	50 - 100	100[a]	38[a]
4 hours	0 - 50	105	41
	50 - 100	95[a]	35[a]

[a]Where percent relative humidity is 50 - 100 and apparatus is designed for escape only, these maximum permissible temperatures will be increased by 5 °C.

§ 84.248-17 Flammability.

(a) Three facepieces shall be tested for flammability for a short period with a test rig as shown on Figure 2, and Details 1 and 2. This test rig consists mainly of a propane storage tank with control device and fine pressure gauge, flash back arresters, 6 propane burners being adjustable in height, and a metal dummy head which pivots vertically and horizontally.

(b) The test rig shall be adjusted as follows: The distance between facepiece and burner tips shall be 250 mm. The pressure reducer shall be adjusted to a flow of 60 liters/min using air at 1.25×10^{1} Newtons/cm^2 (1.81×10^{1} pounds per square inch) gauge.

(c) On the propane burners, the control device for the propane gas supply shall be fully opened, while the control device for the air shall be adjusted to the optimum. The temperature of the flame shall be 950±50 °C.

(d) For the test, the facepiece shall be put on the dummy head. After it has undergone the test for tightness, the facepiece shall be exposed to the flames for a period of 5 seconds. When components like valve(s), speech diaphragm(s) etc. are arranged on other parts of the face blank, the test is repeated with other samples in the appropriate position.

(e) For comparing the tightness of the full mask before and after the flammability test the same dummy head shall be used and a pressure of -1.0×10^{-1} N/cm^2 (-1.45×10^{-1} pounds per square inch) gauge shall be created in the cavity of the mask.

(f) The test results are positive if no portion of the mask continues to burn with its own flame after the 5 second exposure period ends, and if the rise in pressure from -1.0×10^{-1} N/cm^2 (-1.45×10^{-1} pounds per square inch) gauge initial pressure within the cavity of the mask does not exceed 1.0×10^{-2} N/cm^2 (1.45×10^{-2} pounds per square inch) gauge per 60 seconds.

§ 84.248-18 Regulator overpressurization.

(a) Open-circuit self-contained breathing apparatus regulators shall be tested and evaluated in such a way as to simulate overpressurization of the regulator by the user prior to evaluating

the respirator in the face fit test of Subpart R.

(b) The regulator shall be preconditioned to simulate intentional overpressurization by the user. The regulator shall be subjected to a 1 to 2 second simulated attempt to block the regulator flow with the regulator bypass valve set at maximum flow. Such simulation shall be either manual or mechanical as appropriate to the respirator being evaluated. Each regulator shall be subjected to 20 simulated blocking attempts. Following the simulation blocking cycles, the regulator diaphragm shall be inspected and must be found free of damage.

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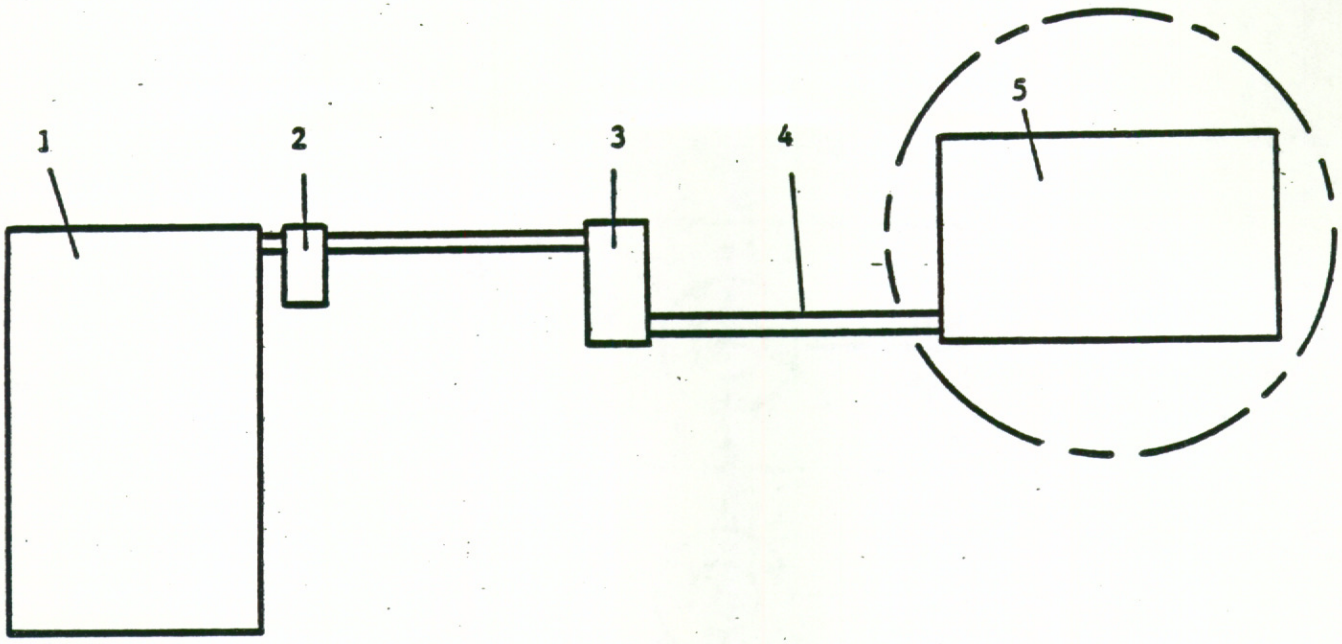
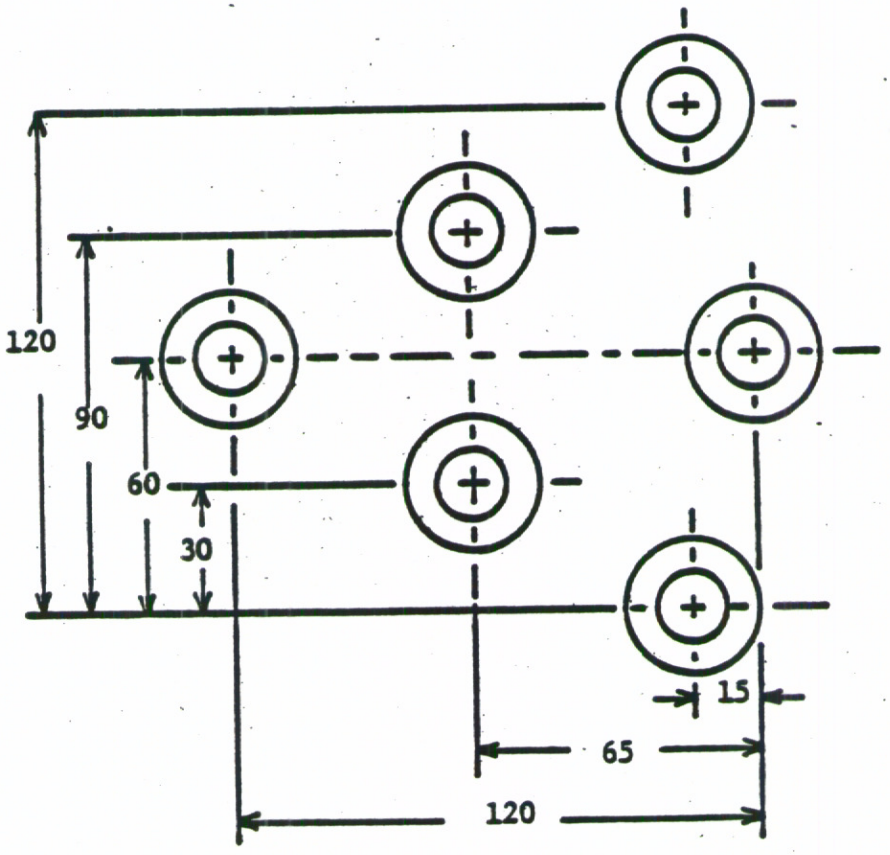
Figure 2. SCHEME OF THE TEST RIG FOR FLAMMABILITY OF A FULL FACE MASK



1. Propane storage tank
2. Fine pressure gauge and control device
3. Flash back arrester
4. Connecting hoses (of same length) leading to the 6 propane burners.
5. Propane burner.

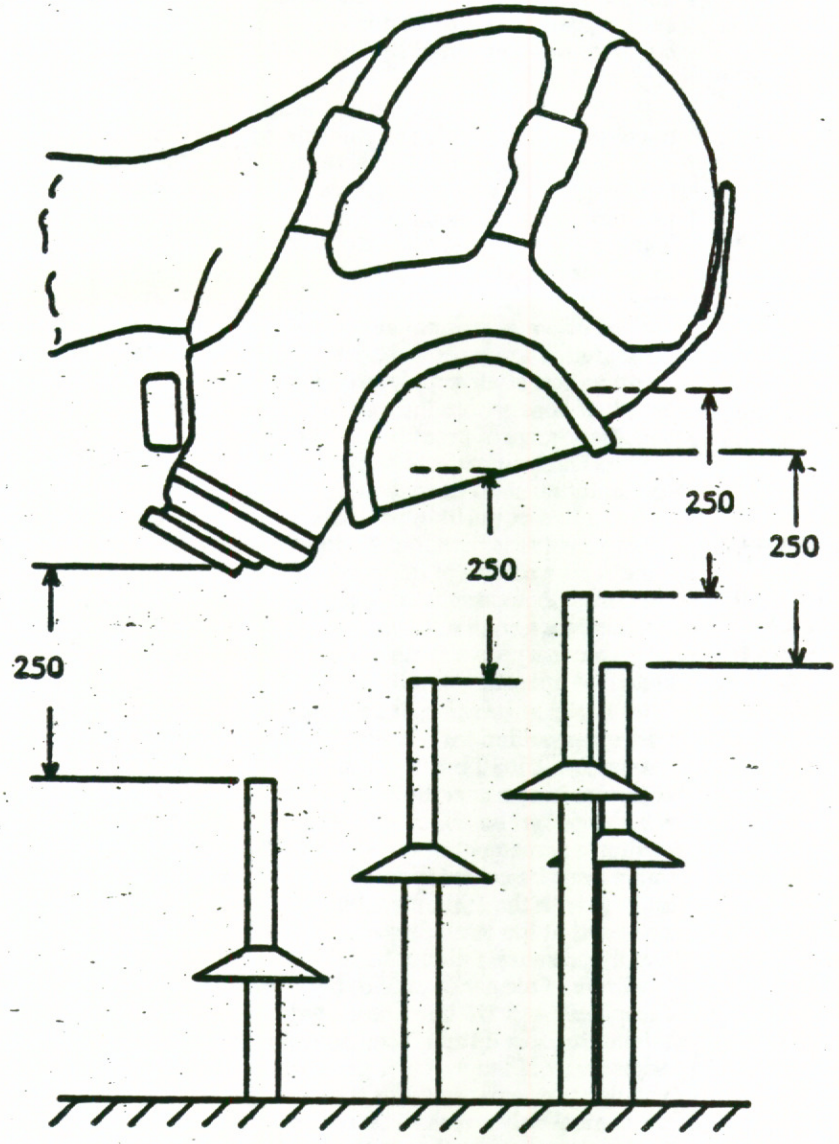
Detail 1:

Top view of arrangement of the six propane burners (dimensions in mm).



Detail 2:

Lateral view of arrangement of the six propane burners (dimensions in mm).



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Subpart T—Air-Line Respirators

§ 84.250 Air-line respirators; Description.

Air-line respirators are atmosphere supplying respirators that use a stationary source of compressed air delivered through a high pressure hose. Air-line respirators are available as negative and positive pressure, regulated, and continuous flow configurations. "Regulator" type air-line respirators operate with a single stage regulator and a maximum airline pressure of 863 kN/m² (125 pounds per square inch) gauge. "Continuous flow" respirators operate with an air flow control valve or orifice and maintain air flow at all times.

§ 84.251 Air-line respirators; Performance requirements; General.

Air-line respirators and the individual components of each such device shall, as appropriate, meet the requirements for performance and protection specified in the tests described in §§ 84.251–1 through 84.251–8.

§ 84.251–1 Air-line respirators; Regulated flow.

(a) The manufacturer shall specify the range of air pressure at the point of attachment of the air supply system, and the range of hose length for the respirator.

(b) The specified air pressure at the point of attachment of the hose to the air supply system shall not exceed 863 kN/m² (125 pounds per souare inch) gauge.

§ 84.251–2 Air-line respirators; Continuous flow.

(a) The pressure at the inlet of the hose connection shall not exceed 863 kN/m² (125 pounds per square inch) gauge.

(b) Where the pressure at any point in the supply system exceeds 863 kN/m² (125 pounds per square inch) gauge, the respirator shall be equipped with a pressure-release mechanism that will prevent the pressure at the hose connection from exceeding 863 kN/m² (125 pounds per square inch) gauge under any conditions.

§ 84.251–3 Air-supply line tests.

Air-supply lines employed on air-line respirators shall meet the following minimum test requirements.

(a) *Length of hose.* A maximum of 91 m. (300 feet) in multiples of 7.6 m. (25 feet) will be supplied. It will be permissible for the applicant to supply hose of the certified type of shorter length than 7.6 m. (25 feet) provided it meets the requirements of this part.

(b) *Air flow.* (1) The air-supply hose with air-regulating valve or orifice shall permit a flow of not less than 115 liters per minute to tightfitting facepieces and 170 liters per minute to loose-fitting facepieces through the maximum length of hose for which approval is granted and at the minimum specified air-supply pressure. The maximum flow shall not exceed 425 liters (15 cubic feet) per minute at the maximum specified air-supply pressure with the minimum length of hose specified by the applicant.

(2) The air-supply hose, detachable coupling, and the negative pressure or positive pressure demand valves for air-line respirators shall be capable of delivering respirable air at a rate of not less than 115 liters per minute to the facepiece and at an inhalation resistance not exceeding 5 millimeters (2 inches) of water-column height, as measured in the facepiece, with any combination of air-supply pressure and length of hose within the applicant's specified range of pressure and hose length. The air-flow rate and resistance to inhalation shall be measured while the negative or positive pressure demand valve is actuated 20 times per minute by a source of intermittent suction. The maximum rate of flow to the facepiece shall not exceed 425 liters (15 cubic feet) per minute under the specified operating conditions.

(c) *Air-control valve.* If an air-control valve is provided for a continuous flow respirator, it shall be so designed that it will remain at a specific adjustment, which will not be affected by the ordinary movement of the wearer. The valve must be so constructed that the air supply, with the maximum length of hose and at the minimum specified air-supply pressure, will not be less than 115 liters of air per minute to tight-fitting facepieces and 170 liters of air per minute to loose-fitting facepieces for any adjustment of the valve. If a negative or positive pressure regulator replaces the air-control valve, it shall be connected to the air-supply at the maximum air pressure specified by the applicant by means of the minimum length of air-supply hose specified by the applicant. The outlet of the negative or positive pressure regulator shall be connected to a source of intermittent suction so that the negative or positive pressure regulator is actuated approximately 20 times per minute for a total of 100,000 inhalations. To expedite this test, the rate of actuation may be increased if mutually agreeable to the applicant and to NIOSH. During this test, the valve shall function without failure and without excessive wear of the moving parts. The negative or positive pressure regulator shall not be damaged in any way when subjected at the outlet to a pressure or suction of 25 cm. (10 inches) of water column height for 2 minutes.

(d) *Non-kinkability.* A 7.6 m. (25 foot) section of the hose shall be placed on a horizontal-plane surface and shaped into a one-loop coil with one end of the hose connected to an airflow meter and the other end of the hose supplied with air at the minimum specified supply pressure. The connection shall be in the plane of the loop. The other end of the hose shall be pulled tangentially to the loop and in the plane of the loop until the hose straightens. To meet the requirements of this test the loop shall maintain a uniform near-circular shape and ultimately unfold as a spiral, without any localized deformation that decreases the flow of air to less than 90 percent of the flow when the hose is tested while remaining in a straight line.

(e) *Strength of hose and couplings.* Hose and couplings shall not exhibit any separation or failure when tested with a pull of 445 newtons (100 pounds) for 5 minutes and when tested by subjection, with blocked outlet, to an internal air pressure of 2 times the maximum respiratory-supply pressure that is specified by the applicant or at 173 kN/m² (25 pounds per square inch) gauge, whichever is higher.

(f) Tightness. Leakage of air exceeding 50 cc. per minute at each coupling shall not be permitted when the hose and couplings are joined, immersed in water, and the respirator is under an air pressure of 173 kN/m² (25 pounds per square inch) gauge applied to the inlet end of the air-supply hose, or under an air pressure of twice the maximum respirator-supply pressure that is specified by the manufacturer, whichever is higher.

(g) *Detachable coupling.* A hand-operated detachable coupling by which the wearer can readily attach or detach the connecting hose shall be provided at a convenient location. This coupling shall be durable, remain connected under all conditions of normal respirator use, and meet the prescribed tests for strength and tightness of hose and couplings.

§ 84.251–4 Harness test.

(a) Belts, rings, and attachments for life lines must withstand a pull of 1334 newtons (300 pounds) for 30 minutes without failure.

(b) The arrangement and suitability of all harness accessories and fittings shall be considered.

(c) The harness shall be easily adjustable to various sizes.

(d) The hose shall be attached to the harness in a manner that will withstand a pull of 445 newtons (100 pounds) for 30

minutes without separating or showing signs of failure.

(e) The design of the harness and attachment of the line shall permit dragging the maximum length of hose considered for certification over a concrete floor without disarranging the harness or exerting a pull on the facepiece.

(f) The harness employed on air-line respirators shall not be uncomfortable, disturbing, or interfere with the movements of the wearer. The harness shall consist of a simple arrangement for attaching the hose to a part of the wearer's clothing in a practical manner that prevents a pull being exerted upon the respiratory-inlet covering equivalent to dragging the maximum length of hose over a concrete floor.

(g) Where air-line respirators have a rigid or partly rigid head covering, a suitable harness shall be required to assist in holding this covering in place.

§ 84.251-5 Breathing tube test.

(a) The breathing tubes employed on air-line respirators shall permit free head movement, ensure against closing off by kinking or by chin or arm pressure, and shall not create a pull that will loosen the facepiece or disturb the wearer.

(b) Air-line respirators of the continuous flow class shall employ one or two flexible breathing tubes of the non-kinking type which extend from the facepiece to a connecting hose coupling attached to the belt or harness; however, an extension of the connecting hose may be employed in lieu of the breathing tubes required.

(c) Air-line respirators of the positive and negative pressure classes shall employ a flexible, non-kinking type breathing tube which extends from the facepiece to the positive or negative pressure regulator, except where the regulator is attached directly to the facepiece.

§ 84.251-6 Airflow resistance test; Air-line respirator, continuous flow class.

The resistance to air flowing from the respirator shall not exceed 25 mm. (1 inch) of water-column height when the air flow into the facepiece is 115 liters per minute.

§ 84.251-7 Airflow resistance test; Air-line respirator, negative pressure class.

(a) Inhalation resistance shall not exceed 50 mm (2 inches) of water column height at an air flow of 115 liters per minute.

(b) The exhalation resistance to a flow of air at a rate of 85 liters per minute shall not exceed 25 mm (1 inch) of water column height.

§ 84.251-8 Airflow resistance test; Air-line respirator, positive pressure class.

(a) The static pressure in the facepiece shall not exceed 38 mm. (1.5 inches) of water-column height.

(b) The pressure in the facepiece shall not fall below atmospheric at inhalation airflows less than 115 liters per minute.

(c) The exhalation resistance to a flow of air at a rate of 85 liters per minute shall not exceed the static pressure in the facepiece by more than 51 mm. (2 inches) of water-column height.

Subpart U—Air-Purifying Respirators; General Requirements

§ 84.260 Air-purifying respirators; Description.

Air-purifying respirators are respirators with air-purifying elements such as cartridges, canisters, or filters, which protect wearers by removing contaminants from the ambient air.

§ 84.261 Cartridges, canisters and filters in parallel; Resistance requirements.

Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be essentially equal.

§ 84.262 Filters used with canisters and cartridges; Location; Replacement.

(a) Particulate filters used in conjunction with a gas and vapor canister or cartridge shall be located on the inlet side of the canister or cartridge.

(b) Filters shall be incorporated into or firmly attached to the canister or cartridge, and each filter assembly shall, where applicable, be designed to permit its easy removal from and replacement on the canister or cartridge.

§ 84.263 Powered air-purifying respirator flow requirements.

Powered air-purifying respirators shall be classified as tight fitting powered air-purifying respirators or loose fitting powered air-purifying respirators depending on their design. The minimum air flow for each is as follows:

(a) Tight fitting air-purifying respirators shall maintain an air flow rate of at least 115 liters per minute for a period of at least 4 hours unless otherwise specified.

(b) Loose fitting air-purifying respirators shall maintain an air flow rate of at least 170 liters per minute for a period of at least 4 hours unless otherwise specified.

(c) Powered air-purifying respirators shall be provided with an acceptable mechanism and appropriate instructions whereby the user can routinely and simply determine that the minimum air flow is maintained.

Subpart V—Particulate Air-Purifying Respirators

§ 84.270 Particulate air-purifying respirators; Description.

(a) Particulate air-purifying respirators, are respirators which employ filters to remove solid and liquid particulates from the ambient air. They are designed for use as respiratory protection from particulate environments (dusts, fume, mists) which are non-IDLH and which contain adequate oxygen to support life.

(b) Particulate air-purifying respirators are classified as Non-powered and Powered, according to their design.

(c) Non-powered particulate air-purifying respirators are classified according to the efficiency of the filter element(s). Low efficiency filters have a minimum efficiency of 95 percent; medium efficiency filters have a minimum efficiency of 99 percent; high efficiency filters have a minimum efficiency of 99.97 percent; as tested according to the requirements of this part.

(d) Particulate powered air-purifying respirators are classified according to the efficiency of the filter element(s). Medium efficiency filters have a minimum efficiency of 99 percent; High efficiency filters have a minimum efficiency of 99.97 percent; as tested according to the requirements of this part.

§ 84.271 Particulate air-purifying respirators; Performance requirements; General.

(a) Each particulate air-purifying respirator shall, as appropriate, meet the minimum construction requirements set forth in Subpart Q, the face seal leakage tests and requirements in Subpart R, the general requirements for particulate air-purifying respirators in Subpart U and the requirements for performance and protection specified in the tests described in § 84.273.

(b) The manufacturer, as part of the application for certification, shall specify the filter efficiency classification (>95, >99, or >99.97 percent efficiency) for which certification is being sought.

§ 84.272 Airflow resistance tests.

(a) Resistance to airflow shall be measured in the facepiece, mouthpiece, hood, or helmet of a particulate respirator (complete respirator) mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, before each test conducted in accordance with § 84.273.

(b) The maximum allowable resistance requirements for particulate

respirators in mm water-column height are as follows:

Initial Inhalation	30
Exhalation	20

§ 84.273 Particulate instantaneous penetration filter test.

Filters of particulate respirators shall be tested for instantaneous penetration filter efficiency against both solid and oil liquid particles in the following manner:

(a) Air-purifying elements of the respirators along with the element's holders and gaskets; where separable, shall be tested for instantaneous filter efficiency as mounted on a test fixture which incorporates the connector in the manner as used on the respirator.

(b) Prior to testing, all air-purifying elements of particulate filter respirators shall be taken out of their packaging and placed in an environment of 85 percent relative humidity at 38±2.5 °C for 24 hours. All tests shall be performed immediately after conditioning.

(c) Where the elements are not separable, the exhalation valves shall be blocked so as to ensure that leakage, if present, is not included in the efficiency evaluation.

(d) Filters shall be tested, each at a continuous airflow rate of 32 and 85 liters per minute for air-purifying respirators with a single filter (where filters are to be used in pairs the flow rate shall be 16 and 42.5 liters per minute, respectively through each filter).

(e) Powered particulate air-purifying respirators shall be tested while operating in their normal operational mode (with fully charged batteries if they possess battery packs). The air flow shall be as follows:

(1) Airflow shall be cycled through the respirator by a breathing machine at the rate of 24 respirations per minute with a minute volume of 40 liters; a breathing machine cam with a work rate of 100 watts (622 Kp-m/min) shall be used.

(2) Air inhaled through the respirator shall be sampled and analyzed for penetration.

(f) *Challenge aerosol.* (1) When testing for penetration of solid particulates, each respirator filter unit shall be challenged with an appropriate neutralized solid aerosol at 25±5 °C and at a relative humidity of less than 30 percent which contains no more than 200 mg/m³ until at least 100±5 mg of the aerosol has contacted the filter unit.

(2) When testing for penetration of oil liquid particulates, each respirator filter unit shall be challenged with an appropriate oil liquid aerosol at 25±5 °C which contains no more than 200 mg/m³ until at least 100±5 mg of the aerosol has contacted the filter unit.

(g) The particle size distribution of the test aerosol shall have an aerodynamic mean diameter of 0.2–0.3 micrometer and the standard geometric deviation shall not exceed 1.6 at the specified flowrate.

(h) The instantaneous penetration shall be monitored and recorded throughout the test period by a suitable light scattering photometer or equivalent instrumentation. If filter penetration is increasing when the 100±5 mg challenge point is reached, the test shall be continued until there is no further increase in penetration.

(i) Throughout the entire test the instantaneous penetration shall never exceed the level specified by the applicant.

Subpart W—Gas and Vapor Air-Purifying Cartridge Respirators

§ 84.280 Gas and vapor air-purifying cartridge respirators; Description.

(a) Gas and vapor air-purifying cartridge respirators (previously called chemical-cartridge respirators) are respirators with cartridge(s) designed to remove a single gas or vapor, a single class of gases or vapors, or a combination of two or more classes of gases or vapors as specified below from air. These respirators are designed for use as respiratory protection during entry into or escape from atmospheres not immediately dangerous to life and health and which contain adequate oxygen to support life. They are described according to the specific gases and vapors against which they are designed to provide respiratory protection, as follows:

Type of gas and vapor cartridge respirator	Maximum use concentration ppm
Ammonia	300
Chlorine	10
Hydrogen chloride	50
Methyl amine	75
Sulfur dioxide	50

(b) Gas and vapor air-purifying cartridge respirators are further classified as Powered, or Non-powered, according to their design.

(c) Gas and vapor air-purifying cartridge respirators are not intended for use against any gases or vapors with poor warning properties unless MSHA approves administrative controls, or the respirator is equipped with an effective, reliable end-of-service-life indicator. Also, they are not for use against gases or vapors which generate high heats of reaction with sorbent material in the cartridges.

(d) Gas and vapor air-purifying cartridge respirators for respiratory protection against gases or vapors which are not specifically listed with their maximum use concentration may be certified according to the requirements set forth in Subpart Z.

§ 84.281 Cartridges; Color and marking requirements.

The color and markings of all cartridges or labels shall conform to the requirements of the American National Standard for Identification of Gas Mask Canisters, ANSI K13.1–1973 standard obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

§ 84.282 Gas and vapor air-purifying cartridge respirators; General performance requirements.

Gas and vapor cartridge respirators and the individual components of each such device shall, as appropriate, meet the minimum construction requirements set forth in Subpart Q, the face seal leakage tests and requirements in Subpart R, the general requirements for air-purifying respirators in Subpart U, and the minimum requirements for performance and protection specified in the tests described in §§ 84.283 and 84.284.

§ 84.283 Breathing resistance test.

(a) Resistance to airflow shall be measured in the facepiece of a gas and vapor air-purifying cartridge respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with § 84.284.

(b) The maximum allowable resistance requirements for gas and vapor air-purifying cartridge respirators are as follows:

MAXIMUM RESISTANCE

(mm water column height)

Type of vapor and gas cartridge respirator	Inhalation		Exhalation
	Initial	Final[a]	
For gases, vapors, or gases and vapors	40	45	20
For gases, vapors, or gases and vapors, and particulates	50	70	20

[a] Measured at end of service life specified in Table 5.

(c) Combination gas and vapor and particulate air-purifying cartridge respirators shall meet the provisions of § 84.211 except that the maximum allowable resistance of such respirators shall not exceed the maximum allowable limits set forth in this § (84.283).

§ 84.284 Gas and vapor cartridge service life test.

(a) The service life of all gas and vapor cartridges shall be determined by continually passing a test atmosphere of known concentration and flow rate through the cartridge while monitoring the downstream concentration.

(b) Cartridges or pairs of cartridges shall be tested as follows:

(1) Units shall be tested at 50±3 percent relative humidity. (2) Units conditioned at 25±2.5° C by passing 25±3 percent relative humidity air through them for 6 hours at the following flow rates—

Type of cartridge	Airflow rate lpm
Air-purifying	25
Powered air-purifying with tight-fitting facepiece	115
Powered air-purifying with loose-fitting hood or helmet	170

—shall be tested at 25 ± 3 percent relative humidity.

(3) Units conditioned at 25±2.5° C by passing 85±3 percent relative humidity air through them for 6 hours at the flow rates stated in paragraph (b)(2) of this section shall be tested at 85±3 percent relative humidity.

(c) The test atmosphere shall be maintained at 25±2.5° C.

(d) The flow rate through the cartridge(s) being tested are as follows:

(1) Non-powered single gas or vapor cartridge air-purifying respirators with exhalation valves shall be tested each at a continuous air flow rate of 64 liters per minute. Where cartridges are to be used in pairs, the flow rate shall be 32 liters per minute through each filter.

(2) Non-powered air-purifying respirators without exhalation valves shall be tested by the same regimen as in § 84.284(b) except that a breathing machine operating according to § 84.273(e) (1), (2), and (3) will be employed instead of continuous flow.

(3) Powered air-purifying respirators with tight-fitting facepieces will each be tested at a flow rate of not less than 115 liters per minute.

(4) Powered air-purifying respirators with loose-fitting facepieces will each be tested at a flow rate of not less than 170 liters per minute.

(e) All conditioned cartridges shall be resealed, kept in an upright position at room temperature, and tested within 8 hours.

(f) Cartridges shall be tested and shall meet the minimum service life requirements set forth in Table 5.

TABLE 5—CARTRIDGE SERVICE LIFE TESTS AND REQUIREMENTS
(42 CFR Part 84, Subpart W, 84.284)

Cartridge	Test atmosphere		Penetration[a] (ppm)	Minimum life[b] (min.)
	Gas or Vapor	Concentration (ppm)		
Ammonia	NH_3	1,000	50	50
Chlorine	Cl_2	500	5	35
Hydrogen chloride	HCl	500	5	50
Methylamine	CH_3NH_2	1,000	10	25
Sulfur dioxide	SO_2	500	5	30

[a] Minimum life shall be determined at the indicated penetration.

[b] Where a respirator is designed for respiratory protection against more than one type of gas or vapor, as for use in ammonia and in chlorine or hydrogen chloride and organic vapors (84.308(b)), the minimum life shall be one-half that shown for each type of gas or vapor. Where a respirator is designed for respiratory protection against more than one gas of a type, as for use in chlorine and sulfur dioxide, the stated minimal life shall apply.

Subpart X—Gas and Vapor Air-Purifying Canister Respirators

§ 84.290 Description and classification.

(a) Gas and vapor air-purifying canister respirators (previously called gas masks) are respirators with canister(s) designed to remove a single gas or vapor, a single class of gases or vapors, or a combination of two or more classes of gases or vapors as specified below from air. Such respirators which contain a full facepiece are designed for use as respiratory protection in atmospheres which contain adequate oxygen to support life as follows: Entry into and escape from non-IDLH atmospheres, and escape from IDLH atmospheres. However, such respirators which do not contain full facepieces but

contain a half facepiece or mouthpiece/noseclamps may only be used for escape.

(b) Gas and vapor air-purifying canister respirators are classified according to their sorbent capacity as follows:

(1) *High capacity.* A gas and vapor air-purifying canister respirator which consists of a full facepiece, canister(s) (previously front or back mounted), and associated harness and connections.

(2) *Low capacity.* A gas and vapor air-purifying canister respirator which consists of a facepiece, canister(s) (previously chin-style or escape), and associated harness and connections.

(c) Gas and vapor air-purifying canister respirators shall be further classified according to the types of gases or vapors against which they are designed to provide respiratory protection, as follows:

Ammonia
Carbon Monoxide
Chlorine
Sulfur Dioxide

Combination of two or more of the above.

(d) Gas and vapor air-purifying canister respirators are not intended for use against any gases or vapors with poor warning properties unless MSHA approves such use or the respirator is equipped with an effective, reliable end-of-service-life indicator. Also, they are not for use against gases or vapors which generate high heats of reaction with sorbent materials in the canisters.

§ 84.291 Canisters; Color and marking requirements.

The color and markings of all canisters or labels shall conform with the requirements of the American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1–1973 standard, obtainable from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

§ 84.292 Performance requirements; General.

Gas and vapor air-purifying canister respirators shall meet the minimum construction requirements set forth in Subpart Q, the face seal leakage tests and requirements in Subpart R, the general requirements for air-purifying respirators in Subpart U, and the requirements for performance and protection specified in the tests described in §§ 84.293 through 84.295.

§ 84.293 Breathing resistance test.

(a) Resistance to airflow shall be measured in the facepiece of a gas and vapor air-purifying canister respirator mounted on a head form both before and after each test conducted in accordance with § 84.295 with air flowing at a continuous rate of 85 liters per minute.

(b) The maximum allowable resistance requirements for gas and vapor air-purifying canister respirators are as follows:

MAXIMUM RESISTANCE
(mm water column height)

Type of gas mask	Inhalation		Exhalation
	Initial	Final[a]	
High capacity			
(w/o particulate filter)	60	75	20
(w/certified particulate filter)	70	85	20
Low capacity			
(without particulate filter)	50	65	20
(w/certified particulate filter)	65	80	20

[a]Measured at end of the service life specified in Tables 6, and 7 in section 84.295.

§ 84.294 Particulate tests; Canisters containing filters.

Gas and vapor air-purifying canister respirators in combination with particulate filter media shall meet the requirements set forth in § 84.211 except that the maximum allowable resistance of complete particulate, and gas, vapor, or gas and vapor canister respirators shall not exceed the maximum allowable limits set forth in § 84.293.

§ 84.295 Canister service life test.

(a) The service life of all gas and vapor canisters, except for carbon monoxide tests, shall be determined by continually passing a test atmosphere of 25±2.5 °C, and known concentration and flow rate through the canisters while monitoring the downstream concentration (see Tables 6 and 7).

(b) Canisters or pairs of canisters, except for carbon monoxide tests, shall be tested as follows:

(1) Units shall be tested at 50±3

(2) Units conditioned at 25±2.5 °C by passing 25±3 percent relative humidity air through them for 6 hours at 64 at the following flow rates:

Type of Respirator	Airflow rate Lpm
Air-purifying	64
Powered air-purifying with tight-fitting facepiece	115
Powered air-purifying with loose-fitting hood or helmet	170

--shall be tested at 25 ± 3 percent relative humidity.

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TABLE 6--CANISTER SERVICE LIFE TESTS AND REQUIREMENTS FOR HIGH CAPACITY GAS AND VAPOR AIR-PURIFYING CANISTERS
(42 CFR Part 84, Subpart X, 84.295)

Canister Type	Test atmosphere: Gas or Vapor	Test atmosphere: Concentration (ppm)	Test atmosphere: Flowrate (Lpm): Nonpowered	Test atmosphere: Flowrate (Lpm): Powered: Tight	Test atmosphere: Flowrate (Lpm): Powered: Loose	Maximum allowable penetration (ppm)	Minimum service life (min.)
Chlorine. . . .	Cl_2	20,000	64	115	170	5	12
Sulfur Dioxide.	SO_2	20,000	64	115	170	5	12
Ammonia	NH_3	30,000	64	115	170	50	12
Carbon monoxide	CO	20,000	64[b]			(c)	60[d]
	CO	5,000	32[d]			(c)	60
	CO	3,000	32[b]			(c)	60
Combination of 2 or 3 of above types[e]							
Combination of all of above types plus organic vapor (84.308(a)[f]							

[a]Minimum life shall be determined at the indicated penetration.

[b]Relative humidity of test atmosphere shall be 95 ± 3 percent; temperature of test atmosphere shall be 25 ± 2.5 °C.

[c]Maximum allowable CO penetration shall be 385 cm^3 during the minimum life. The penetration shall not exceed 500 p/m during this time.

[d]Relative humidity of test atmosphere will be 95 ± 3 percent; temperature of test atmosphere entering the test fixture shall be between 0 °C and +2.5 °C.

[e]Test conditions and requirements shall be applicable as shown above.

[f]Test conditions and requirements shall be applicable as shown above, except the minimum service lives for Cl_2, SO_2, organic vapor, and ammonia shall be 6 min. instead of 12 min.

TABLE 7--CANISTER SERVICE LIFE TESTS AND REQUIREMENTS FOR LOW CAPACITY GAS AND VAPOR AIR-PURIFYING CANISTERS
(42 CFR Part 84, Subpart X, 84.295)

Canister Type	Test atmosphere: Gas or Vapor	Test atmosphere: Concentration (ppm)	Test atmosphere: Flowrate (Lpm): Nonpowered	Test atmosphere: Flowrate (Lpm): Powered: Tight	Test atmosphere: Flowrate (Lpm): Powered: Loose	Maximum allowable penetration (ppm)	Minimum service life (min.)
Chlorine	Cl_2	5,000	64	115	170	5	12
Sulfur Dioxide	SO_2	5,000	64	115	170	5	12
Ammonia	NH_3	5,000	64	115	170	50	12
Carbon monoxide	CO	20,000[h]	64[b]			(c)	60
	CO	10,000[i]	64[b]			(c)	60[g]
	CO	5,000	32[d]			(c)	60
	CO	3,000	32[b]			(c)	60
Combination of 2 or 3 of above types[e]							
Combination of all of above types plus organic vapor (84.308 (a)[f]							

[a]Minimum life will be determined at the indicated penetration.

[b]Relative humidity of test atmosphere shall be 95 ± 3 percent temperature of test atmosphere shall be 25 ± 2.5 °C.

[c]Maximum allowable CO penetration shall be 385 cm^3 during the minimum life. The penetration shall not exceed 500 p/m during this time.

[d]Relative humidity of test atmosphere shall be 95 ± 3 percent; temperature of test atmosphere entering the test fixture shall be between 0 °C and +2.5 °C.

[e]Test conditions and requirements shall be applicable as shown above.

[f]Test conditions and requirements shall be applicable as shown above, except the minimum service lives for Cl_2, SO_2, organic vapor, and ammonia shall be 6 min. instead of 12 min.

[g]If effluent temperature exceeds 100 °C during this test for a gas mask for escape only, it shall be equipped with an effective heat exchanger.

[h]Low capacity full facepiece devices for entry into and escape from appropriate non-IDLH atmospheres.

[i]Low capacity mouthpiece/noseclamp devices for escape only from appropriate non-IDLH atmospheres.

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(3) Units conditioned at 25±2.5 °C by passing 85±3 percent relative humidity air through them for 6 hours at the flowrates stated in (b)(2) of this section shall be tested at 85±3 percent relative humidity.

(c) The conditioned canisters shall be resealed, kept in an upright position at room temperature, and tested within 8 hours.

(d) High capacity gas and vapor canisters shall be tested according to and shall meet the minimum requirements set forth in Table 6.

(e) Low capacity gas and vapor canisters will be tested according to and shall meet the minimum requirements set forth in Table 7.

(f) (1) Since carbon monoxide does not have adequate warning properties, all gas and vapor canisters, except those with mouthpieces/noseclamps, designated as providing respiratory protection against carbon monoxide shall have a window or other indicator to warn the wearer at 80±10 percent of the total service life.

(2) Other canisters may also be equipped with a window or other indicator to warn of imminent leakage of other gases or vapors.

(3) The window indicator canisters shall be tested as regular canisters, but shall show a satisfactory indicator change or other warning at 80±10 percent of the total service life.

Subpart Y—Organic Gas and Vapor Air-Purifying Cartridge and Canister Respirators

§ 84.300 Description and limitations.

(a) Organic gas and vapor air-purifying respirators are respirators which have cartridges or canisters which are designed to remove gases and vapors from air. They are for use only in environments which contain adequate oxygen to support life and are not intended for use against any organic gases or vapors with poor warning properties unless MSHA approves such use controls, or where the respirator is equipped with an effective, reliable end-of-service-life indicator. Also, they are not for use against gases or vapors which generate high heats of reaction with sorbent material.

(b) Organic gas and vapor air-purifying respirators for protection against organic gases or vapors which do not have adequate warning properties may be certified according to the requirements as set forth in Subpart Z.

§ 84.301 Organic gas and vapor air-purifying cartridge respirators.

(a) Organic gas and vapor air-purifying cartridge respirators (previously called chemical-cartridge respirators) are designed for use as respiratory protection during entry into and escape from non-IDLH atmospheres. They may be used in a concentration of organic gas and vapor which is non-IDLH, or up to a maximum concentration of 1,000 ppm of the organic vapor or gas, whichever concentration is lower.

(b) Organic gas and vapor air-purifying cartridge respirators are further classified as Powered or Non-powered according to their design.

§ 84.302 Organic gas and vapor air-purifying canister respirators.

(a) Organic gas and vapor air-purifying canister respirators (previously called gas masks) which contain a full facepiece are designed for use as respiratory protection in atmospheres which contain adequate oxygen to support life as follows:

(1) Entry into and escape from non-IDLH atmospheres, and

(2) Escape from IDLH atmospheres. However, those respirators which do not contain full facepieces but contain a half facepiece or mouthpiece/noseclamps may only be used for escape.

(b) Organic gas and vapor air-purifying canister respirators are classified according to their sorbent capacity as follows:

(1) *High capacity.* A gas and vapor air-purifying canister respirator which consists of a full facepiece, canister(s) (previously front or back mounted), and associated harness and connections.

(2) *Low capacity.* A gas and vapor air-purifying canister respirator which consists of a facepiece, canister(s) (previously chin-style or escape), and associated harness and connections.

§ 84.303 Labeling requirements.

(a) The manufacturer shall provide as part of the labeling a list of organic vapor(s) and gas(es) which have adequate warning properties and against which their respirators provide adequate protection for the wearer.

(b) A warning shall be placed on the labeling or instructions of each organic gas and vapor air purifying cartridge and canister respirator, and on the label of each canister and cartridge respirator, alerting the wearer that they do not provide protection against all organic vapor and gas air contaminants and that they are not intended to be used against substances with inadequate warning properties, except as indicated in § 84.300.

§ 84.304 Color and marking requirements.

The color and markings of all canisters and cartridges or labels shall conform with the requirements of the American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI, K13.1–1973 standard, obtainable from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

§ 84.305 Performance requirements; General.

Organic gas and vapor air-purifying canister and cartridge respirators, and the individual components of each device shall, as appropriate, meet the minimum construction requirements set forth in Subpart Q, the face seal leakage tests and requirements in Subpart R, the general requirements for air-purifying respirators in Subpart U, and the requirements for performance and protection specified in the tests described in §§ 84.306 through 84.308.

§ 84.306 Breathing resistance test.

(a) Organic gas and vapor air-purifying cartridge respirators shall meet the breathing resistances set forth in § 84.283 except that the resistance shall be measured at the end of service life specified in § 84.308(b).

(b) Organic gas and vapor air purifying canister respirators shall meet the breathing resistances set forth in § 84.293 except that the resistance shall be measured at the end of service life specified in § 84.308(a).

§ 84.307 Particulate tests; Canisters and cartridges containing filters.

Organic gas and vapor air-purifying respirators in combination with particulate filter media shall meet the requirements set forth in § 84.211 except that the maximum allowable resistance of complete particulate and gas, vapor, or gas and vapor respirators shall not exceed the maximum allowable limits required under § 84.306.

§ 84.308 Service life test.

(a) The service life of all organic gas and vapor canisters shall be determined by continually passing a CCl_4 test atmosphere of 25±2.5° C, known concentration and flow rate through the canister while monitoring the downstream concentration. The canisters will be tested as described in Subpart X § 84.295 except that the service life test shall be as follows:

Canister Type	Test atmosphere: Gas or Vapor	Test atmosphere: Concentration (ppm)	Flowrate (Lpm): Nonpowered	Flowrate (Lpm): Powered Tight	Flowrate (Lpm): Powered Loose	Maximum allowable penetration (ppm)	Minimum service life (min.)
High capacity.....	CCl_4	20,000	64	115	170	5	12
Low capacity.....	CCl_4	5,000	64	115	170	5	12

(b) The service life of all organic gas and vapor cartridges shall be determined by continually passing a CCl_4 test atmosphere at 25±2.5° C, known concentration, and flow rate through the cartridge while monitoring the downstream concentration. The cartridge shall be tested as described in Subpart W § 84.284 except that the service life test shall be as follows:

Cartridge	Test atmosphere: Gas or Vapor	Test atmosphere: Concentration (ppm)	Penetration (ppm)	Minimum life (min.)
OV cartridge	CCl_4	1000	5	50

Where a respirator is designed for respiratory protection against more than just organic vapor(s) and gas(es) (also ammonia, chlorine, hydrogen chloride, methylamine, or sulfur dioxide), the minimum service life shall be one-half that for each type as listed above or in § 84.284 Table 5.

Subpart Z—Gas and Vapor Air-Purifying Respirators for Unlisted Contaminants

§ 84.310 Description.

Some gas and vapor air-purifying respirators are designed for respiratory protection against a specific vapor or gas contaminant which was not addressed in Subpart W, Subpart X, or Subpart Y of this part. Such respirators are designed for protection from atmospheres containing the specific contaminant and containing adequate oxygen to support life. They are described according to their construction as follows:

(a) High capacity gas and vapor air-purifying canister respirators;

(b) Low capacity gas and vapor air-purifying canister respirators;

(c) Gas and vapor air-purifying cartridge respirators;

(d) Powered gas and vapor air-purifying respirators; and

(e) Other devices, including combination respirators.

§ 84.311 Application for certification.

Each such respirator may be certified if the applicant submits a request for such certification to NIOSH. NIOSH shall consider each such application and accept or reject the application after a review of the application's scientific merit and supporting data, and/or appropriate testing, and/or a review of the effects on the wearer's health and safety, and in light of any field experience in use of gas and vapor air-purifying respirators as protection against such hazards.

§ 84.312 General test requirements.

(a) All applications for certification of such respirators designed as respiratory protection against substances not specifically set forth in Part 84 shall contain but not be limited to the following information and supporting data:

(1) Data on desorption of gases and vapors from the sorbent including a flow-temperature study at low and high temperatures and humidities: Data shall be sufficient to demonstrate that the desorbed level of gases and vapors will not be harmful to the wearer.

(2) Data on desorption of impregnating agents used in the cartridge/canister including a flow-temperature study at low and high temperatures and humidities: Data shall be sufficient to demonstrate safe levels of desorbed agents.

(3) A list of catalytic products produced in the reaction of the sorbent with the contaminant gases and vapors, their concentrations and their toxicities.

(4) Data on the toxicity of the impregnating agent(s) sufficient to ensure that there is no creation of hazard to the wearer.

(5) A family of breakthrough time curves at low and high temperatures, humidities and concentrations.

(6) Data on the effects of the commonly found interferences which could impair the ability of the respirator to protect the wearer (i.e., decreased service life). Studies and/or data demonstrating that the unlisted substance has "adequate warning properties" for those respirators that are not equipped with end-of-service-life indicators.

(b) NIOSH reserves the right to require additional pertinent data needed in order to determine the intrinsic safety of the respirator.

§ 84.313 Performance requirements.

Such respirators and the individual components of each device shall, as appropriate, meet the minimum construction requirements set forth in Subpart Q, the quantitative leakage tests and requirements set forth in Subpart R, the general requirements for air-purifying respirators set forth in Subpart U, and the minimum requirements for performance as established by NIOSH on a case by case basis considering factors such as the contaminant's PEL, normal environmental concentration ranges, the contaminant's inherent toxicity, work exposure time requirements, normal environmental use conditions, and effects on the wearer's health and safety.

§ 84.314 Requirements for end-of-service-life indicators.

(a) Each canister or cartridge respirator submitted for testing and certification in accordance with this subpart shall be equipped with an end-of-service-life indicator (ESLI) (except for those respirators intended for use against substances having adequate warning properties) which shows a satisfactory indicator change or other obvious warning before the NIOSH established limit is reached. The

indicator shall show such change or afford such warning less than or equal to 90 percent of the total service life.

(b) The applicant shall provide the following data:

(1) Data demonstrating that the ESLI is a reliable indicator of sorbent depletion (less than or equal to 90 percent of service life). These data shall include the results of a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are reasonably representative of actual workplace conditions where it is anticipated that a given respirator will be used. A minimum of 2 contaminant levels must be utilized for each study, including the limit level (threshold limit value, etc.) and the limit level times the assigned protection factor for the respirator type.

(2) Data on desorption of any impregnating agents used in the indicator. These data shall include the results of a flow-temperature study at low and high temperatures and humidities which are reasonably representative of actual workplace conditions where it is anticipated that a given respirator will be used. Data shall be sufficient to demonstrate safe levels of desorbed agents.

(3) Data on the effects of interferences which are commonly found in the kinds of workplaces where it is anticipated that a given respirator will be used. Data should be sufficient to show which interferences could impair the effectiveness of the indicator and the degree of impairment and to show which substances will not affect the indicator.

(4) Data on any reaction products produced in the reaction between the sorbent and the contaminant gases and vapors against which it is designed to protect, including the concentrations and toxicities of such products.

(5) Data which predicts the storage life of the indicator. Simulated aging tests will be acceptable.

(c) All passive ESLI shall be visible to the wearer and shall be detectable to people with physical impairments such as color blindness.

(d) If color change is utilized, reference colors for the initial color of the indicator and final color of the indicator shall be placed adjacent to the indicator.

(e) For all active and passive indicators:

(1) The ESLI shall not interfere with the effectiveness of the face seal.

(2) The ESLI shall not change the weight distribution of the respirator to the detriment of the facepiece fit.

(3) The ESLI shall not interfere with required lines of sight.

(4) Any ESLI that is permanently installed in the respirator facepiece shall be capable of withstanding cleaning and a drop from a 6-foot height. Replaceable ESLI must be capable of being easily removed and shall also be capable of withstanding a drop from a 6-foot height.

(5) A respirator with an ESLI shall still meet all other applicable requirements set forth in 42 CFR Part 84.

(6) Any electrical components utilized in an ESLI shall conform to the provisions of the National Electrical Code and be "intrinsically safe." Where permissibility is required, the respirator shall meet the requirements for permissibility and intrinsic safety set forth in 30 CFR Part 18, Subpart D, § 18.82, Permit to use experimental electric face equipment in a gassy mine or tunnel. Also, the electrical system shall include an automatic warning mechanism that indicates a loss of power.

(7) Effects of interferences for substances which are commonly found in workplaces where it is anticipated that a given respirator will be used must be determined and those substances which hinder ESLI performance shall be identified. Substances which are commonly found where the respirator is to be used must be investigated. Data sufficient to indicate whether the performance is affected must be submitted to NIOSH. Manufacturers of respirators equipped with ESLI shall label the respirator in such a manner to make the user aware of use conditions that could cause false positive and negative ESLI responses.

(8) The ESLI shall not create any hazard to the wearer's health or safety.

(9) Consideration shall be given to the potential impact of common human physical impairments on the effectiveness of the ESLI.

(f) A cartridge or canister respirator without an ESLI may be certified for use but usage will be strictly limited to the environmental conditions and use situations which shall be prominently displayed on the label.

Appendix A.—Assumed Conditions of Use

The use of respirators referenced to in this part are governed by MSHA. However, for the purpose of certifying respirators under the provisions of this part, the following general assumptions are made about the conditions in which respirators are to be used:

(a) Cartridge respirators, canister respirators, particulate respirators, and air-line respirators will only be used in atmospheres which are not immediately dangerous to life and health (IDLH) except that canister respirators may be used to escape from, but not entry into, IDLH atmospheres which have adequate oxygen.

(b) Positive pressure self-contained breathing apparatus will be used in all hazardous atmospheres including IDLH atmospheres, provided appropriate use practices are followed. Negative pressure long duration (over 1 hour), closed-circuit devices may be used where IDLH and flammable or explosive atmospheres are present, such as for mine rescue, where the applicable regulatory agency so approves.

(c) Respirators incorporating a mouthpiece will be used only for emergency escape and will not be used for entry into any hazardous atmosphere.

(d) Gas and vapor respirators without end-of-service-life indicators will not be used for protection against gases and vapors that do not have adequate warning properties unless MSHA approves such use.

(e) Gas and vapor respirators will be used only when adequate warning properties of the contaminant exist to warn the wearer of sorbent breakthrough; such warning properties shall not be compromised by the presence of additional substances or situations which interfere with the odor or irritation threshold of the wearer. Adequate warning properties means that a gas or vapor has a reliable and persistent odor or irritation threshold which is less than three times its threshold limit value level and, if a ceiling limit is established, less than one-third its ceiling level.

(f) Gas and vapor cartridge respirators will be used in concentrations in excess of the maximum use concentrations specified in this part.

(g) Atmosphere supplying respirators will only be used when supplied with breathing gas that meets the following standards, as applicable:

(1) Compressed, gaseous breathing air shall meet the applicable minimum requirements for Type I, Grade D of ANSI Z86.1–1973 standard.

(2) Compressed, liquefied breathing air shall meet the applicable minimum requirements of Type II, Grade D of ANSI Z86.1–1973 standard.

(3) Oxygen, including liquid oxygen, shall meet the minimum requirements for medical or breathing oxygen set forth in the U.S. Pharmacopoeia, 20th revision, 15th edition of the National Formulary (USP20NF15) dated July 1, 1980, and chemically generated oxygen shall meet the requirements of Military Specification MIL–O–83252, dated 1972, or Military Specification MIL–O–15633, dated 1964, whichever is applicable.

(h) Airline respirators are used only in non-IDLH atmospheres.

(i) Respirators certified under the provisions of this part will only be used as part of a complete respirator program which encompasses all aspects of respirator use including: hazard definition, selection, fitting, training, maintenance, storage, monitoring, use supervision, and administration.

(j) The breathing gas contained in self-contained breathing apparatus shall meet the following requirements as applicable:

(1) Oxygen, including liquid oxygen, shall meet the minimum requirements for medical or breathing oxygen set forth in the U.S. Pharmacopoeia, 20th revision, 15th edition of

the National Formulary (USP20NF15) dated July 1, 1980, and chemically generated oxygen shall meet the requirements of Military Specification MIL–O–83252, dated 1972, or Military Specification MIL–O–15633, dated 1964, whichever is applicable.

(2) Except as prescribed in paragraph (c) of this section, compressed gaseous breathing air shall meet the requirements for Type I, Grade D of ANSI Z86.1–1973 standard.

(3) Where necessary to assure a concentration of 19.5 percent oxygen in the wearer's breathing zone with a closed- or open-circuit self-contained breathing apparatus, the concentration of oxygen may exceed the 23 percent maximum concentration prescribed in ANSI Z86.1–1973 standard for Type I, Grade D in mixed compressed gaseous breathing air, but shall not exceed 30 percent maximum concentration.

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