42 CFR Part 84

Revision of Tests and Requirements for Certification of Respiratory Protective Devices

SECOND NOTICE OF PROPOSED RULEMAKING

September 18, 1989

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control

42 CFR Part 84

National Institute for Occupational Safety and Health (NIOSH) Revision of Tests and Requirements for Certification of Respiratory Protective Devices

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

ACTION: Second notice of proposed rulemaking

SUMMARY: On August 27, 1987, the National Institute for Occupational Safety and Health (NIOSH) published in the Federal Register (52 FR 32401) a Notice of Proposed Rulemaking (NPRM) for certification of respiratory protective devices. The Notice proposed a regulation for 42 CFR Part 84. Upon promulgation, 42 CFR Part 84 will replace 30 CFR Part 11. On October 8, 1987, additional information regarding procedures for public comment on the

proposed rule was published in the Federal Register (52 FR 37639), and the public comment period was extended to December 28, 1987. Public meetings on the proposed rule were held January 20, 1988, in San Francisco, California, and January 27–28, 1988, in Washington, D.C. On February 25, 1988, NIOSH published a Federal Register notice (53 FR 5595) announcing a second extension of the public comment period to March 28, 1988.

In the first NPRM of August 1987, NIOSH proposed extensive changes in the current performance test requirements for certifying respirators. These requirements were last promulgated as 30 CFR Part 11 in 1972 (37 FR 6244) with only minor amendments since that date. Concurrent with the publication of the proposed 42 CFR Part 84, the Mine Safety and Health Administration (MSHA) of the Department of Labor published a notice in the Federal Register (52 FR 32313) proposing the withdrawal of 30 CFR Part 11, upon final publication of 42 CFR Part 84.

During a 7-month comment period, NIOSH received 271 comments in response to the first proposal of August 27, 1987. The principal technical issues addressed in the comments included the focus of the proposed regulation on respirators used in mines and mining, the requirement that certification applicants perform workplace or simulated-workplace tests demonstrating respirator safety and efficacy, the requirement that particulate respirators be performance tested against both solid and liquid aerosols, and the requirement that chemical cartridges be both preconditioned and performance tested at 85% relative humidity. In developing this second NPRM, NIOSH considered all written com-

ments submitted to the Docket before the closing date of March 28, 1988, during the 7-month comment period.

NIOSH has concluded that this second proposed rule, if implemented, would create significant health benefits for up to 6.6 million users of NIOSH-certified respirators. This number could grow to up to 10 million users by the mid-1990s. Additionally, Part 84 will provide significant economic and other benefits to 32 domestic respirator manufacturers, owners of about 7 million nondisposable respirators, and those employers who annually purchase over 110 million disposable respirators. In general these benefits cannot be quantified.[1] However they will be obtained at reasonable economic cost to respirator owners, purchasers, and manufacturers.[2]

This second proposal is the result of the informal rulemaking process. It represents the best efforts of NIOSH to respond to public comments received on the first proposal of August 1987. The Institute has made extensive changes to the original proposal. In addition to more than 100 minor technical and administrative changes, the following major changes have been incorporated in this proposal:

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[1]National Institute for Occupational Safety and Health: Preliminary Regulatory Impact Analysis: 42 CFR Part 84, Second Notice of Proposed Rulemaking–Revision of Tests and Requirements for Certification of Respiratory Protective Devices, (September 1989), Section C.

[2]Ibid., Sections D and E.

- Deletion of workplace or simulated-workplace performance testing (former §§ 84.31, 84.32).

- Deletion of optional certification at higher performance levels (i.e., above class minima) for individual "better performing" makes and models (former § 84.33).

- Deletion of "mines and mining" language regarding NIOSH certifications (§ 84.1).

- Revision of Sunset Clause for Part 11 certifications (§ 84.2(b)(1)) from 5-year expirations to 5-, 6-, and 8-year expirations for different respirator classes.

- Addition of requirement for NIOSH to conduct "selective tests on each respirator submission" to substantiate test results from manufacturers (§ 84.31).

- Addition of triennial-audit testing to the quality assurance requirements (§ 84.20(f)).

- Addition of optional "upgrade kits" certification procedures (§§ 84.2 (b)(3), 84.11(a)(9)).

- Addition of two more certification classes for particulate respirators (§ 84.293). Certifications would be available for solid only, liquid only, or both solid and liquid particulates.

- Revision of requirements for human subject protection (§ 84.11(a)(11)).

- Revision of statistical methods for analysis of data from performance tests. The required sample size for most performance tests will increase from the current sample of three (under 30 CFR Part 11) to a proposed value of six samples for each performance test (§ 84.229).

- Deletion of high-humidity preconditioning for all gas and vapor sorbents. To maintain equivalent protection for users, a "shelf-life disclosure" requirement has been added (§§ 84.304(h) and 84.315(g)).

Interested and affected parties are invited to participate in this second proposed rulemaking by submitting such written views or arguments as they may desire. In particular, NIOSH is interested in receiving suggestions for alternative means of accomplishing the objectives given in this preamble at lower costs to respirator owners and manufacturers, while providing equal or superior protection to respirator users.

As part of the public comment process on this second proposal, NIOSH intends to conduct a Technical Clarifications Meeting in Morgantown, West Virginia no less than 6 weeks after the publication of this second NPRM. To aid interested parties in preparing their comments to the record, NIOSH will provide a panel of technical experts to clarify technical issues contained in this second proposal. To make the meeting as productive as possible, parties will be requested to submit their questions in advance. The specific date, time, address, and other supplementary information for this meeting will be announced in the next few weeks in a Federal Register notice.

No written submission, or any portion thereof, made in response to this Notice will be received or held in confidence. NIOSH will consider all written comments received before the specified closing date before taking action on this proposed rule. This second proposal may be changed in light of the comments received.

DATE: Written comments on the second proposed rule must be received at the NIOSH Docket Office on or before the close of business on [Insert date 90 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Comments on the proposed rule should be mailed in triplicate to: NIOSH Docket Office, Room S-112, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505. The administrative record of this rulemaking is located at the same address and is available for viewing and copying between

8:00 a.m. and 4:30 p.m., Monday through Friday, except for Federal holidays. The telephone number of the NIOSH Docket Office is (304) 291–4597.

FOR FURTHER INFORMATION CONTACT: Robert H. Schutz, Docket Officer, National Institute for Occupational Safety and Health, Division of Safety Research, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505, telephone (304) 291–4597.

SUPPLEMENTARY INFORMATION: In 1972 the Departments of the Interior and of Health, Education, and Welfare issued substantial revisions to the Federal regulation in 30 CFR Part 11. This regulation specifies the performance tests and certification criteria for industrial respirators used to protect workers from hazardous atmospheres in American workplaces. Under this regulation the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) jointly issue approval certificates to respirator manufacturers. Currently more than 1,600 NIOSH/MSHA certifications are in effect for more than 7,000 industrial respirator models.

Up to 6.6 million American workers use NIOSH-certified respirators, either full time or part time, to protect themselves from hazards in their workplaces. Occupational Safety and Health Administration (OSHA) regulations require that NIOSH/MSHA-certified respirators be used by many of these workers. Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-certified respirators.

Many of these workers must wear their NIOSH-certified respirators as an involuntary condition of employment. Hundreds of thousands of American workers wear NIOSH-certified respirators in highly toxic and lethal environments in which a momentary lapse in respiratory protection can result in serious injury or death.

Additionally, over the next several years (possibly until December 31, 1993) several million American workers may have to wear NIOSH-certified respirators so that their employers can comply with a recent OSHA amendment to its Air Contaminants standard (29 CFR 1910.1000 including Tables Z-1, Z-2, and Z-3).[3] In this amendment OSHA lowered 212 Permissible Exposure Limits (PEL) listed in these three tables and set new PELs for 164 substances that had not been previously regulated. OSHA estimated that over 4.5 million workers are currently exposed above the new PELs.[4] The OSHA amendment permits the use of any compliance methodology, possibly until December 31, 1993, to comply with the new PELs for millions of workers. Over the several years during which feasible engineering controls are being installed in the 131,005 affected plants,[5] it is logical to presume that many employers will require their employees to wear NIOSH-certified respirators.

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[3]Occupational Safety and Health Administration: Final Rule, Air Contaminants, 29 CFR Part 1910, Federal Register 54(12):2332-2983 (January 19, 1989).

[4]Ibid., p. 2725.

[5]Ibid., p. 2863.

During the last 17 years, NIOSH and MSHA have made only minor amendments to the certification test criteria. For more than 10 years there has been a growing consensus among respirator manufacturers and user communities that NIOSH and MSHA should substantially revise the 1972 performance requirements. Many of the current certification tests are obsolete, application-specific, and do not represent typical use conditions for many NIOSH-certified respirators. The current certification categories stifle design flexibility, hamper innovation, and hinder the marketing of more cost-effective respirators. Therefore, respirator users, owners, and manufacturers will substantially benefit from the replacement of design- and application-specific standards with those that are performance-based.

Respirator purchasers, owners, and users must recognize that the use of NIOSH-certified respirators affected by this proposal is governed by other Federal agencies (e.g., MSHA, OSHA, EPA, NRC). This second proposal will result in certification standards that can be used as the foundation for strong and effective respirator use regulations. During the development of 42 CFR Part 84, NIOSH recognized that many current requirements in 30 CFR Part 11 are the responsibility and under the authority of these agencies. NIOSH looks forward to working with other Federal agencies to achieve a unified and consistent body of Federal regulations for respirator certification and use.

In order to propose and promulgate the necessary regulatory revisions, NIOSH had to build an extensive research database. NIOSH was able to develop this regulatory proposal because of substantial technical advances in respira-

tor devices and test methods that have occurred during the last 15 years. This proposal has three major advantages compared with the present certification requirements:

- substantial technical upgrading of laboratory performance tests,

- addition of quantitative face-seal performance tests in the laboratory on 25-person panels for all negative-pressure respirators, and

- substantial opportunity for respirator manufacturers to market innovative new respirators by replacing many current certification tests for respirator components that are design-or application-specific with certification tests that are performance-based.

NIOSH requires the procedures and performance tests contained in this proposal to adequately fulfill its legislatively mandated responsibilities for certifying respirators (30 U.S.C. §§ 842(h), 844, and 957). Before NIOSH grants a certification, it must have sufficient evidence of safety and adequate performance. Health and safety professionals and respirator purchasers appear to rely on these government certifications when they purchase respirators. For example, Howard J. Cohen, corporate manager of industrial hygiene services for Olin Corporation, recently made the following statement to an industry trade publication:

Most users really can't distinguish between a good and a marginal device. They rely on NIOSH certification, which is like an Underwriters' Laboratories' approval.[6]

Additionally, a major respirator manufacturer has for several years placed an advertisement in health and safety journals that states in large bold letters,

TO MEASURE SAFETY, COMPANIES COMPARE THEIR RESPIRATORS WITH THIS STANDARD

followed by a picture of a NIOSH/MSHA certification label.[7]

Essentially all of these certifications have questionable reliability due to the following performance testing and quality assurance requirements in the Part 11 regulation:

- All current certifications were originally issued on the basis of test results from a limited number of samples. For example, many laboratory tests are performed on only three samples. For this sample size, only when 63% or more of a particular model is ineffective will a sample of three have a substantial chance of rejecting the model. For the 7,000+ makes and models holding certifications

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[6]Minter, S. G.: Breathing New Life Into OSHA's Respirator Rule, Occupational Hazards 51(5):89–93 (May 1989).

[7]North Safety Equipment advertisement, Occupation Hazards 51(3):4 (March 1989).

under Part 11, the certification means only that at least 37% of each make and model met the test requirements of Part 11 at the time of the original testing, if the tested samples were representative of each production make and model. This problem will be addressed by new statistical methodology and increased sample size given in § 84.229. To compound the problem of questionable assurance provided by a sample of three, NIOSH has reason to suspect that some of the current certifications were issued after testing of "laboratory queens" that were given extraordinary attention by manufacturers before they were submitted for certification testing. This issue will be addressed by requirements in § 84.11(a)(4).

- None of the current certifications are based on reliable testing for face seal efficacy. A respirator face seal is one of the most critical components affecting safety and efficacy on any respirator. The current testing of this component with qualitative fit tests may be unreliable for detecting unsafe or ineffective face seals. This area will be addressed with the requirements of Subpart R.

- Over 50% of the current certifications under 30 CFR Part 11 are for air-purifying, charcoal sorbent devices (e.g., gas masks and chemical cartridge half-masks). Currently the majority of these devices are used for protection against organic vapors (OV). Current certifications effectively permit users to be unknowingly provided with OV sorbents that are likely to have substantially reduced service lives if they have been stored in high humidity conditions. If a

sorbent is unsafe or ineffective, the respirator will be unsafe or ineffective. Additionally, any respirators with marginal effectiveness due to short service lives are undetectable to the user when they are taken out of the packing container and put into use. Thus the safety and efficacy of currently certified sorbent respirators is questionable under high-humidity storage conditions. This issue will be addressed by the "shelf-life disclosure" requirements of §§ 84.304(h) and 84.315(g).

■ Over 10% of the current certifications under 30 CFR Part 11 are for widely-used, air-purifying, filter respirators (e.g., (1) dust, fume, and mist; (2) dust and mist; (3) paint lacquer and enamel mist). These certifications were granted on the basis of results from filter tests that are invalid for many current use conditions in American workplaces. Additionally, there are substantial reliability and validity problems with the current tests. NIOSH researchers have published articles concluding that the current tests are "non-reproducible," are "insensitive" (i.e., cannot discriminate between poor and high efficiency filters), and "have gradually become irrelevant."[8,9] If a filter is unsafe or ineffective, the respirator will be unsafe or ineffective. Additionally, unsafe or ineffective filters

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[8]Reed, L. D., D. L. Smith, and E. S. Moyer: Comparison of Respirator Particulate Filter Test Methods, J. I.S.R.P. 4(3):43–60 (1986).

[9]Moyer, E. S.: "Respirator Filtration Efficiency Testing," Fluid Filtration: Gas, Volume I, ASTM STP 975, R. R. Raber, Ed., American Society for Testing Materials, Philadelphia, PA, (1986), pp. 167–180.

are undetectable to the user. Thus the safety and efficacy of certified filter respirators is of substantial concern. The current filter tests will be substantially revised as provided for in the Subpart V provisions.

- Lastly, for all current certifications under Part 11 (both air-purifying and atmosphere-supplying respirators), the quality assurance (QA) regulatory requirements for production-line respirators (those shipped to the public on a daily basis) cannot provide assurance to respirator users that they will receive a respirator meeting 30 CFR Part 11 requirements. Current certifications require manufacturers to use "AQL-type" QA sampling plans that favor respirator manufacturers. For example, 30 CFR 11.41 appears to permit shipment to users only if less than 1.0% of the respirators in a production lot have "major-A" defects. A "major-A defect" is defined by 30 CFR 11.41(d)(2) as "a defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a defect that reduces protection and is not detectable to the wearer." However, the specification standards in the current QA regulations of 30 CFR Part 11 permit manufacturers to ship lots that substantially exceed the 1.0% defects standard. Any lots with 2.0% major-A defects, twice the NIOSH standard, have almost an 80% chance of reaching purchasers and users. Any lots with 4.0% major-A defects, four times the NIOSH standard, have about one chance in three of reaching users. Any grossly defective lots with six times the percentage of defects permitted by the NIOSH standard (6.0% major-A defects) have about a 1 in 10 chance of reaching users.

This area will be addressed with the QA performance requirements given in Subpart C.

Without the procedures and tests in this proposal, NIOSH will be unable to adequately evaluate respirator safety and efficacy. The certification test criteria in the current 30 CFR Part 11 provide insufficient evidence for NIOSH to reliably certify industrial respirators. The present regulatory criteria cannot assure the safety and performance of these devices in all cases. NIOSH respirator certifications must be based on rigorous and realistic performance testing. The primary objective of this proposed regulatory revision is to establish this type of testing for future NIOSH certifications.

For most respirators, it is not feasible to test safety and efficacy for an entire range of use conditions that may adversely affect their performance. Thus, for many performance tests NIOSH selected severe-use test conditions representing demanding use conditions. NIOSH used this performance-test philosophy to ensure adequate safety and efficacy for respirator users.

In response to the large number of comments submitted to the Record on the first proposal, NIOSH has revised and deleted a large number of provisions in the first 42 CFR Part 84 proposal of August 1987. Many changes were made in the first proposal to reduce recertification costs under the new performance requirements. Compared with the first proposal, at least seventeen changes incorporated in this proposal will produce cost savings for respirator owners, manufacturers, and purchasers. Six of these will produce major savings (i.e., §§

84.2(b)(1), 84.2(b(3) with 84.11(a)(9), 84.11(a)(11), 84.290(a), 84.293(e), and 84.304 with 84.314) and eleven will produce significant savings (i.e., §§ 84.11(a)(4), 84.11(a)(6), 84.40(a), 84.50, 84.70, 84.220(e), 84.223, 84.225, former 84.248–3, 84.263, and 84.303(a)). Although NIOSH is well aware of the additional total costs to respirator owners and manufacturers that will be created by the new regulation, the Institute's primary responsibility is to adequately protect the health and lives of respirator users.

Many changes were also made to the first proposal to provide additional flexibility in respirator design and permit innovative approaches to safe and effective respirators. This second proposal contains substantially more performance-based certification tests. Respirator manufacturers will have greater opportunity and motivation to develop and market innovative and cost-effective respirators for workers. This regulatory proposal places increased responsibility on the respirator industry to market safe and effective respirators. This proposal provides a substantially expanded role in the certification process for respirator manufacturers. Yet this proposal has ample flexibility for those manufacturers to expand their role even further. This second proposal will permit respirator manufacturers to design and market respirators that best meet the needs of their customers and respirator users. NIOSH has also made many revisions to the administrative requirements of the regulation. These were made in response to requests for better explanation of the administrative procedures for issuance, denial, and withdrawal of certification and to prescribe new and/or revised quality assurance, defect notification, and applicant reporting procedures.

Concurrent with the NIOSH rulemaking, MSHA published a notice proposing to revoke 30 CFR Part 11 (52 FR 32313). However this revocation will be contingent on publication of the NIOSH final rule. MSHA anticipates that the Final Rule for 42 CFR Part 84 will be consistent with current practices of NIOSH and MSHA. NIOSH will continue to have primary responsibility for approving industrial respirators. MSHA will continue to test electrical components of respirators used in mines and will issue MSHA certifications and approvals under 30 CFR Part 18 for these components. As proposed, 42 CFR Part 84 will also preserve a consultative role for MSHA in the certification of emergency respirators used in mining. MSHA will preserve all respirator-use provisions in the current 30 CFR Part 11 and codify them elsewhere in Title 30 of the Code of Federal Regulations.

Respirator purchasers, users, and manufacturers should note that OSHA intends to propose a revision of their respirator-use standards (e.g., 29 CFR 1910.134). The current OSHA standards on respiratory protection were adopted from a voluntary consensus standard about 16 years ago. OSHA has concluded that since that time new developments in respiratory protection technology have occurred and their current standard does not reflect these changes in the state of the art.[10] The purpose of their rulemaking is to update their current respirator use standard to provide more guidance to employers regarding respiratory protection programs and to help ensure better protection for those employees

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[10]Regulatory Program of the United States Government, April 1, 1987-March 31, 1988, U. S. Government Printing Office, Washington, D. C., p. 286 (1987).

who wear respirators. The proposed standard will establish requirements for the respiratory protection program to be implemented once the decision is made that respirators are to be used to control employee exposure to hazardous materials. The OSHA proposal will include requirements for a written respiratory protection program that must cover procedures for selecting respirator, medical surveillance requirements, fit-testing procedures, requirements for using respirators, training, and evaluation of program effectiveness.[11]

Additionally, respirator purchasers and users should also note that OSHA has published an NPRM to modify the existing provisions for controlling employee exposures to toxic substances found in 29 CFR 1910.1000(e) and .134(a)(1).[12] These are known as the "methods of compliance" provisions. By further clarifying the circumstances under which more extensive use of respirators may be appropriate, OSHA proposes to modify existing requirements in these two provisions that specify primary reliance on feasible engineering and work practice controls. OSHA has proposed five sets of circumstances where there will be no need for employers to show that engineering and work practice controls are not feasible before an employer can rely on respirators to reduce employee exposure to required levels.

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[11]Ibid., p. 287.

[12]Occupational Safety and Health Administration: Health Standards; Methods of Compliance, 29 CFR Part 1910, Federal Register 54(106):23991-23998 (June 5, 1989).

For the purpose of certifying respirators under the provisions of this proposal, NIOSH has provided a nonmandatory Appendix A that contains the generic assumptions concerning the conditions under which NIOSH-certified respirators will be used. Most importantly, NIOSH assumes that all NIOSH-certified respirators will be properly used in accordance with a complete respirator program. Such a program should include, but is not limited to, the following elements:[13]

- Adequate program administration
- Adequate written standard operating procedures
- Proper respirator selection for given hazard(s)
- Appropriate medical surveillance of wearers
- Adequate training programs for both supervisors and workers
- Adequate fitting and testing for inadequate fits on each wearer
- Respirator inspection, cleaning, maintenance, and storage

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[13]Bollinger, N. J. and R. H. Schutz: NIOSH Guide to Industrial Respiratory Protection, DHHS (NIOSH) Publication #87-116, Cincinnati, OH (September 1, 1987).

- Surveillance of workplace conditions and worker exposures

- Respirator program evaluation for safety and effectiveness

In the formulative stages of the first proposal during the past decade, NIOSH solicited and received extensive comments regarding necessary changes to the current 30 CFR Part 11 regulation. Federal agencies in related program areas (i.e., MSHA and OSHA in the Department of Labor) reviewed draft versions of 42 CFR Part 84 several times during the last few years. Voluminous public comments were received at two public meetings held by NIOSH in 1977 and 1980. There were 327 pages of comments received at the 1977 public meeting on new and improved performance requirements for future revisions of 30 CFR Part 11.[14] There were 740 pages of comments received at the 1980 public meeting on the NIOSH Testing and Certification Program.[15]

Five months after publication of the first proposal, NIOSH held two informal public meetings to provide further opportunity for the public to comment on the proposal. The first meeting was held in San Francisco, California,[16] on

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[14]NIOSH Docket for 42 CFR Part 84, Exhibit 84-23.

[15]Ibid., Exhibit 84-25.

[16]Ibid., Exhibits 84-142 and 84-191.

January 20, 1988, and the second was held in Washington, D.C.,[17] on January 27 and 28, 1988. The NIOSH Docket on the first proposal was held open for a total of 7 months to receive public comments. The Docket closed on March 28, 1988, two months after the public hearings. Affected parties such as respirator manufacturers, respirator purchasers, labor groups, other end users, professional associations, and other governmental agencies had sufficient opportunity to contribute their technical expertise and other constructive comments during the lengthy 7-month comment period. NIOSH considered 271 written comments, totalling more than 4,000 pages that were received on the first proposal.

The original provisions in the first proposal requiring workplace testing of respirators (former §§ 84.32 and 84.33) were considered necessary by the Institute so that an applicant would provide NIOSH with substantial evidence of respirator safety and effectiveness in the actual environment in which the device will be used—the workplace. Workplace testing would enable an applicant to provide evidence that a respirator performs as expected in at least one workplace and is free from defects or characteristics that might make it unsafe for its intended use in the workplace.

There is ample precedent for requiring workplace testing for respirators. For the past 12 years, the manufacturer of a medical device regulated by the Food and Drug Administration (FDA) under the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act has had to demonstrate both the safety and efficacy (i.e., adequate performance) of the device to receive the necessary gov-

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[17]Ibid., Exhibits 84-143 and 84-208.

ernment approval before marketing. Demonstrating efficacy means that appropriate testing indicates the device actually does what the manufacturer says it will. FDA pre-market approval for a Class III device (e.g., one that is life-supporting or life-sustaining, or for a use that is of substantial importance in preventing impairment of human health[18]) depends on the manufacturer conducting clinical studies showing the safety and efficacy of the device. Respirators certified by NIOSH meet several FDA criteria for a Class III medical device. These include the criterion that the "device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of health."

The 1976 Medical Device Amendments protect consumers when the complexity of the technology prohibits them from personally assessing the safety and efficacy of the products used to prevent their illnesses. Because the nature and technology of industrial respirators also prevent users from assessing the safety and efficacy of the devices they must wear, NIOSH believes that workplace testing requirements for respirators are necessary to protect the health and safety of respirator users.

For the past 26 years, any manufacturer of a drug regulated by the FDA under the Drug Amendments of 1962 to the Food, Drug, and Cosmetic Act has also had to show that the drug is effective before marketing is permitted. Thus before any drug is marketed in the United States, FDA decides whether laboratory studies (in animals) and clinical studies (in human patients) submitted by the manufacturer demonstrate safety and effectiveness for its intended use.

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[18]21 CFR 860.3(c)(3) in Part 860–Medical Device Classification Procedures.

As with drugs and medical devices, for several decades health professionals have been concerned with measuring and assuring respirator efficacy for users. Beginning almost 20 years ago in the late 1960s and early 1970s, researchers sought to determine the efficacy of protection actually provided to respirator wearers in industrial workplaces (e.g., Caldwell and Schnell,[19] Harris et al.,[20] Revoir,[21] and Moore and Smith[22]). For respirators, the quantitative levels of protection provided to a user were originally reported by these early researchers as protection factors. Later this term would be more carefully specified as "workplace protection factors" (WPFs).[23] About the same time as the early workplace

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[19]Caldwell, R. and E. Schnell: Respirator Effectiveness in an Enriched Uranium Plant, paper presented at the 1968 American Industrial Hygiene Conference, St. Louis, Missouri (May 1968).

[20]Harris, H. E., W. C. DeSieghardt, W. A. Burgess, and P. C. Reist: Respirator Usage and Effectiveness in Bituminous Coal Mining Operations, Am. Ind. Hyg. Assoc. J. 35:159-164 (1974).

[21]Revoir, W. H.: Respirators for Protection Against Cotton Dust, Am. Ind. Hyg. Assoc. J. 35:503-510 (1974).

[22]Moore, D. E. and T. J. Smith: Measurement of Protection Factors of Chemical Cartridge, Half-Mask Respirators Under Working Conditions in a Copper Smelter, Am. Ind. Hyg. Assoc. J. 37:453-458 (1976).

[23]Myers, W. R., S. W. Lenhart, D. Campbell, and G. Provost: Letter to the Editor, Am. Ind. Hyg. Assoc. J. 44(3):B25-B26 (1983).

studies, laboratory-based "assigned protection factors" (APFs) were developed at the Los Alamos Scientific Laboratory (LASL).[24,25,26]

The majority of the comments received on the proposed workplace testing requirement claimed that suitable protocols for determining WPFs were not available. In contrast, several comments stated that workplace or simulated-workplace testing should be required by NIOSH. In order to provide the most reliable evaluation of respirator safety and efficacy, NIOSH remains convinced that certification performance tests must include workplace or simulated-workplace testing. Consequently, the Institute intends to sponsor a public meeting (e.g., technical conference) on this issue in the near future. The purpose of this meeting will be to solicit opinions on the available research in this area and to identify possible critical knowledge gaps. Most importantly, comments will be solicited on appropriate means for implementing field testing as a condition for certification.

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[24]Hyatt, E. C., J. A. Pritchard, and C. P. Richards: Protection Factors for Respirators, paper presented at the 16th Annual Meeting of the Health Physics Society (July 1971).

[25]Hyatt, E. C. and C. P. Richards: A Study of Facepiece Leakage of Self-Contained Breathing Apparatus by DOP Man Tests, Los Alamos Scientific Laboratory Report LA-4927-PR, Los Alamos, NM (1972).

[26]Hyatt, E. C.: Respirator Protection Factors, Los Alamos Scientific Laboratory Report LA-6084-MS, Los Alamos, NM (1976).

In order not to delay needlessly the major advances in laboratory performance tests contained in this proposal, the requirement for workplace or simulated-workplace testing is not included. NIOSH will publish a separate regulatory proposal to implement this type of performance testing in the future. The separate proposal will provide ample opportunity to address public comments on workplace testing.

NIOSH has concluded that the provisions contained in this second proposal for 42 CFR Part 84 will result in better-performing, safer, and more reliable NIOSH-certified respirators. The proposed rule, if implemented, would create significant health benefits for up to 6.6 million users of NIOSH-certified respirators. This number could grow to up to 10 million users by the mid-1990s. Additionally, Part 84 will provide significant economic and other benefits to 32 domestic respirator manufacturers, owners of about 7 million nondisposable respirators, and those employers who annually purchase over 110 million disposable respirators. In general these benefits cannot be quantified.[27] However they will be obtained at reasonable economic cost to respirator owners, purchasers, and manufacturers.[28]

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[27]National Institute for Occupational Safety and Health: Preliminary Regulatory Impact Analysis: 42 CFR Part 84, Second Notice of Proposed Rulemaking–Revision of Tests and Requirements for Certification of Respiratory Protective Devices, (September 1989), Section C.

[28]Ibid., Sections D and E.

The current proposal is a complete and comprehensive certification standard for substantially improved laboratory performance testing of respirators. It is a feasible standard that is based on available research findings and the public record for the first proposal. As additional research findings become available, and as the Institute deems necessary, additional rulemaking proposals will be forthcoming to further strengthen the NIOSH program for respirator certification.

Associated with the proposal for workplace testing was the proposed certification of individual makes and models at higher performance levels (former § 84.33), that is, certification for assigned protection factors higher than the class minima given in the former § 84.32. NIOSH originally proposed this approach so that respirator users might be offered devices certified at several different performance levels. Offering certification at multiple performance levels has the potential to stimulate market competition and result in the marketing of more cost-effective respirators. Yet it will still permit respirator manufacturers to market respirators that best meet the needs of their customers and users. The Federal regulation for automobile tires that provides for tire grading at multiple performance levels for tread life, traction, and temperature resistance (49 CFR 575) is a successful example of this approach.

However, with the removal of workplace test requirements, NIOSH will not have relevant data in order be able to certify higher performance levels [i.e., assigned protection factors (APFs)] for individual respirator makes and models. Several years ago, after reviewing multiple research studies, NIOSH concluded

that respirators cannot be certified for quantitative protection levels based only on laboratory data.[29,30,31,32,33,34,35,36] In 1983, NIOSH stated that "Existing or new

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[29]Hinton, J. J.: Reliability of Quantitative Fit Protection Factors in Assessing Face-to-Facepiece Seals, unpublished thesis, University of Texas, Health Science Center, Houston, TX (1980).

[30]Myers, W. R. and M. J. Peach, III: Performance Measurements on a Powered Air-Purifying Respirator Made During Actual Field Use in a Silica Bagging Operation, Ann. Occup. Hyg. 27(3):251–259 (1983).

[31]Que Hee, S. S. and P. Lawrence: Inhalation Exposure of Lead in Brass Foundry Workers: The Evaluation of the Effectiveness of a Powered Air-Purifying Respirator and Engineering Controls, Am. Ind. Hyg. Assoc. J. 44(10):746–751 (1983).

[32]Lenhart, S. W. and D. L. Campbell: Assigned Protection Factors for Two Respirator Types Based Upon Workplace Performance Testing, Ann. Occup. Hyg. 28(2):173–182 (1984).

[33]Myers, W. R., M. J. Peach, and J. Allender: Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter–Test Protocol, Am. Ind. Hyg. Assoc. J. 45(4):236–241 (1984).

[34]Myers, W. R., M. J. Peach, III, K. Cutright, and W. Iskander: Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter–Results and Discussion, Am. Ind. Hyg. Assoc. J. 45(10):681–688 (1984).

technology respirators that appear to have achieved effective performance in laboratory tests still must demonstrate adequate performance under actual workplace conditions before respirator programs can be confidently relied upon to protect workers."[37] In 1987, NIOSH cautioned, "APF's based solely on laboratory fit testing should be viewed and applied with particular caution, even when the laboratory testing involves a simulated work regimen."[38] Therefore, NIOSH has reluctantly removed this certification option from this second proposal. However, NIOSH intends to pursue this approach in conjunction with the regulatory initiative on workplace testing. Another objective of the public hearing on workplace testing will be to solicit opinions on the most appropriate means for

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[35](...continued)
[35]Dixon, S. W. and T. J. Nelson: Workplace Protection Factors for Negative Pressure Half-Mask Respirators, J. Int. Soc. Respir. Prot. 2(4):347–361 (1984).

[36]Dixon, S. W., T. J. Nelson, and J. E. Wright: Program Protection Factor Study on the 3M W316 Airhat™, paper presented at the 1984 American Industrial Hygiene Conference, Detroit, MI (May 22, 1984).

[37]National Institute for Occupational Safety and Health: Comments to OSHA for Docket H-160: Health Standards: Methods of Compliance, (June 1983), p. 7.

[38]National Institute for Occupational Safety and Health: NIOSH Respirator Decision Logic, DHHS (NIOSH) Publication No. 87–108, Cincinnati, OH, (1987), p. 2.

implementing certification for individual makes and models at multiple performance levels.

With regard to assigned protection factors, it is important to recognize the fundamental differences between APFs specified in OSHA respirator selection tables and the leakage values proposed as maximum test criteria for certification purposes in Table 1 of § 84.232(h). Because of such differences it is perfectly appropriate that OSHA should require the use of NIOSH-certified respirators in respirator programs, while classifying such respirators in a manner appropriate to OSHA regulation and proposing additional selection and use criteria including APFs that are consistent with the OSHA rulemaking record.

The NIOSH performance criteria in Table 1 of this Part for a limited range of respirator facepiece and test filter combinations cannot be interpreted as equivalent to APF values. A respirator meeting the requirements of § 84.232(h) has demonstrated that a component of the respirator—the facepiece seal—has achieved a required level of performance under a very specific set of laboratory test conditions. On the basis of results from the laboratory test for face seal leakage, results from other laboratory tests, and other specified information, NIOSH then determines whether or not a given respirator should be certified. Although § 84.232(h) specifies maximum allowable leakages for a 25-person test panel under specific laboratory test conditions, in some workplaces the actual leakages for wearers may exceed the test criteria. Thus the test criteria may not be used to calculate APFs. OSHA (and other Federal agencies such as MSHA, EPA, and the NRC) have the regulatory authority and responsibility to deter-

mine, propose, and promulgate assigned protection factors establishing limits to the specific use of specific respirators in the workplace that are based on information resulting from protection factor studies that have been entered in the OSHA rulemaking record. Regulatory agencies, employers, or qualified individuals determining permissible conditions for respirator use must not only consider the NIOSH-certified laboratory performance for a respirator type, but they must also consider determinant (causal) factors affecting respirator leakage that are a function of respirator design, wearer facial conditions, and the other numerous and highly variable conditions at points-of-use.

In other OSHA rulemakings, NIOSH has suggested numerous factors that affect respirator effectiveness for individual wearers in the workplace.[39,40] Some of the more important ones are (1) filter or sorbent efficiency against the hazardous agent, (2) facepiece design, (3) whether tight-fitting facepieces can be validly fit checked before each donning at the point-of-use, (4) whether the required fit can be achieved by the user for each of several to many donnings, and (5) respirator ruggedness and reliability as it affects continued safety and efficacy. Re-

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[39]National Institute for Occupational Safety and Health: Supplemental Report to OSHA for Docket H-049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users, (October 1982), pp. 20-21.

[40]National Institute for Occupational Safety and Health: Comments to OSHA for Docket H-160: Health Standards: Methods of Compliance, (June 1983), p. 7.

garding the second factor, 42 CFR Part 84 will establish face-seal certification categories that do not refer to specific facepiece designs (e.g., single-use, disposable, reusable, valveless). For face-seal performance testing, only two facepiece categories are specified: (1) quarter and halfmask facepieces and (2) fullface facepieces. However, for regulating respirator use, where appropriate OSHA generally further subdivides these two categories into relevant types (e.g., disposable dust and mist, as distinct from either reusable respirators or those with higher filter efficiencies). Because certification and respirator-use regulations have different objectives, both NIOSH and OSHA regard differences in respirator categories between 42 CFR Part 84 and the proposed revision to 29 CFR 1910.134 to be proper, necessary, and mutually consistent. Therefore, it is perfectly appropriate that OSHA should require the use of NIOSH-certified respirators in respirator programs, while classifying such respirators in a manner appropriate to OSHA regulation and proposing additional selection and use criteria including APFs that are consistent with the OSHA rulemaking record.

NIOSH is proposing that some respirators and components be certified in multiple performance categories (e.g., filters at Types I, II, and III efficiency categories; sorbent canisters at low- and high-capacities, multiple service lives for SCBAs, low-temperature operating categories for SCBAs, flame-resistant and non-flame-resistant SCBA facepieces, heat-resistant and conventional SCBA harnesses). In order to encourage respirator innovation and design of more protective respirators for users, the Institute wishes to expand this approach where feasible and appropriate. The Institute requests comments and suggestions on

additional component performance parameters that could and should be certified in multiple performance categories.

For example, NIOSH is considering air-line and powered air-purifying respirator certifications at multiple flow rates. Analysis of current certifications under 30 CFR Part 11 indicates that many continuous-flow, supplied-air respirators will meet higher flow rate criteria. Research has shown that higher flow rates provide greater protection for wearers.[41] Since there have been no user problems reported for respirators providing these higher flow rates, NIOSH has determined that providing for high flow-rate certification classes is feasible. NIOSH is seeking comments on certifying air-line devices and PAPRs according to the following:

Loose-fitting hood and helmet flow rates: Class I for those meeting or exceeding 170 L/min (6.00 cubic feet per minute (cfm)) but less than 230 L/min (8.12 cfm) and Class II for those meeting or exceeding 230 L/min (8.12 cfm),

Tight-fitting facepiece flow rates: Class I for those meeting or exceeding 115 L/min (4.06 cfm) but less than 170 L/min (6.00 cfm) and Class II for those meeting or exceeding 170 L/min (6.00 cfm).

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[41]Hack, A. L., O. D. Bradley, and A. Trujillo: Respirator Protection Factors: Part II–Protection Factors of Supplied-Air Respirators, Am. Ind. Hyg. Assoc. J. 45:376–381 (1980).

A second example of possible certification in multiple performance categories would be for longer service lives of sorbent cartridges and canisters. The Institute invites comments on whether this is feasible and useful.

The following material is a summary of significant comments received on the proposed rule and NIOSH responses to those comments. This portion of the Preamble is designed to clarify the intent of the proposed provisions, as well as to identify important issues NIOSH is aware of and would particularly like to receive comments on. Comments are also invited on other relevant issues that are not specifically raised in this discussion. All such comments should clearly identify the provision of the regulation to which they apply, as well as the position taken on that provision. It is most helpful, and makes the record more accessible, when comments are organized in the same order that the regulation is written and are indexed to the particular provisions of the regulation to which they refer. It should also be noted that on technical issues, substantiation should be presented as well as opinion on the appropriateness of a particular requirement. Such substantiation may take the form of anecdotes, professional experience, scientific studies, etc. Submission of substantive comments helps NIOSH build a thorough record upon which to base the final regulation. A complete record on all the issues will help ensure that the Final Rule is appropriately drawn to address the issue of respirator certification.

Subpart A—General Provisions. Subpart A establishes the procedures and requirements for the certification of respirators. Provisions are given for the

expiration of respirator certifications granted under the current 30 CFR Part 11, certification of complete respirators, and resubmission of upgraded respirators for certification. A glossary of nontechnical terms and definitions is provided in this Subpart. Technical definitions are given in Subpart O.

§ 84.1—Purpose. All comments on § 84.1 requested that NIOSH respirator certifications apply to all industrial applications, not just mines and mining worksites. In addition, commenters stated that although the Mine Safety and Health Act mandates the Department of Health and Human Services to approve respirators for use in mines and mining, it does not preclude the Department from certifying respirators for non-mining use. It was never the intent of NIOSH to limit the use of certified respirators to such a narrow focus of workplaces. NIOSH noted the universal thrust of comments that requested broader certification coverage and has revised § 84.1 by deleting the references to "mines and mining."

Additionally, 42 CFR Part 84 certifications are issued by the U.S. government under a program conducted and administered by NIOSH. This has been noted in this first provision.

§ 84.2—Certified respirators

§ 84.2(a). Commenters stated that NIOSH testing assures that all certified respirators have met the same requirements with the same consistency, lending credence to the certification. Another commenter stated that the NIOSH proposal to base the certification on test reports supplied by the applicant will allow NIOSH to focus its resources on quality assurance and monitoring of compliance through audits and problem investigations. Other commenters stated that reviewing test reports instead of verifying test results could be biased and might not ensure a safe respirator, that each applicant must be treated in a consistent manner, and that NIOSH employee turnover could add to inconsistency due to subjectivity of review.

NIOSH has addressed some of these comments in the response below to § 84.30. Additionally, § 84.31(b) was added to indicate that NIOSH will conduct selected tests on each respirator submitted. Section 84.2(b)(3) was added to provide for certification of respirators modified to meet the new performance requirements of this Part.

§ 84.2(b)(1). Commenters claimed that a 5-year expiration period for Part 11 certifications will not allow sufficient time for manufacturers to change respirators to meet requirements of 42 CFR Part 84, to make sufficient respirators available to users, and to allow for smooth transition to Part 84. Some comments suggested 10 years instead of 5 years. Other commenters recommended allowing Part 11 certifications to continue for the useful life of each type of

respirator, citing the cost of replacement respirators and the possible interruption of respirator programs as reasons. These commenters doubted that NIOSH has sufficient personnel to handle all required certifications in the 5-year period. Commenters claimed that there is no research or medical evidence to justify the expirations of Part 11 certifications and that NIOSH has not demonstrated that Part 11 certifications are inadequate. One commenter claimed that the expiration will create an unreasonable and unwarranted burden on the mining industry.

The substance of these comments is that 5 years is an insufficient time for the manufacturers to design and produce and for the users to purchase and introduce the improved respirator models certified under 42 CFR Part 84. NIOSH recognizes the impact of this requirement. However, NIOSH believes that workers that have to wear respirators must be provided with respirators having the best assurance of safety and efficacy. This will be accomplished by requiring respirators to be certified to the more demanding performance and quality assurance requirements of Part 84. Thus it is essential to terminate current NIOSH/MSHA certifications in a timely, appropriate, and responsible fashion.

Based on cost analyses conducted with process and spreadsheet models developed for the PRIA[42] and a reanalysis of the benefits created by each regulatory

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[42]National Institute for Occupational Safety and Health: Preliminary Regulatory Impact Analysis: 42 CFR Part 84, Second Notice of Proposed Rulemaking–Revision of Tests and Requirements for Certification of Respiratory Protective Devices, (September 1989).

Subpart, NIOSH substantially revised this provision to provide for 5-, 6-, and 8-year expiration periods instead of the single 5-year expiration period proposed in the first NPRM. Potential total costs to respirator owners due to the original Sunset Clause were reduced by over $56 million with no significant reduction in protection for wearers.

NIOSH is proposing three different expiration periods for Part 11 certifications based on respirator class and intended use. Respirators certified under 30 CFR Part 11 shall continue to be NIOSH/MSHA-certified after the effective date of Part 84 as follows:

- self-contained breathing apparatus used in nonfirefighting environments, 8 years;
- self-contained breathing apparatus used in firefighting environments, 5 years;
- supplied-air (air-line) respirators, 6 years;
- chemical cartridge and all particulate (e.g., dust, fume, mist, high efficiency) filter respirators, 5 years; and
- gas masks (canister respirators), 6 years.

Respirator manufacturers with respirators certified under Part 11 shall not market those respirators as NIOSH/MSHA-certified after the respective expiration dates.

Gas masks (canister respirators), are generally used in substantially higher hazardous concentrations than halfmask respirators and are accepted by OSHA for escape-only use in hazardous atmospheres (even those that are potentially immediately dangerous to life or health (IDLH)). Additionally, NIOSH expects

that upgrade kits for this respirator class will average about $10 each and new Part 84 fullface respirators will cost about $125 each. Therefore NIOSH concluded that the potential benefits gained from leaving the expiration period for gas masks at 5 years substantially outweighed the relatively small potential cost savings achieved by extending it to 6 years.

NIOSH concluded that essentially all supplied-air (air-line) respirators in use today will meet essentially all performance requirements under Part 84 for this respirator class. There will be some important generic certification improvements for this respirator class reflected in Part 84 requirements. These include:

- increase in sample size and revision of statistical methods used for analysis of data from performance tests (§ 84.229),
- addition of quantitative face-seal performance tests in the laboratory on 25-person panels for negative-pressure respirators (Subpart R), and
- improved quality assurance (QA) program requirements (Subpart C).

However, NIOSH concluded that the potential benefits received by users in 1995–1996 due to a 5-year expiration period for supplied-air respirators would not outweigh the potential cost savings to owners of $30 million achieved by extending it one year to a total of six years after the effective date of Part 84.[43]

Since 1982 NIOSH has been collecting field performance data on SCBAs used by firefighters and others. A study of respirators involved in approximately 15 firefighter fatalities, plus numerous injuries and reports of defective SCBAs, have shown significant deficiencies in existing Part 11 certification requirements.

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[43]Ibid., Tables XVII and XVIII.

In particular, deficiencies exist in some Part 11 SCBAs with regard to flame, heat, and vibration resistance. There is a greater need for manufacturer responsiveness to reporting of SCBA defects or potential defects to users whose lives depend daily on these devices. NIOSH concluded that the potential benefits received by firefighters resulting from a 5-year expiration period for firefighter SCBAs far outweighed the potential average cost to SCBA owners of under $8 million/year for 1990–1995.

For the approximately 72,000 SCBAs used in nonfirefighting environments, NIOSH concluded that most of these devices in use today will meet essentially all performance requirements under Part 84 for this respirator class and use. There will be the same important generic certification improvements for this respirator class reflected in Part 84 requirements as for the supplied-air class. However, NIOSH concluded that the potential benefits received by users in 1995–1998 due to leaving the expiration period for nonfirefighting SCBAs at 5 years did not outweigh the potential cost savings of almost $7 million achieved by extending it to 8 years.[44]

NIOSH concludes that the owners of almost 80% of the atmosphere-supplying respirators in 1990 (i.e., about 1.1 million supplied-air, 0.07 million nonfirefighting entry-SCBAs, and 0.16 million escape-only SCBAs[45]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices

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[44]Ibid., Tables XVII and XVIII.

[45]Ibid., Table XVIII.

are the same as the new 6- or 8-year phase-out periods for Part 11 respirators provided for these devices under the revised Sunset Clause in this NPRM. Owners of about 1 in 7 of the approximately 400,000 entry-SCBA respirators used in firefighting applications will incur essentially all potential costs resulting from the revised Sunset Clause.[46] Over the entire population of about 400,000 firefighter SCBAs in 1990, about 11% (41,000) of these devices should require upgrade kits at about $350 each after 1995 and less than 4% (15,000) should need complete replacement with Part 84 firefighting SCBAs after 1995, where the average cost for a new firefighter SCBA is $1,600.

NIOSH also concludes that the owners of almost 93% of the air-purifying respirators in 1990 (i.e., over 5 million nondisposable chemical cartridge and particulate respirators[47]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as their 5-year phase-out period. The only air-purifying respirator owners affected by the Sunset Clause will be those owning about 1 in 20 of the 380,000 gas masks in 1990.[48] From the population of 380,000 gas masks, only 1% (4,700) of these devices should require upgrade kits at about $10 each after 1995 and only 4% (16,000) should need complete replacement with Part 84 fullface respirators after 1995, where the average cost of a new respirator is about $125.

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[46]Ibid.

[47]Ibid.

[48]Ibid.

§ 84.2(b)(3). After careful consideration of comments received on the issue of recertification, NIOSH is proposing new procedures for upgrading respirators that are currently certified under 30 CFR Part 11 requirements to recertification under 42 CFR Part 84. This new approach will permit manufacturers of MSHA/NIOSH-certified respirators to upgrade, rather than replacing with new models, many of the more than 7,000 makes and models of respirators currently marketed under NIOSH certifications. Alternatively, manufacturers can authorize such upgrading by factory-trained personnel, in accordance with protocols and/or through use of replacement parts if necessary, that have been accepted by NIOSH. NIOSH will accept applications for respirator upgrades as new applications for certification. The Institute will review an applicant's test report, test selected samples of upgraded respirators to substantiate the applicant's test report, and then certify satisfactorily-upgraded respirators. NIOSH will specify that defects such as worn or damaged parts must be corrected or repaired before the upgraded Part 84 certification is effective. These corrections or repairs should be considered by owners as routine and responsible maintenance, which is also required by 30 CFR Part 11.2 to maintain existing Part 11 approvals. This new procedure responds to both the manufacturers' concern about NIOSH processing of new certifications and users' concern about the availability and cost of respirators certified under 42 CFR Part 84. Compared with the first proposal, this new upgrade procedure substantially reduces recertification costs to own-

ers during the 5-, 6-, or 8-year expiration periods of § 84.2(b)(1) after the effective date of 42 CFR Part 84.

§ 84.2(b)(4). Commenters suggested that NIOSH issue certifications for "Buddy Breathers" and respirator components used by firefighters for emergency rescue purposes. NIOSH has repeatedly considered the possibility of certifying respirator components, that will permit a component from one manufacturer's respirator to be used on another manufacturer's respirator, or will permit certification of a component manufactured by an organization that does not hold a certification on a complete respirator. NIOSH has concluded that such certification is impractical and may result in respiratory protection that is unsafe and of questionable efficacy.

Unless the respirator manufacturing industry were to develop consensus design-specification and manufacturing-specification standards, it is not possible for NIOSH, respirator manufacturers, third-party manufacturers, respirator purchasers, owners, or users to determine and assure that respirators with interchangeable components will provide safe, reliable, and effective protection. For example, the original manufacturer holding the certification for a given model mask may change design or manufacturing specifications so that third-party components may no longer be compatible.

In order to assure safety and effectiveness for respirators with third-party components, NIOSH would have to add design specifications to Part 84. This would virtually eliminate the design flexibility manufacturers will have under

Part 84 to obtain certifications for respirators that are innovative, improved, or meet specific needs or preferences. Component testing, for all possible respirator assemblies, would be costly and time consuming.

In the opinion of NIOSH, the certification of "Buddy Breathers," where a self-contained breathing apparatus wearer shares breathing air with another person, raises safety and efficacy considerations that have not been satisfactorily addressed by proponents of this certification. NIOSH has concluded that adequate evaluation and control of respirator performance cannot be assured if component certification is conducted by the Institute.

§ 84.3—Administrative definitions. Commenters suggested redefining the term "major modification" for clarity. NIOSH has redefined both "major modification" and "minor modification," as suggested by commenters, by referring to the performance of certified respirators as related to the general construction or technical requirements of Part 84. The holder of a NIOSH certification has the responsibility and best qualifications to make the expert professional judgment as to whether a modification will affect the performance (e.g., safety, efficacy, reliability, adherence to technical and construction requirements of this Part) of a certified respirator. NIOSH defines reliability as the probability that a respirator will provide failure-free performance of its intended protective functions during its reasonably anticipated lifetime while it is properly used and maintained.

For example, cosmetic changes such as color changes would generally require no testing or inspections. Changes such as purchasing fittings from a different

vendor could generally be handled by utilizing normal quality control specifications and inspections. However, testing might be required for changes such as revisions to a filter cover, in order to determine that filter efficacy will still meet performance criteria.

Commenters suggested redefinitions of "respirator," "workplace," and "simulated workplace" to include hazardous atmospheres, or in effect, to include all workplaces. NIOSH has redefined the term "respirator" by deleting the words "engaged in mining and designed," and "mines or mining," as appropriate, from the definitions. The terms "simulated workplace" and "workplace" have been deleted because they no longer appear in the proposed rule.

A definition of "critical characteristics" has been added in response to comments on § 84.20. A definition of "upgraded respirator" has also been added in response to changes in § 84.2. A definition of "Director" has been added to designate the Director of NIOSH.

Subpart B—Application Procedure. Subpart B establishes the procedures and requirements for submitting an application for NIOSH respirator certification. During development of the requirements incorporated in the proposed 42 CFR Part 84, the manufacturers repeatedly requested an amplification and clarification of procedures for applying for certification. NIOSH has made a number of changes in these procedures, including a clearer delineation of new certifications and modifications of certifications, elimination of the need to obtain prior certification of minor modifications of certifications, and a decrease in

the amount and variety of material needed for documentation. NIOSH has also required submission of test reports and test-failure reports, adequate health and safety protection for human test subjects, and elimination of prototype respirator testing.

To maintain control and traceability of changes, NIOSH has established two modification classes, major and minor. NIOSH requires that the manufacturer test respirators to determine the effects of all major modifications and submit such modifications for certification, before they are made. Manufacturers must continue to keep records of minor modifications, but they need not report them on a regular basis.

One commenter suggested that a new section be added to Subpart B, prescribing a mandatory waiting period before resubmitting the certification application, after an applicant experiences a denial or withdrawal of certification under 30 CFR Part 11. A time of 6 months was recommended.

NIOSH has incorporated the intent of this comment by inserting a new § 84.32(c), requiring submission of a report to NIOSH, to accompany a reapplication for certification, detailing the failure, the methods of its correction, and the test data supporting the correction, in the event a denial or withdrawal of certification is made by NIOSH.

§ 84.10—Submission of an application. One commenter suggested a change from "Part 18 of this chapter," to the correct designation. NIOSH has deleted this reference from 42 CFR Part 84 because it is an MSHA regulation related only to permissibility for use in mines. NIOSH will continue liaison with MSHA concerning respirators used in mine rescue and escape, in accordance with a Memorandum of Understanding to be developed between the two agencies.

§ 84.11—Required contents of an application to NIOSH

§ 84.11(a) and (b). After reviewing § 84.11, NIOSH has found that combining contents of applications for certifications and for major modifications of certifications in a single requirement, could be misinterpreted. NIOSH has redrafted § 84.11 into two paragraphs. The new paragraph (a) applies only to applications for certification. The new paragraph (b) applies only to applications for modifications of certification.

§ 84.11(a)(4) (formerly .11(d)). Commenters claimed that requiring respirators used for performance testing to be made on production tooling is unacceptable, costly, unreasonable, and should be deleted. Based on more than 15 years of testing experience with preproduction respirator samples, NIOSH has concluded that certification testing of specially-prepared preproduction samples is not appropriate. This is a research and development function that is expensive for NIOSH to maintain, it is not requested or needed by all manufacturers, and is

not a proper role for a certifying Federal agency to become involved in a manufacturer's proprietary research and development program.

In recognition of the potential costs involved, NIOSH has deleted the controversial requirement that respirators submitted for certification testing be produced on production tooling. Compared to the first proposal, this change should reduce costs for respirator manufacturers and purchasers. However, note that § 84.11(a)(4) will still prohibit test respirators from being produced with any operation that will not be incorporated in regular production processing (e.g., production-line manufacturing, inspection, testing). Once a certified respirator has entered production, any change in respirator design or manufacturing process that adversely affects respirator performance must be submitted to NIOSH as required by § 84.60.

Other commenters suggested that the minimum number of respirators submitted to NIOSH be increased to four or six. NIOSH has determined the minimum number of each type of respirator that is required for substantiation testing. Because NIOSH may perform additional tests, as stated in § 84.31(c), NIOSH may need to request additional respirator samples. This paragraph has been revised to show six as the minimum number of respirators required by NIOSH.

§ 84.11(a)(5) (formerly .11(e)). Commenters stated that manufacturers' advertising and sales literature should not be required by NIOSH. NIOSH has revised this paragraph by deleting the word "informational" because NIOSH does not evaluate manufacturers' advertising and sales literature. Usually these materials are not available until sometime after a certification has been issued.

§ 84.11(a)(6) (formerly .11(f)). Commenters requested that NIOSH clarify the requirement for provision of drawings. NIOSH has determined, from certification experience, that it needs only top assembly drawings and drawings of major respirator components. Reflecting this, NIOSH issued a letter to respirator manufacturers on September 15, 1987. In view of this letter and the manufacturers' ready compliance with this requirement, NIOSH has revised this paragraph to require only top assembly drawings and drawings of major respirator components. Compared with the first proposal, this change will reduce certification costs for respirator manufacturers and purchasers. Major respirator components are defined in Appendix B.

§ 84.11(a)(7) (formerly .11(g)). Commenters stated that NIOSH should not request a complete parts list. As with paragraph (a)(6), NIOSH has revised this paragraph to require only major respirator components specified in Appendix B of this Part.

One commenter requested that computer printouts of parts should be included. NIOSH will accept any satisfactory form of such parts lists, that provides the necessary information.

Another comment stated that parts lists should include material identification of all materials in contact with the breathing medium. The specification of material in contact with the breathing medium will normally be provided to NIOSH under the requirements of this paragraph.

§ 84.11(a)(8) (formerly .11(h)). A commenter asked whether engineering drawings must state "material is proprietary." The purpose of this requirement, now designated as paragraph (a)(8), is to assure that applicant's documents containing confidential, privileged, or trade secret information, will be clearly identified as such in the event they are evaluated at a future date for possible release under the Freedom of Information Act. It is important for respirator manufacturers, owners, purchasers, users, and other interested parties to note that NIOSH will not disclose any data and information submitted or divulged to the Institute that falls within the DHHS Freedom of Information regulatory definitions (45 CFR 5.65) of trade secrets and commercial or financial information that is privileged or confidential. For example, 45 CFR 5.65(a) defines a trade secret as a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."

See additional discussion on this issue in the Preamble at § 84.33—Availability of respirator test results.

§ 84.11(a)(9). After reviewing § 84.11, NIOSH determined that it should prescribe requirements for "upgraded respirators" where they may be submitted for certification under Part 84. NIOSH has revised § 84.11 by adding a new paragraph (a)(9) to prescribe the additional requirements necessary for applications for certification of "upgraded respirators."

§ 84.11(a)(10) (formerly .11(i)). Commenters were concerned that applicants should be advised beforehand of the total certification fee, or at least of a maximum limit of the fee. In response to the comments, NIOSH has proposed a fee schedule in the Preamble (see discussion at § 84.90) and is proposing a regulatory procedure (§ 84.90) for notice on any future changes in the fee schedule .

§ 84.11(a)(11) (formerly .11(j)). Commenters stated that the proposed requirement for complying fully with human subjects testing requirements of 45 CFR Part 46 is too restrictive. They pointed out that the cited regulation applies to clinical research relating to drugs, vaccines, and medical devices and that it will create a considerable burden of paper work, delay the certification process, and increase costs.

The withdrawal of the requirement for workplace testing of respirators under this second NPRM eliminated a significant segment of testing requiring the protection of human subjects. The remaining testing will be conducted in the laboratory and does not pose a significant risk to human subjects. For example, under Subpart R, only exposure with minimal risk would occur (i.e., to nontoxic aerosols or oil mists during face-seal performance tests). On the other hand, under Subpart S, there is a risk of over-exertion associated with testing the self-contained breathing apparatus.

As a matter of policy for this proposal, NIOSH is maintaining a human subjects requirement consistent with the provisions of 45 CFR Part 46. The provisions of 45 CFR Part 46 are consistent with the Proposed Model Federal Policy for the Protection of Human Subjects published at 51 Federal Register 20204 by the Office of Science and Technology Policy on June 3, 1986.

Within the context of the NPRM, the provisions of Appendix C are meant to apply to the use of human subjects in testing under Subpart S that involves some risk of over-exertion while performing various tasks with self-contained breathing apparatus worn by the subjects (i.e., §§ 84. 255, 84.257, 84.259, 84.260, 84.261, 84.262). NIOSH does not contemplate that these human subject requirements would apply to fit testing under Subpart R so long as nontoxic aerosols or oil mists are used. Accordingly, NIOSH does not expect that this narrow application of the human subjects protection requirement would place a significant economic burden on respirator manufacturers who seek certification of respirators from NIOSH under this Part. Furthermore, NIOSH concludes that this

proposed application of Appendix C will protect human subjects who may be exposed to more than minimal risk in the certification process. NIOSH solicits comments on this issue.

§ 84.11(a)(12). This is a new paragraph that specifies that the applicant shall identify those respirators designed for firefighting environments and mine rescue and other mine emergencies. This requirement will enable NIOSH to readily identify those applications that will require MSHA review and concurrence and/or testing as firefighting and/or mine-rescue respirators.

§ 84.12—Withdrawal of an application and § 84.13—Evaluation of an application. After reviewing these sections, NIOSH determined that the words "for certification" and "for certification of a respirator" were not appropriate because the sections applied to major modifications as well as certifications. NIOSH has revised §§ 84.12 and 84.13, by deleting the words "for certification" and "for certification of a respirator," where they appeared.

Subpart C—Quality Assurance. The function of Subpart C is to set forth the minimum performance requirements for respirator manufacturers' quality assurance (QA) programs used in the manufacture and distribution of NIOSH-certified respirators. The accepted practices of a satisfactory quality assurance program are a vital factor in assuring that only safe and effective respirators reach users in the workplace. NIOSH uses the term "quality assurance" to embody

the total efforts of a respirator manufacturer's quality control and quality engineering activities. Quality control activities are designed to minimize the incidence of nonconformance during and after production. Specifications and tolerances are established, process capabilities ascertained, and tests and inspections performed to compare actual against standard performance. In instances of off-standard production, a response mechanism must provide for (1) correction and (2) steps to prevent recurrence of respirator defects. Quality engineering is analysis of the respirator manufacturing system at all stages of development, including evaluation of designs, process optimization studies, and development of process capabilities. Quality engineering utilizes such analytical techniques as reliability evaluation, human factors studies, operations research, and cost and effectiveness analyses.[49]

The current 30 CFR 11.41 requires respirator manufacturers to develop and operate QA plans "in accordance with procedures set forth in Military Standard MIL-STD-105D." This specification standard incorporates a statistical sampling strategy based on a quality standard known as "acceptable quality level" (AQL). Section 11.41 specifies the following AQL levels for "outgoing" respirators or components (i.e., those shipped to respirator users): (A) 1.0% defective for those with "major A" defects, (B) 2.5% defects for those with "major B" defects, and (C) 4.0% for those with "minor" defects. Bowker and Lieberman

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[49]Enrick, N. L.: Quality Control and Reliability, Sixth Edition, Industrial Press Inc., New York, New York, (1972), p. 301.

state that "The AQL may be viewed as the highest percent defective that is acceptable as a process average."[50]

The fundamental problem with the AQL-specification standards in the current regulation is that they neglect the percentage of defective respirators shipped to respirator users. The primary effect of AQL standards in QA programs is to reduce production and QA costs for manufacturers. Bowker and Lieberman state ". . . this type of classification does not specify anything about the protection the consumer has against the acceptance of a lot worse than the AQL."[51]

The impact of a "1% defective" AQL standard can be estimated from an operating characteristic (OC) curve such as Figure 1, which is based on Figure 13.5 in Bowker and Lieberman.[52] This curve would apply to major A defects in 30 CFR Part 11.41. Figure 1 shows that those lots with 2% defective items (e.g., 20 in a lot of 1,000) would have almost an 80% chance of reaching respirator users. Those lots with 4.0% major A defective items would have about a 1 in 3 chance of reaching workers. Grossly defective lots with 6.0% major A defects (i.e., exceeding the AQL standard by 600%) would have almost a 1 in 10 chance of reaching users.

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[50]Bowker, A. H. and G. J. Lieberman: Engineering Statistics, Second Edition, Prentice-Hall, Inc., Englewood Cliffs, New Jersey, (1972), p. 511.

[51]Ibid., p. 511.

[52]Ibid., p. 513.

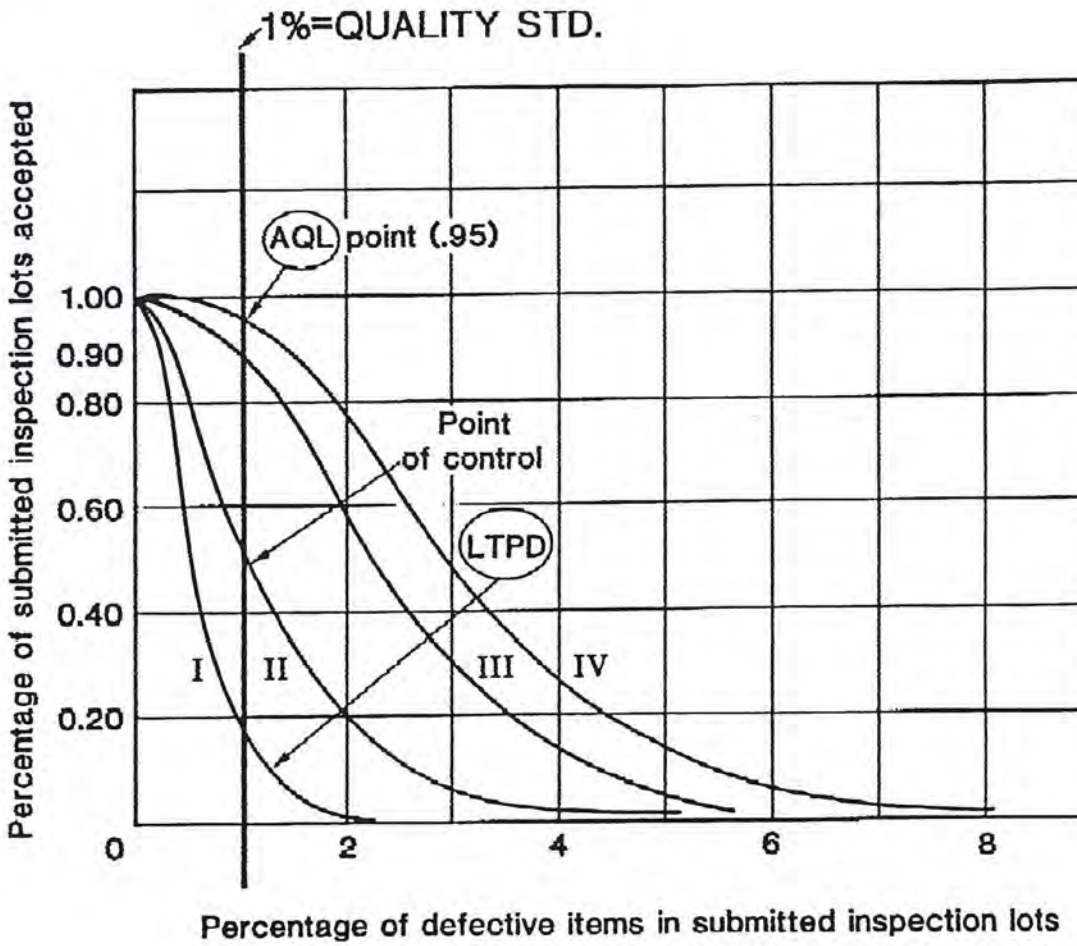

Fig. 1 Single sampling classified on:
I. 1% LTPD.
II. Point of control
III. 1% AOQL:
IV. AQL = 1%

Figure 1–Operating characteristic curves for 1%-defective quality standard.

In contrast to AQL-specification standards, other QA standards are available that assure lots with unacceptable percentages of defectives will have a minimal chance of being shipped to users. One of these is the "lot tolerance percent defective" (LTPD) standard. With this type of QA standard, the "consumers

risk" of receiving an unacceptable lot (i.e., a lot exceeding the quality standard) is set to a low value such as 10%. Figure 1 indicates that for an LTPD QA plan, the consumers risk drops rapidly to almost zero at twice the quality standard. This is sharp contrast to the results from AQL QA plans. The most widely used LTPD plans are the Dodge-Romig tables.

The focus of the proposed 42 CFR Part 84 is to place on respirator manufacturers the responsibility for implementing and maintaining QA programs that adequately protect users. In place of the detailed quality assurance requirements and AQL-specification standards in the current 30 CFR Part 11, NIOSH has identified only a few of the critical components of quality assurance. This will permit respirator manufacturers considerably more flexibility in designing a quality assurance programs that protect users. This flexibility should also enable manufacturers to reduce quality assurance costs.

In addition to pre- and post-production quality assurance, NIOSH is concerned with the manufacturer's ability to trace product sales, and should the need arise, to contact users and purchasers of defective respirators. Thus, NIOSH has provided specific requirements for notification of defects to NIOSH and to respirator users.

§ 84.20—Quality assurance

§§ 84.20(a, b, and d). Commenters stated that NIOSH had not defined "critical characteristics." In view of the importance of the concept of "critical characteristics," NIOSH defined this term in § 84.3, as a feature capable of adversely affecting product safety and efficacy.

§§ 84.20(c and h). A commenter said that required drawings and specifications may employ use of computer-aided design and manufacturing systems. NIOSH has always and will continue to accept any drawing and/or specification that provides sufficient detail for its intended purpose, the description of the respirator design and construction. Use of computer-aided design is satisfactory if these minimum requirements are met.

§ 84.20(e). Commenters said that NIOSH personnel should conduct periodic plant audits, with advance notice, whether they believe the manufacturer is distributing noncompliant respirators or not. NIOSH agrees with this comment except for the limitation of advance notice. The Institute has revised the provision to permit NIOSH to conduct routine periodic plant audits without cause. Additionally, NIOSH may conduct without prior notice special plant audits when NIOSH has cause to believe a certified respirator is noncompliant with any requirement of this Part.

One comment stated that plant audits should be at a time mutually agreeable to the manufacturer and NIOSH. There may be instances, such as discovery of

a serious defect in a respirator, when NIOSH may wish to insist upon conducting a plant audit at the earliest possible date. Therefore NIOSH did not accept the proposal for selection of a time mutually agreeable to the manufacturer.

§ 84.20(f). Commenters stated that NIOSH should specify the number of respirators needed for audit-testing purposes. One comment stated that NIOSH should purchase all audit samples. NIOSH has considered all of the comments and concludes that it will be more appropriate for the manufacturer to conduct regular audit tests of each respirator and for NIOSH to purchase samples for its ongoing audit testing from the open market rather than have samples supplied by the manufacturer. However, for cause, NIOSH will still require a manufacturer to supply respirators without charge to NIOSH for examination and testing. In this way the samples tested by NIOSH are more likely to be representative of respirators that are supplied to workers in the years following the initial certification. Another advantage of this approach is that the audit testing conducted by the manufacturer and the audit testing conducted by NIOSH will be independent activities. Separation of these activities is considered by NIOSH to be in the best interest of workers who depend on respirators for safe and effective respiratory protection.

Considerable NIOSH experience in performing post-certification audits and analyzing complaints reported to the Institute's Respirator Complaint Coordinator indicates that the majority of problems with certified respirators are related to poor quality control practices. Therefore, NIOSH maintains that production-

line respirators need to be periodically tested by the manufacturer to assure that they maintain compliance with certification performance criteria.

NIOSH is proposing to eliminate all of the specification-standard requirements for manufacturer quality control that are contained in Subpart E of the current 30 CFR Part 11 (e.g., §§ 11.41 and 11.43). In their place NIOSH is proposing the performance-based requirements of § 84.20. These new performance standards permit manufacturers broad leeway to design and implement quality assurance programs that are more economical, effective, and that better meet their individual needs than those specified under the current Part 11. This provision has significant cost-savings potential for respirator manufacturers and purchasers.

However, typical quality assurance programs are not designed to assure that production respirators will meet all applicable performance requirements of this Part. In particular, most quality assurance programs examine only respirator components, not entire respirator assemblies as received by the user. During several years of respirator production, manufacturing variations may accumulate and result in a noncomplying respirator. Therefore, NIOSH has revised § 84.20(f) to require each respirator manufacturer to perform audit testing of each certified respirator at least every 3 years. After several years of experience with this provision and an evaluation of information received under the requirements of other sections (e.g., §§ 84.21, 84.22, 84.25), NIOSH will evaluate if 3 years is an appropriate minimum period for this provision.

In its deliberations on the requirement for periodic audit testing, NIOSH considered the possibility of different mandatory periods for different performance tests. Less critical or important tests would need to be repeated less often than other tests (e.g., at least every five years). NIOSH invites comments, supported by suitable scientific rationale, for alternative scheduling of the necessary audit testing required in this provision.

In order to minimize the triennial audit burden for each respirator manufacturer and yet provide an unbiased and valid periodic audit of certified respirators, NIOSH has determined that test samples shall be randomly selected from respirators that are in production during the year. The complete respirator is to be tested, unless a respirator component is used on several respirators in the same class of respirators. In that event, a representative sample of that component from any respirator certified under that class may be tested. NIOSH must be notified of any respirator not conforming to 42 CFR Part 84 requirements that is observed during a manufacturer's audit testing as prescribed in § 84.22.

Another commenter asked if NIOSH will audit only newly manufactured respirators or respirators used in the workplace. NIOSH intends that the audit tests by both NIOSH and the respirator manufacturer will be conducted on new rather than used respirators. Testing of new respirators is appropriate for audit testing because the performance requirements of this Part are developed for new devices. Problems and defects that occur during respirator use are the focus of other aspects of this Part.

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

§ 84.21(a). Commenters were concerned that the words "produced or assembled" could be interpreted to apply to all respirators, including those produced but not released because of quality assurance rejection. NIOSH is concerned that all respirators released for sale shall comply with the requirements of 42 CFR Part 84. NIOSH recognizes that all manufacturers may, on occasion, produce a defective respirator. However, it is assumed that these defective respirators are found during quality assurance inspection and are not released for sale. NIOSH has revised § 84.21(a) by changing "produced or assembled by him" with the words "released for sale or distribution."

§ 84.21(b). Commenters suggested that the term "reasonable time" be replaced with "ten working days." To create a minimal burden for manufacturers, NIOSH will permit 30 days for manufacturers to notify NIOSH of defective respirators. This length of time should not create a hazard for respirator users because this requirement applies only to defects that do not pose an immediate or significant threat of serious injury or death.

§ 84.21(c). Commenters stated that records should be kept so that subsequent users can be located. Although most manufacturers may be able to locate the first purchasers of respirators, subsequent transfers of ownership are very difficult to trace. Apparently, the resale of used self-contained breathing apparatus is a

common practice, and records of such resales may not be available to the manufacturers.

One comment stated that notification should be required only when defects detract from the level of protection afforded the user. NIOSH has seen instances where defects do not detract from the level of protection afforded the wearer but do affect respirator comfort and acceptance. Rather than attempting to broadly define a level of protection, NIOSH prefers to judge each defect on the basis of its effect on respirator safety and efficacy. Examples of defects that do not detract from protection but may require notification include hazards created by sharp edges on a device, discomfort caused by high-temperature breathing gas, vision distortion due to the facepiece lens, and dermatitis due to a manufacturer's facepiece cleaning agent.

§ 84.22—Notification by the manufacturer to NIOSH. To clarify this requirement, NIOSH has identified its Division of Safety Research as the division responsible for respirator certifications.

§ 84.22(b). Several comments stated that NIOSH should not be concerned about the total number of respirators produced, only the number that have been distributed or sold. To enable NIOSH to make an evaluation of the total extent of defects in relation to the total production of a respirator, the total number judged acceptable by the manufacturer's quality assurance program must be

reported to NIOSH. This is particularly important with new products that remain at the manufacturer's facility.

§ 84.23—Notification by the manufacturer to affected persons

§ 84.23(a). During the development of this provision and § 84.21(c), NIOSH envisioned situations in which a manufacturer might recover all units of a potentially defective respirator from dealers and distributors before any units were shipped to purchasers. In those instances no owner or user would be affected. Therefore notification to dealers and distributors would be sufficient.

§ 84.23(b). Commenters stated that notification by certified mail to respirator users should be limited to those known to the manufacturer and, where known to the manufacturer, to subsequent transferees. Because it does not appear feasible to require manufacturers to identify all subsequent transfers of ownership, NIOSH has revised § 84.23(b) by adding the words "where known to the manufacturer."

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

§§ 84.25(a and b). Commenters stated that "deployed respirators" should not be expected to perform "as new." Section 84.25(a) must apply to both new and deployed respirators because defects may be inherent in a respirator design but may not become apparent except through actual use in workplaces.

Subpart D—Laboratory Respirator Testing. The function of Subpart D is to set forth the generic requirements for the laboratory-performance testing conducted by manufacturers and NIOSH. The original proposal for Subpart D contained the requirement that applicants perform all tests and provide a comprehensive test report to NIOSH. NIOSH would then review the test report, perform substantiation tests, and if appropriate, would issue the certification. Manufacturers and users of respirators had several concerns regarding this proposal, and their concerns are expressed in the following comments. These concerns are addressed in the responses to these comments.

§ 84.30—Laboratory testing by applicant. Commenters indicated that NIOSH should repeat all the tests conducted by the applicant. There were two basic reasons for these recommendations. First, there was a concern that the intention of NIOSH was to rely only on the testing conducted by the manufacturer. It was perceived that NIOSH certification will become a self-certification program in which manufacturers will self-certify their respirators. Second, there was a concern that if NIOSH were to duplicate selected tests rather than all tests, it will be unfair to manufacturers because NIOSH will not necessarily duplicate the same test for each applicant and this will introduce a bias into the respirator evaluation.

NIOSH has revised the wording of § 84.2(a) and added a new § 84.31—NIOSH evaluation of respirator performance to indicate that NIOSH will con-

duct selected tests on each respirator submission in order to substantiate the accuracy and validity of the test methods, results, and conclusions included in an applicant's test report. This will also serve to reduce any bias that may be introduced by applicant's or third-party's testing or by NIOSH substantiation tests. NIOSH will provide standard test procedures for performing the substantiation tests contained in this second NPRM. All test procedures will be designed so that tests will be performed within the parameters and tolerances specified in Subparts Q through Z of this Part. Any respirator that fails when tested at any test condition that falls within a range or tolerance specified in this Part will be denied certification. NIOSH will analyze performance test data using the statistical procedure specified in this Part.

It was not and is not the intention of NIOSH to base the Institute's certifications only upon test results reported by respirator manufacturers. Instead, it is the intent of NIOSH that certifications be based on four testing elements. First, manufacturer will conduct tests required by this Part and submit documents to demonstrate that the manufacturer is both capable of properly conducting the certification tests and that all test criteria were satisfactorily met. Second, selected tests will be performed by NIOSH to substantiate that a manufacturer's test results are valid and accurate. Third, as a part of its quality assurance program, a manufacturer must periodically conduct certification testing to assure continued compliance with the performance requirements of this Part in the years following initial certification. Fourth, on a regular basis after the issuance

of a certification, NIOSH will conduct audit testing to substantiate continued compliance with the performance requirements of this Part.

The audit testing conducted both by NIOSH and by the manufacturer on a continuing basis following the initial certification is as important, or more important, than the initial testing conducted by NIOSH and manufacturers to obtain a certification. The follow-up audit tests assure the safety and efficacy of respirators that are actually supplied to workers. Because of the importance of the continued performance testing by manufacturers during the many years in which a respirator may be marketed, NIOSH maintains that it is essential to assure not only that the respirator samples initially submitted comply with the performance requirements of this part, but that the manufacturer is capable of conducting the ongoing tests in an accurate and valid manner. Toward this goal, NIOSH will carefully review the original test reports submitted to NIOSH with the initial application to assure that a manufacturer has demonstrated the ability to properly conduct the required performance tests.

In order to give proper emphasis to its audit testing, it is essential to make the initial certification testing as efficient and relevant as possible. To this end NIOSH must be able to select the particular tests that it will substantiate in its initial certification testing. Such selection will be based on the following considerations.

(1) A review of the manufacturer's test report. If, for example, there were questions about any of a manufacturer's test methods or results, these tests will be repeated by NIOSH.

(2) A review of the respirator design. If there were, for example, unusual or unproven design features that could affect performance in a particular test or tests, that test or tests will be duplicated by NIOSH.

(3) A consideration of the past testing results for a particular manufacturer. If, for example, a manufacturer has had a history of submitting test results that are inconsistent with NIOSH test results, NIOSH may elect to repeat these tests. This is not unfair to that manufacturer because all respirators are required to pass all the performance tests. In any case, the protection of respirator users must take precedence over any concerns of unfairness. NIOSH maintains that workers are best served if NIOSH is permitted to exercise discretionary judgment in the initial certification tests conducted by the Institute.

Former § 84.31—Guidelines for workplace or simulated-workplace testing, former § 84.32—Workplace or simulated-workplace testing by applicant: Certification of minimum performance level, and former § 84.33—Workplace or simulated-workplace testing by applicant: Certification of higher performance level. NIOSH received numerous comments on the proposed workplace or simulated-workplace testing of respirators. Commenters claimed that the technology for such tests was not available, that NIOSH had not provided protocols for performing tests for public comment, and that the tests would be very costly for applicants to perform. However, many of the comments did recognize the value of workplace respirator testing and suggested that NIOSH develop the protocols

through further research and incorporate this requirement in a future amendment to 42 CFR Part 84.

Please refer to the discussion at the beginning of this Preamble regarding the former provisions for workplace or simulated-workplace testing. As noted earlier, in order not to needlessly delay the major advances contained in this proposal and provide ample opportunity to address public concerns on workplace testing, NIOSH has removed the requirement for workplace or simulated-workplace testing from this proposal. NIOSH will publish a separate regulatory proposal to implement this type of performance testing in the future. Compared with the first proposal, this change will substantially reduce certification costs for respirator manufacturers and purchasers.

§ 84.32—Issuance of denial of certification. The former §§ 84.31, 84.32, and 84.33 contained, in addition to prescribed workplace and simulated-workplace tests, a description of the procedures to be used by NIOSH for issuance or denial of certifications. NIOSH has drafted a new § 84.32 to prescribe the procedures to be followed by NIOSH for issuance and denial of certifications. Appeals of denials are also described. The new requirements in § 84.32 refer to evaluation of test reports specified in § 84.30 and the test report required with any application resubmission after a denial of certification by NIOSH. The Institute will require the latter report to analyze the cause of failure to pass the NIOSH test(s), demonstrate that the manufacturer has corrected the defects that

caused the failure, and demonstrate that the manufacturer has performed tests necessary to assure conformance with the certification requirements.

§ 84.33 (former .34)—Availability of respirator test results. Commenters stated that laboratory and workplace test results and test protocols should not be made available for public review if they contain trade secrets and/or confidential or financial information. NIOSH maintains that the public has a right to examine the test results on which a certification is based. At present, under the Freedom of Information Act (5 U.S.C. § 552), NIOSH test results from certifications issued under 30 CFR Part 11 can be released to the public. NIOSH has revised § 84.34 to specify that all results of laboratory tests conducted under the provisions of this Part will be available for public review. NIOSH will make the fullest possible disclosure of performance test data to the public, consistent with the rights of individuals to privacy, the property right of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its certification activities without disruption. In order to assure that a manufacturer's confidential or trade secret information in an application is not inadvertently released, test results (all of which are nonconfidential) should be furnished in a separate section of the performance test report so that confidential information is not intermingled with nonconfidential material.

Performance test results from both NIOSH (e.g., from tests conducted under § 84.31) and applicants (e.g., received as part of certification applications) can

provide valuable information to assist in adequate respirator selection to respirator purchasers, owners, and users. Therefore, NIOSH intends to periodically publish in a timely fashion (e.g., as summary tables in the NIOSH Certified Equipment List[53]) relevant performance test results such as, but not limited to, the following:

Particulate, air-purifying respirators: Face-seal leakage, filter penetration.

Sorbent cartridge and canister respirators: Face-seal leakage, service life for most severe gas or vapor test.

Powered air-purifying respirators (PAPRs): Same as for applicable particulate or sorbent respirator, flow rate.

Air-line respirators, pressure-demand and demand modes: Pressure range, breathing resistance.

Air-line respirators, continuous-flow mode: Pressure range, breathing resistance, flow rate.

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[53]National Institute for Occupational Safety and Health: NIOSH Certified Equipment List as of December 31, 1988, DHHS (NIOSH) Publication #89-105, Cincinnati, OH (January 1989).

Self-contained breathing apparatus (SCBA), open-circuit: Service life, weight, sound level, certified low-temperature level, regulator location, high- or low-pressure cylinders, use of bypass valve.

Self-contained breathing apparatus (SCBA), closed-circuit: Same as for open-circuit SCBAs, maximum oxygen concentration in facepiece.

The Institute requests comments and suggestions on other descriptive or performance information that NIOSH could publish to assist purchasers, owners, and users in appropriate respirator selection.

Subpart E—NIOSH Certification Label. The function of Subpart E is to set forth the requirements for the certification label that must be affixed to every NIOSH-certified respirator. The NIOSH certification label serves as the manufacturer's proof of certification, the guide to the proper component parts and use, and states use limitations and cautions. Thus it is an important notice to the respirator purchaser and user. This Subpart prescribes certain minimal label designs and component-marking requirements. It also states that NIOSH may add certain cautionary and certification limitation statements, as necessary, for specific types of respirators.

§ 84.40—Required contents of a certification label

§ 84.40(a). Commenters suggested adding statements to the certification label that the respirator must be used in accordance with a complete respirator program and that the use of air-purifying respirators should be prohibited for protection against contaminants without adequate warning properties and in atmospheres immediately dangerous to life or health. NIOSH has clarified in Appendix A that use in accordance with a complete respirator program is an assumed condition of use for these respirators. The other requested precautions are generally included on the appropriate labels, where necessary.

Former § 84.40(a)(3). Commenters stated that lot number and date of manufacture need not appear on the certification label because they are more appropriately required in § 84.41(b) as applied to component parts of the respirator. NIOSH has revised § 84.40(a) by deleting the requirement of marking the certification label with lot number and date of manufacture because § 84.41(b) has the requirement for marking of component parts. Compared with the first proposal, this revision will reduce costs for both respirator manufacturers and purchasers.

§ 84.40(a)(3) (former (a)(4)). Commenters stated that the term "Certified by the U.S. Government" is inappropriate and that NIOSH can only certify in the name of NIOSH. Because respirator users and manufacturers contact NIOSH with questions and reports about certified respirators, it is important that NIOSH

be identified on the label as the certifying agency. NIOSH has revised the requirement to read "Certified for the U. S. Government by the National Institute for Occupational Safety and Health under 42 CFR Part 84."

§ 84.41—General label and marking requirements.

§ 84.41(a). A commenter stated that the certification label for self-contained breathing apparatus should not appear on the harness assembly. Because the fabric parts of the harness are subject to wear and frequent replacement, the proper location for the label is on the harness carrier assembly. Section 84.41(a) has been revised to indicate this.

§ 84.41(b). Commenters said that NIOSH should define major component. NIOSH has defined "major respirator component" in § 84.3, and is requiring that only these components be labeled. It is not feasible or practical to mark all individual components.

Commenters stated that the manufacturer should determine which components are to be traceable. NIOSH will continue to require traceability of any component that, if seriously defective, would create a hazard to the wearer of the respirator.

One comment stated that manufacturers should use serial numbers to include lot number or date of manufacture. NIOSH will accept marking of lot number, serial number, or date of manufacture as long as the particular lot of respirators or respirator components is traceable.

Subpart F—Maintenance and Instructional Materials. The function of Subpart F is to set forth the requirements for maintenance and instructional materials for NIOSH-certified respirators. NIOSH maintains that instructional materials for the users, including both elementary and complete maintenance manuals, where necessary, must be made available by the manufacturer. During investigations of respirator problems, NIOSH has found that improper or insufficient instructions and maintenance manuals have resulted in improper use and maintenance. This Subpart has been revised to promote the availability of the most complete and useful instructional and maintenance documents.

§ 84.50—User instructions. Commenters stated that maintenance manuals should not be furnished with respirators because they are not required for the simple respirators and encourage unqualified persons to repair the more complicated respirators. Although NIOSH agrees that detailed maintenance manuals need not be provided to all users, they must be available for use by qualified maintenance and repair personnel. Also, basic maintenance instructions must be provided with all respirators. NIOSH has revised § 84.50 to cover user instructions and added a new § 84.51—Maintenance manuals to clarify and amplify these requirements. Compared with the first proposal, these changes should reduce costs for both respirator manufacturers and purchasers. Section 84.50 also requires that user instructions be provided with each respirator.

Subpart G—Modification of MSHA/NIOSH Certified Respirators. The function of Subpart G is to set forth the procedures and requirements for modifying a respirator currently certified under 30 CFR Part 11 requirements. NIOSH recognizes that respirator manufacturers will need to modify MSHA/NIOSH-certified respirators to take advantage of new materials, to replace components and/or materials that are no longer available from suppliers, and to revise production processes to reduce costs and/or increase respirator safety and efficacy.

§ 84.60—Major modifications of MSHA/NIOSH certified respirators. Commenters requested a better definition of "major modification." NIOSH has redefined "major modification," as suggested by the commenters, to be any modification that affects the performance of a certified respirator, as related to the requirements of this Part. NIOSH has also clarified the language of § 84.60 by indicating that MSHA/NIOSH-certified devices may be modified and that such modifications shall meet the requirements of 30 CFR Part 11 that are incorporated in this part as Appendix C. Modifications to NIOSH certifications granted under 42 CFR Part 84 are now included in § 84.11.

Subpart H—Withdrawal of Certification. The function of Subpart H is to set forth the withdrawal procedures for a NIOSH certification. It details the causes that would prompt NIOSH to seek a withdrawal of a respirator certification and outlines the procedures the manufacturer must follow to appeal such withdrawal action. NIOSH maintains that these requirements are necessary to assure that

only those respirators that are in compliance with the requirements of 42 CFR Part 84, and are otherwise non-hazardous to the user, are distributed and sold by the manufacturers.

§ 84.70—Withdrawal of certification for cause

§ 84.70(g). Commenters stated that defects in undistributed respirators should not be cause for withdrawal of certification. NIOSH recognizes that most respirator defects are found by the manufacturer during normal quality assurance inspection procedures and that defective respirators usually do not leave the manufacturing facility. Thus this paragraph has been revised to include the requested change. Compared with the possible effect of the first proposal, this revision will reduce costs for both respirator manufacturers and purchasers.

§ 84.70(h). Commenters were concerned that a certification might be withdrawn if NIOSH has not specified a proper test or test method to assure reasonable protection to a respirator user. NIOSH has revised § 84.70(h) to specify withdrawal of a certification if a test in the applicant's report is invalid. In accepting the applicant's test report, NIOSH is, in effect, placing reliance on the applicant's ability to conduct the tests in a reliable and accurate manner. If NIOSH later finds that the applicant's test report is invalid (e.g., incorrect data, incorrect assumptions, incorrect data interpretation), then the invalid test report will be a cause for withdrawal of certification.

Additionally, if any applicants knowingly and willfully falsify, conceal, or cover up by trick, scheme, or device a material fact; or make any false, fictitious or fraudulent statements or representations to NIOSH; or make or use any false writing or document in an application to NIOSH while knowing the same to contain any false, fictitious, or fraudulent statement or entry, they will be subject to a fine of up to $10,000 or imprisonment of up to 5 years, or both as provided for in 18 U.S.C. § 1001.

§ 84.71—Procedure for withdrawal of certification for cause and manufacturer's right to appeal. A commenter stated that "stop sale" orders should be issued to manufacturers to prevent more defective products from reaching the market place during the withdrawal proceeding. Under 30 CFR Part 11, NIOSH has frequently requested that manufacturers stop the sale of defective respirators as MSHA/NIOSH-certified until the defect is corrected and, when necessary, defective respirators or components have been recalled. This voluntary stop-sale procedure has worked satisfactorily for the past several years and NIOSH prefers to continue it.

Subpart I—Appeals. The function of Subpart I is to set forth the procedure for a manufacturer to appeal a NIOSH denial or withdrawal of a respirator certification. This Subpart sets forth an administrative appeal procedure to be used by a respirator applicant who is denied a certification and by a manufacturer whose certification may be withdrawn.

§ 84.80—Appeal procedure. Commenters stated that the recommendations or decision of the Administrative Law Judge should be binding on the Director of NIOSH, pending any further appeals under the Administrative Procedure Act. NIOSH disagrees with this position. NIOSH maintains that the purpose of the hearing before the Administrative Law Judge is to obtain that judge's impartial review of the facts presented by NIOSH and the applicant or manufacturer. Applicants or manufacturers may seek further legal recourse under the Administrative Procedure Act.

Subpart J—Certification Service Fees. The function of Subpart J is to establish certification service fees for certification applicants. In accordance with Centers for Disease Control Appropriations Acts (e.g., Pub. L. 99-591, Pub. L. 100-202), NIOSH will charge these fees for respirator certification services performed under this Part. The system for fee calculation establishes a fair and reasonable assessment for services rendered. NIOSH's goal in Subpart J is to revise the current system under 30 CFR Part 11 for charging fees to enable the U.S. Government to fully recover costs it incurs for activities that result in the issuance of respirator certifications. The certification of a respirator by NIOSH constitutes a license that authorizes the manufacturer to build and distribute the device as certified by NIOSH for the U. S. Government.

NIOSH will maintain a fee schedule that contains both flat-rate and variable rate fees. This Subpart has been expanded to four provisions covering the fol-

lowing issues associated with the service fees: purpose, scope, calculation, administration, and revision. The structure of this Subpart is based on a fee system promulgated by MSHA for similar services (30 CFR Part 5).[54]

§ 84.93—Fee revisions. Commenters stated that certification fees should be: (1) specified in 42 CFR Part 84, (2) subject to public comment before adoption, and (3) based on the time and cost (hourly rate) of NIOSH employees. Regarding point (1), NIOSH concludes that this requirement would create an unnecessary and inappropriate rulemaking burden for the Institute because the fee schedule will be changed every one to three years. For point (2), NIOSH concludes this also is unnecessary and inappropriate since fees will always be based on criteria stated in §§ 84.90 and 84.91 of this Part. The public will have ample opportunity to comment on these criteria as part of the present rulemaking. For point (3), NIOSH agrees that hourly compensation costs for Institute employees should be part of each fee. However, NIOSH has concluded that fees should include all direct and indirect costs associated with the certification services as listed in §§ 84.90 and 84.91 of this Part. This Subpart endeavors to structure a fee system that is based on equitable distribution of costs for specific services to those individuals who are the direct recipient and beneficiary of those services. Once established by NIOSH, a fee schedule will be published in the Federal Register

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[54]Fees for Testing, Evaluation, and Approval of Mining Products, Department of Labor, Mine Safety and Health Administration, Federal Register 52:17506 (May 8, 1987).

and otherwise made publicly available to respirator manufacturers. NIOSH is proposing the following flat-rate fee schedule to be effective as of the promulgation date of the Final Rule for this Part:

Documentation review	$200

plus one of the following fees:

Self-contained breathing apparatus	$6,000
Air-line respirators	$3,000
Air-purifying particulate, canister, or cartridge respirators	$2,500

The current fee schedule will be available from the Certification Branch, Division of Safety Research, NIOSH. This schedule will be periodically revised to reflect recent NIOSH operational time and costs associated with this program. To provide an element of fairness and stability, the fee schedule will not be revised more frequently than once a year, or less frequently than once every three years.

NIOSH has also determined that the holder of a NIOSH respirator certification shall be charged the actual cost of any post-certification, in-plant, quality-assurance audit conducted by NIOSH for cause as provided for under § 84.20(e)(2) and (3). Adequate cause includes, but is not limited to, evidence

that a NIOSH-certified respirator is not in compliance with the technical requirements of this Part or evidence that a manufacturer fails to meet the quality assurance requirements of Subpart C. The audit fee will be calculated based on the actual time necessary to conduct the audit and the actual travel expenses incurred by the NIOSH personnel.

Subpart K—Mine Rescue and Emergency Respirators. The function of Subpart K is to establish the procedures for NIOSH and MSHA joint action on certifications for respirators designed for mine rescue or other mine emergencies. As will be prescribed by a Memorandum of Understanding between MSHA and NIOSH, the two agencies will work jointly on this special certification issue.

Subpart O—Technical Definitions. The function of Subpart O is to define important technical terms that appear in 42 CFR Part 84. In general, the technical definitions are derived from the accepted understanding of each term and the NIOSH policy applicable to that term. Definitions are based on respirator safety and efficacy and may vary slightly from definitions that are based on respirator use such as those adopted by regulatory agencies.

Subpart P—Classification. The function of Subpart P is to establish appropriate categories for certification testing. For clear presentation and understanding of the respirator performance requirements in this Part, they are presented in certification categories related to respirator classifications. The principal categories

are atmosphere-supplying (subclassified into self-contained and air-line) and air-purifying (subclassified into devices for protection against particulates and against gases and vapor). Each classification category and subcategory is further subclassified as necessary. In response to comments received on the original proposal, minor descriptive revisions have been made to the classification system. For example, filters have been reclassified as Types I, II, and III. Commenters noted that classifying filters as "low" or "medium" efficiency may have a negative connotation, even though those filters may provide adequate protection for certain uses.

Subpart Q—General Construction and Performance Requirements. The function of Subpart Q is to set forth the general construction and performance requirements common to all respirator types. Because there are a number of requirements that are applicable to all classifications of respirators, NIOSH has brought them together in this Subpart. Although a number of these requirements are qualitative in nature, NIOSH concludes that they are adequate to enable a certification applicant to evaluate a respirator. In some cases, testing is not required, and the applicant is required to make an expert evaluation of the respirator in response to such requirements. An applicant must state in the test report that the respirator meets the general construction requirements and the basis for that determination. NIOSH will judge each respirator submitted for certification on the basis of recognized professional principles of safe and effective respirator design and performance.

§ 84.220—General construction requirements

§ 84.220(e). Commenters stated that the ANSI Z87.1-1979 standard does not provide for testing respirator lenses for impact and penetration. In response, NIOSH has incorporated the performance requirements for lens impact and penetration in § 84.220(e) in place of referencing ANSI Z87.1.

Commenters stated that users should have the option of wearing safety spectacles under facepieces or helmet type respirators. NIOSH agrees and has made this an optional requirement. Compared to the first proposal, this change should reduce costs for some respirator manufacturers and purchasers. To replace the former provision, the Institute has added a requirement that all respirators with eyepiece(s) or windows that do not meet the § 84.220(e) criteria be legibly and permanently marked as such so as to adequately warn owners and users of these devices of the reduced eye protection.

§ 84.220(f, h, i, and j). Commenters stated that NIOSH should provide specific requirements and tests for respirator performance characteristics such as "adequate vision," "fogging," "corrosion resistance," and "skin irritation." NIOSH recognizes that these criteria are subjective and are not supported by performance tests. Instead of performance testing, the applicant is required to consider each such characteristic in a respirator design, based on generally recognized professional criteria for safe and effective respirator performance. Under § 84.30(b)(4) an applicant is required to include a statement in the laboratory

test report on each such performance characteristic, describing the applicant's consideration of the requirement and reasons for believing the respirator meets such requirement. This approach will allow design flexibility and innovation. It also has the purpose of reducing a manufacturer's costs for certification testing.

NIOSH has added a new performance standard to § 84.220(a), requiring that respirators shall be designed to ensure against release of toxic vapors or harmful particles.

§ 84.223—Body harnesses

§ 84.223(c). A commenter asked the rationale for the high-temperature, body-harness test. The high-temperature test has been requested by the fire services, who are principal users of NIOSH-certified self-contained breathing apparatus. NIOSH has included this test because there have been numerous incidents of heat and flame damage to the harnesses of self-contained breathing apparatus. However, NIOSH recognizes that SCBAs are used for many applications other than firefighting. Heat-resistant harnesses may not have adequate resistance to attack by chemicals encountered by SCBA wearers in nonfirefighting uses. Therefore, this test criterion will apply only to those SCBAs designated by the manufacturer as designed and intended for use by firefighters and mine rescue teams. Compared to the first proposal, this optional certification should reduce costs for some respirator manufacturers and purchasers.

One comment suggested that NIOSH change the performance-test criterion to 500 degrees F for 5 minutes. This suggested change appears to be more repre-

sentative of fire-service usage. It has been adopted by the NFPA[55] and other fire-service organizations. Therefore, NIOSH has revised the performance-test criterion from 400 degrees F for 30 minutes to 500 degrees F for 5 minutes.

§ 84.224—Respirator containers. A commenter stated that § 84.224(c) should apply only to escape respirators. NIOSH disagrees because the requirement must apply to both types of respirators since both entry and escape respirators may need to be quickly removed from their containers during emergency-entry and escape use.

Former § 84.225—Head harnesses. Several commenters stated that requirements, such as those for head harnesses, that were not supported by performance requirements should be so supported or should be deleted. Upon review of the head-harness requirements, NIOSH determined that the face-seal leakage tests, performed as required by Subpart R, would satisfactorily test the head harness assembly of each respirator and that these performance tests are more appropriate. Therefore, § 84.225, Head harnesses, has been deleted.

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[55]NFPA 1981, Standard on open-circuit self-contained breathing apparatus for firefighters, 1987 edition.

§ 84.225—Testing tolerances. In response to several comments, a new § 84.225 has been added to indicate that the operational tolerances for all test parameters (e.g., test temperature, humidity, flow rate, test-agent concentration) shall be ± 5% of any specified value unless otherwise specified in any section of this Part. This new provision is included by NIOSH to lower a manufacturer's testing costs by eliminating unnecessarily restrictive operating conditions for performance testing. This provision better specifies the testing conditions for performance testing and should reduce intra- and interlaboratory variability. NIOSH invites comments on this general operating tolerance specification.

§ 84.227—Exhalation-valve leakage test. One comment stated that allowing up to 30 mL/min leakage is excessive for exhalation valves. NIOSH agrees and has lowered the performance-test criterion to a maximum exhalation-valve leakage of 10 mL/min. This revision will assure a minimal hazard to wearers from excessive exhalation-valve leakage. The new test criterion was determined after reviewing test data for currently-certified respirators. Current exhalation valve technology is such that the majority of currently certified masks meet the 10 mL/min criterion. Since lower valve leakage will result in increased protection for users, NIOSH concluded it is appropriate to tighten the leakage criterion to the lower value.

§ 84.229—Statistical procedure for analysis of performance-test results. Commenters questioned the applicability of the sequential analysis procedure to respirator performance testing for certification. They claimed that because the sample size will be too small and the assumption of normality of distributed population is not true, an accurate and reliable statistical analysis cannot be obtained. Commenters also requested that an applicant should be permitted to perform additional trials if required to establish compliance to the requirements of 42 CFR Part 84. In response to these comments, NIOSH has revised its first proposal for a statistical sampling plan and data analysis protocol for performance testing of respirator components and devices.

Currently, many of the certification tests in 30 CFR Part 11 specify a sample of only three components or devices for pass/fail decisionmaking. When NIOSH tests three samples, the current decision rule is that all three must meet the applicable performance criterion. However, when a sample proportion is zero "failures" from three tests, the one-sided upper binomial confidence limit indicates that the true proportion of test failures could be as high as 63% in the population. Thus the best one can say about currently certified devices is that there is a 95% or better probability that the true percentage of unacceptable respirators (i.e., components or devices not meeting the certification performance criteria) is 63% or less of the components or devices represented by the NIOSH sample.

The fundamental problem with current certification sampling plans is that they cannot assure that users will receive certified components or devices con-

taining a low percentage of "failures." This problem has two basic causes. First, a binomial response variable (e.g., pass or fail) is used for the decision protocol even though the performance tests yield quantitative results. Second, by converting quantitative results to binomial data, a considerable amount of performance information is "thrown away" from the sample.

Quality control plan provisions in the current regulation (30 CFR 11.41) require manufacturers to develop and operate quality assurance plans meeting requirements in military standard MIL-STD-105D. This standard is based on a sampling plan standard known as "acceptable quality level" (AQL). The purpose of AQL-type plans is to limit the risk to a manufacturer that an "acceptable" production lot will be rejected, thus reducing production costs. However, with a pure AQL plan, the user's risk of receiving an unacceptable component or device can go as high as 95%.

The reasoning behind an AQL has been explained by Enrick as follows:

> The idea of an acceptable quality level is arrived at from the following consideration: under the speed of mass production, it is often impossible to turn out continually 100 percent satisfactory product. One must assume that a certain proportion of defectives will always occur on certain processes. However, if the percentage does not exceed a certain limit, it is often more economical to al-

low the defectives to go through rather than to screen each lot. This limit is called the acceptable quality level (AQL).[56]

In contrast to AQL sampling plans, lot tolerance percent defective (LTPD) limits, for Lot Quality Protection plans, insure that the user's risk of receiving an "unacceptable" product is controlled to a low level (e.g., 10%). Compared with the current AQL standards, LTPD standards would provide substantially better quality assurance protection to respirator users. However, compared with the current AQL quality control standards, LTPD plans are more costly for respirator manufacturers.

To remedy the minimal protection to the user in the current certification sampling plans, NIOSH initially proposed quantitative decision criteria based on use of one-sided upper tolerance limits for measured performance parameters (e.g., percent filter penetration, sorbent service life in minutes, exhalation-valve leakage in mL/min) as a statistical criterion for acceptance or rejection of the corresponding population of components. In order to minimize testing costs, a small random sample (3 or 6) was to be taken (i.e., the number of components or devices tested in the particular performance test) and a one-sided tolerance limit for the performance results of individual devices was to be computed. The tolerance limit would then be compared with a quantitative performance criterion (e.g., maximum allowable penetration or minimum allowable service life).

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[56]Enrick, N. L.: Quality Control and Reliability, Sixth Edition, Industrial Press Inc., New York, New York, (1972), p. 10.

This tolerance limit approach effectively achieved the Institute's primary responsibility, hence design objective, of strictly limiting the "users's risk" to a small probability. The user's risk is defined as the probability that NIOSH will accept (pass) a component or device in a particular test when, in fact, the component or device is unacceptable (i.e., performs unacceptably in more than a designated small proportion of cases).

Several commenters claimed that the small sample sizes in the original proposal would severely handicap a manufacturer's ability to obtain "pass" decisions for non-marginally acceptable components or devices. They requested that NIOSH permit manufacturers to conduct tests on as many as 18 or more respirator samples in order to pass a given performance test. In more than 15 years of respirator certifying, it is NIOSH's experience that respirators generally either substantially fail or substantially pass performance tests. It is unusual for a respirator to exhibit marginal or borderline-pass behavior. It is important that all respirator manufacturers, whether large or small, compete on a level playing field in their attempts to obtain NIOSH certifications. It would be unreasonable and unfair to permit the few large respirator manufacturers, who have substantial resources unavailable to most other manufacturers that can be devoted to respirator certification testing, to conduct tests on large number of test respirators so that a marginal respirator can pass a certification test. Therefore, in order to minimize certification testing costs for NIOSH and this industry, NIOSH concluded it is necessary to maintain the sample size as low as possible

for all manufacturers and still be consistent with the objective of the original proposal and consistent with adequate user protection.

In response to comments from respirator manufacturers, NIOSH is proposing a revised statistical sampling plan that incorporates the best points of both AQL and LTPD sampling plans. Specifically, NIOSH proposes to use the classical technique[57,58,59] of "acceptance sampling by variables to control fraction defective" for certification testing. Based on these references, NIOSH developed a sampling plan having the following four constraints: user's risk of 5% or less, LTPD of 10% or less, AQL of 1% or less, and sample size of six or less (i.e., minimal testing costs for manufacturers).

The proposed sampling plan is a single-sample plan for acceptance sampling by variables. For the same level of protection for the user, the required sample size is lower than required for attributes sampling (i.e., recording each test result as merely "pass" or "fail" rather than as a quantitative result X). The sampling

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[57]Duncan, A. J.: Quality Control and Industrial Statistics, Fourth Edition, Richard D. Irwin, Inc., Homewood, Illinois (1974).

[58]Juran, J. M., Editor: Quality Control Handbook, Third Edition, McGraw-Hill Book Company, New York, New York (1974).

[59]Wallis, W. A.: Use of Variables in Acceptance Inspection for Percent Defective, Chapter 1 in Techniques of Statistical Analysis, Eisenhart, et al., Eds, McGraw-Hill Book Company, New York, New York (1947), pp. 7–93.

plan in the current regulation uses the inefficient attributes sampling approach combined with an inadequate sample size of only three.

The proposed sampling plan uses the following two decision rules. For a performance test with an upper bound (X_{max}) on the measured variable, the Decision Rule will be: Fail (not accept) the component or device if the test statistic [$U = m + (2.9624)(s)$] exceeds X_{max} and pass (accept) if U is less than or equal to X_{max}. The variables (m) and (s) are the sample mean and sample standard deviation, respectively, computed from results obtained with the single-sample of six components or devices. For a performance test with a lower bound (X_{min}) on the measured variable, the Decision Rule will be: Fail (not accept) the component or device if the test statistic [$L = m - (2.9624)(s)$] is less than X_{min} and pass (accept) if L equals or exceeds X_{min}.

NIOSH also investigated the possibility of using sequential decision theory, in connection with acceptance sampling by variables to control percent defective, because lower average sample sizes would be realized. However, NIOSH concluded that the necessary theory applied to the case of acceptance sampling by variables to control percent defective has not been published. The derivation of the necessary statistical theory to support the sequential-testing methodology would be a complex statistical undertaking. The absence of such sequential sampling theory is a disappointment, because in simpler applications such as acceptance sampling by attributes, the use of sequential decision theory yields average sample sizes that are about one half those required by single-sample plans. NIOSH requests comments and additional information on alternative

sampling plans, particularly those based on sequential decision theory for variables, that can achieve the same or higher user protection as the one proposed.

Subpart R—Face-Seal Leakage. The function of Subpart R is to set forth the minimum performance requirements for face-seal efficacy of negative-pressure respirators. The testing required in this Subpart is essential to provide assurance that each negative-pressure, NIOSH-certified respirator has adequate face-seal capability for a wide range of facial sizes and shapes. Currently, most NIOSH-certified respirators have not been validly tested where it really counts—on human faces.

The performance criteria proposed in Table 1 for § 84.232(h) have been established as the best means for evaluating face-seal performance. NIOSH does not intend that the performance criteria predict or assure specified levels of protection from complete respirator assemblies in the workplace under actual use conditions. NIOSH will not recommend assigned protection factors or respirator performance levels for classes of respirators or individual respirator makes and models that are based on or derived from the face-seal performance criteria.

NIOSH does not intend that a certified respirator must accommodate every conceivable user. Instead, each certified respirator must be able to provide effective protection to a majority of prospective facial sizes and shapes. In particular, prospective wearers with small facial sizes (e.g., women, Hispanics, Asians) should have a sound probability of receiving an adequate fit with a NIOSH-certified respirator.

The use of the proposed 25-person panel for respirator design and evaluation is not new to the respirator industry. Mr. Dick Flynn of North Safety Equipment recently said that, "many respirator manufacturers now use a 25-person panel to develop and test-respirator fit characteristics."[60] Additionally, he noted that "The panel is made up so that you have all different facial sizes, from the very large to the very small."

It is not the intent of NIOSH that the face-seal performance tests of this Part reduce in any manner the need for individual respirator wearers to be fit tested by their employer prior to respirator selection and use. NIOSH expects that workers will have the option of selecting from a number of facepiece sizes and respirator models. Also, for each individual prospective wearer, fit testing will be used to identify and select the best-fitting model and facepiece size as well as to determine that the fit on the wearer is adequate.

For negative-pressure, air-purifying respirators and non-powered atmosphere-supplying respirators, the ability of the facepiece to seal with the wearer's face is the functional aspect that typically limits the protection provided to respirator wearers. Therefore, it is considered essential that these NIOSH-certified respirators demonstrate adequate fitting characteristics. This is especially true in the absence of respirator performance tests in workplace or simulated-workplace settings. Facepiece-sealing characteristics are less important for positive-pressure

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[60]PPE: Balancing Supply and Demand, Occupational Hazards (August 1988), p. 41.

continuous-flow, or powered respirators, and therefore, they are not subject to the provisions of this Subpart.

§ 84.230—Applicability. A question was posed concerning the applicability of the prescribed face-seal performance test to a closed-circuit, self-contained breathing apparatus (SCBA). It was suggested that the proposed test method is inappropriate because contaminants leaking into the facepiece will accumulate during time due to the recirculating nature of this device.

NIOSH maintains that a performance test for face-seal leakage is necessary for all negative-pressure respirators, including closed-circuit SCBA. As with all negative-pressure respirators, the ability of a closed-circuit SCBA facepiece to accommodate a wide range of facial sizes and shapes with minimal leakage is important to ensure adequate protection to most users in a working population. If the challenge contaminant leaks into the facepiece and builds up over time, it is appropriate for the test method to detect this elevated concentration because this is the concentration inhaled by the respirator wearer. NIOSH recognizes that the user of a closed-circuit SCBA in the workplace may be exposed to other contaminants in which the build-up characteristics inside the facepiece may differ from those of the challenge contaminant used during testing. In the absence of performing workplace testing, NIOSH has concluded that testing the facepiece with a challenge contaminant is the most appropriate method to evaluate leakage and assess any adverse effects due to contaminant build-up.

Several commenters questioned the appropriateness and feasibility of measuring face-seal leakage for all specified respirator types. Specific comments were made regarding the feasibility of testing mouthpiece respirators and suggested that testing certain positive-pressure SCBA will not be possible unless they were equipped with a negative-pressure mode. Other commenters questioned the relevance of testing positive-pressure, atmosphere-supplying respirators.

NIOSH considers face-sealing characteristics to be of critical importance for wearer protection with all negative-pressure or non-powered respirators. These face-sealing characteristics can limit the ability of a negative-pressure or non-powered respirator to reliably protect the respirator wearer. However, face-sealing characteristics are less critical for positive-pressure or continuous-flow, atmosphere-supplying respirators and powered air-purifying respirators. Therefore, NIOSH has revised § 84.230 so that the face-seal performance test applies only to negative-pressure or non-powered respirators that require adequate contact sealing on the wearer's face. Mouthpiece respirators do not need to be tested in the same manner because the sealing characteristics are not subject to the same uncertainty and variability as those respirators that seal on the wearer's face.

§ 84.231—General. Several commenters expressed concern with the proposed requirement to analytically determine filter penetration so that a differentiation can be made from leakage occurring at the respirator face seal. It was stated that if a differentiation is necessary, further guidance on a prescribed analytical

test will be required. These commenters argued that it will be more appropriate to measure total inward leakage of the respirator. NIOSH agrees that measuring total inward leakage is an appropriate quantitative assessment and will eliminate the dependence on analytical methods to differentiate between filter penetration and face-seal leakage. The performance criteria given in § 84.232 have been modified to reflect this change in test procedures. Compared with the first proposal, this change should reduce the cost of certification testing for filter respirator manufacturers.

Some commenters expressed concern that certain gas and vapor respirators may not have compatible particulate filters necessary for conducting the face-seal leakage tests with the specified challenge aerosol. NIOSH considers this to be a valid concern and has addressed the problem by making two major revisions to this section.

First, provisions have been made to permit gas and vapor respirators to be temporarily modified to allow the use of a high-efficiency particulate filter during the face-seal leakage test. The face-seal leakage test on these respirators may be conducted using any manufacturer's particulate filter. The particulate filters used for the temporary respirator modifications must have a weight and shape similar to that of the respirator's standard gas and vapor cartridge elements so that the facepiece fit is not substantially changed by the filter modification.

Second, in the event that improvising a particulate filter modification is not feasible or practical, a challenge gas or vapor appropriate for the respirator

being tested may be substituted for the aerosol challenge agent. These revisions have been incorporated into § 84.233.

§ 84.232(a, b)—Filter Selection and Panel Selection. A number of commenters were opposed to the facepiece marking and sizing system proposed by NIOSH. Several of these commenters were concerned that the proposed size marking could be misleading, cause less reliance on individual fit testing, and possibly limit the selection of available facepieces. One commenter was concerned that the proposed sizing requirement will require extensive training of the workforce on how to select the appropriate respirator. Another commenter suggested that each respirator model, except those of special sizes, should contain a series of facepieces that will fit at least 95% of the American working population as determined by the Los Alamos anthropometric panel. A few commenters proposed the idea of having a sizing plan for respirators in which a series of multiple-sized facepieces will be available for each respirator and the manufacturer will have the flexibility to specify the size of the facepiece from which to choose.

NIOSH has adopted an alternative sizing plan as suggested by several commenters. It is NIOSH's intent that the proposed size marking be used only as a starting point in selecting an appropriate facepiece. NIOSH does not wish to limit an employer's or user's opportunity to select from a range of available facepieces. Because there is a possibility that the marking of a facepiece with a specific size will reduce the opportunity of individual wearers to select from a range of facepieces, NIOSH concludes that deleting this requirement for such

size marking is appropriate. Therefore the face-seal performance test has been revised to require that each facepiece style be provided in one or more sizes such that the size(s) will accommodate a large proportion (i.e., 90%) of the adult American working population. Selection guidance for the most appropriate facepiece size must be included in the user instructions that must be provided with each respirator (§ 84.50). If a group of facepiece sizes contains a size or sizes intended for individuals with certain facial characteristics, guidance to these prospective users for its (their) proper selection must be provided in the user instructions. The intent of NIOSH in changing the sizing plan performance requirement is to encourage the development of appropriate facepiece styles and sizes and to allow innovation in facepiece labeling to aid each user in selecting the most appropriate facepiece. This sizing plan change does not reduce or eliminate the vital requirement for selection fit testing and point-of-use fit checks for each individual wearer.

§ 84.232(b)—Panel Selection. Several commenters disagreed with the required use of an anthropometric panel for the face-seal performance testing. In addition, they disagreed with the panel selection criteria that used face length and width as the parameters for sizing and ensuring proper fit. They also claimed that the development of this panel structure, as recommended in a 1974 report

from the Los Alamos National Laboratory (LASL),[61] was for research purposes only.

NIOSH has determined that use of an anthropometric panel is a necessary requirement for face-seal performance testing. The anthropometric specifications for the panel provide necessary test parameters to the respirator manufacturers for the testing. NIOSH acknowledges that facial attributes other than length and width need to be addressed by the manufacturers to develop respirators for those persons not included in the anthropometric panel.

After discussions with professional staff at LASL, NIOSH confirmed that the recommended anthropometric panel was intended by LASL to be used for selecting an anthropometric panel representative of a large proportion of the adult American working population (i.e., prospective respirator wearers). Both men and women were used to develop the parameters of this test panel. To date, NIOSH is not aware of any other criteria that are appropriate for or are routinely used to identify appropriate facial characteristics for facepiece testing.

The 1974 LASL report recommended a 2-panel testing system: a full facepiece panel based on face length and width and a half facepiece panel based on face length and lip length. Based on fit-testing experience by LASL subsequent to 1974, the Laboratory recommended to NIOSH a single test panel, based on face length and width, for both half and full facepiece respirators. LASL deter-

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[61]Hack, A., et al.: Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes, Los Alamos Scientific Laboratory, Report LA-5488, Los Alamos, New Mexico (March 1974).

mined that lip length is less important than facial width in determining adequate respirator fit. This 1-panel approach for testing was also recommended to NIOSH in 1981 by the ANSI Z88 Ad Hoc Respirator Committee.[62] NIOSH agrees with the single-panel approach for testing both half and fullface respirators.

Additionally, the 1974 LASL report noted that the gender specifications given in each anthropometric box were advisory only, and members of the opposite gender could be substituted. To minimize a manufacturer's costs for face-seal performance testing, NIOSH has deleted gender specifications from the anthropometric panel in Figure 1 of 42 CFR Part 84. Compared with the first proposal, this change will reduce certification costs for respirator manufacturers and purchasers.

The face-seal performance standard for the panel data is based on one developed by the ANSI Z88 Ad Hoc Respirator Committee.[63] They recommended that a respirator be "considered to fit satisfactorily either the entire panel, or some portion of it, when there is 95% confidence that 90% of test subjects" achieve the minimum fit factor. However, NIOSH maintains that 90% of the

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[62]American National Standards Institute, Z88 Committee for Respiratory Protection, Ad Hoc Subcommittee for Respirator Test and Approval, December 11, 1981, recommendations transmitted in a letter from Mr. Alan Hack to Mr. Don Wilmes, December 15, 1981, NIOSH Docket for 42 CFR Part 84, Exhibit 84–26.

[63]Ibid., p. 4.

adult American workers should achieve the minimum fit factor, not just 90% of the test panel. This is because the test panel represents only 95% of adult American workers. A performance standard for 90% of the panel would mean that up to 15% of adult American workers might not achieve the minimum fit factor with a NIOSH-certified respirator. NIOSH considers this high a percentage to be unacceptable.

§ 84.232(c)—Pretest Fitting. Several commenters stated that manufacturers should design negative-pressure respirators so that a negative- and positive-pressure seal check can be made by the wearer to assure that the facepiece is seated properly on the face. NIOSH recognizes that many current negative-pressure respirators are designed to permit a "crude" estimation by the wearer of excessive face-seal leakage under negative- and positive-pressure conditions. NIOSH agrees that respirators designed to facilitate those types of "fit checks" are advantageous. However, performance requirements for these fit checks have not been established. It is not possible for NIOSH to require a respirator characteristic for an unspecified performance standard.

§ 84.232(d)—Spectacles. Several comments were received regarding the proper selection of eye wear when half- and quarter-facepiece respirators must be worn. One commenter supported the requirement that all half and quarter facepieces be tested with the panel members wearing industrial safety glasses because many work conditions require the use of safety glasses as well as respiratory protec-

tion. Another commenter, however, stated that the respirator manufacturer should be able to designate the type of safety glasses that should be worn with the specified respirator.

NIOSH agrees that it is appropriate for the respirator manufacturer to provide guidance concerning the selection of safety glasses that are compatible with its respirator. Such guidance should be in terms of recommending generic types of safety glasses in order to provide the respirator wearer with a varied selection of compatible eye wear. NIOSH maintains that this guidance should be provided in the user instructions. Accordingly, § 84.232(d) has been modified so that appropriate safety glasses can be selected by the panel members in accordance with the manufacturers' recommendations contained in the user instructions.

§ 84.232(e)—Test Hardware. A few commenters expressed concern that the requirement to check facepiece leakage using a challenge aerosol concentration that did not vary more than ± 10 percent is unreasonable. The commenters noted that a variation of less than ± 20 percent is difficult to maintain in a large test chamber. One commenter stated that a 10% linearity requirement on the aerosol detector is probably very difficult to achieve when respirators are tested for the highest protection factors.

NIOSH has concluded that the ± 10 percent performance tolerance in the challenge aerosol concentration is achievable in test chambers used to determine facepiece leakage. However, test equipment that monitors the chamber air si-

multaneously with measurements of in-facepiece aerosol concentrations is less affected by variations in aerosol concentrations. Thus, a rewording of the test conditions has been made to permit a greater operational tolerance in the aerosol concentration within the chamber when chamber measurements are made at the same time as in-facepiece measurements. NIOSH has also required an operational tolerance of ± 10% for detector linearity.

In order to minimize the facepiece sampling bias associated with incomplete mixing of the contaminant in the facepiece, design specifications for the facepiece probe are defined in this paragraph. This method has been shown by recent research by NIOSH and others to reduce facepiece sampling bias to statistically tolerable levels[64,65,66,67,68]

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[64]Myers, W.R., J. Allender, R. Plummer, and T. Stobbe: Parameters that Bias the Measurement of Airborne Concentration Within a Respirator, Am. Ind. Hyg. Assoc. J. 47(2):106-114 (1986).

[65]Holton, P.M., D.L. Tackett, and K. Willeke: Particle Size Dependent Leakage and Losses of Aerosols in Respirators, Am. Ind. Hyg. Assoc. J. 48(10):848-854 (1987).

[66]Myers, W.R., J.R. Allender, W. Iskander and C. Stanley: Causes of In-Facepiece Sampling Bias–I. Half-Facepiece Respirators, Ann. Occ. Hyg. 32(3):345-359 (1988).

[67]Myers, W.R. and J.R. Allender: Causes of In-Facepiece Sampling Bias–II. Full-Facepiece Respirators, Ann. Occ. Hyg. 32(3):361-372 (1988).

§ 84.232(f)—Exercise Regimen. Several commenters felt that "grimacing or frowning" should not be one of the prescribed test exercises and that further explanation be given on how to perform each exercise. Some of the commenters expressed concern that the prescribed exercises have been used by others as a means of purposefully inducing a face-seal leak to check the resealing of the facepiece on the wearer's face. In addition, one commenter expressed concern that no supporting data were given for requiring the test exercise that requires "repeatedly raising arms upward and simultaneously looking upward." In contrast, one comment stated that the test exercises do not involve sufficient movement by the test subjects to adequately determine leakage rates.

NIOSH has revised its exercise sequence requirements to coincide with those presently used as part of the OSHA quantitative-fit-test procedure in the lead standard (29 CFR 1910.1025). NIOSH has concluded that any test exercise is arbitrary, but does provide useful information to evaluate face-seal characteristics and to compare differences between respirator types. A valid evaluation of the respirator fit on any given user can best be ascertained by fit-test exercises that have been demonstrated to correlate with workplace testing. To date this has not been done.

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[68](...continued)
[68]Myers, W. R. and R. W. Hornung: Evaluation of New In-facepiece Sampling Procedure for Full Facepieces, Report on I.A.G. DW 75931135-01-2 (September 1987).

A comment was made that the 1-minute exercise regimen required for each fit test is unnecessary and that a 30-second duration provided the same assurance of fit measurement. This recommendation was consistent with that proposed in ANSI Z88.10. NIOSH has concluded that reducing the time period from 1 minute to 30 seconds for the deep-breathing exercise is appropriate and will help to minimize the risk of hyperventilation by the test subject.

§ 84.232(h) (formerly .232(h, j)—Performance Criteria and Statistical Data Analysis. Comments were divided on the leakage criteria for the face-seal performance test. Some commenters felt that the maximum-allowed face-seal leakages are far too low, while others felt they are too high. In general, those who thought the proposed performance criteria are too strict did so because a statistical analysis will be applied to the face-seal leakage data. Those who thought the proposed performance criteria are too lenient felt that the allowed penetration should be as low as one tenth of the reciprocal of the assigned protection factor for a respirator facepiece. One commenter proposed reducing the severity of the statistical test by replacing the proposed parametric statistical test with a nonparametric statistical test because the measured fit factors are highly variable.

After considering both points of view, NIOSH has concluded that the proposed performance criteria of Table 1 are appropriate when used in conjunction with the revised parametric statistical test given in this section. The maximum allowable face-seal leakages have been adjusted to account for the previously

discussed decision to measure performance in this test as total inward leakage rather than as face-seal leakage alone.

The recommendation to replace the proposed statistical test with a nonparametric test was rejected. It was indicated by the commenter that because face-seal leakage is highly variable, more powerful statistical methods are not appropriate. NIOSH disagrees and maintains that the parametric statistical method proposed in this section is necessary because of the fundamental high variability in leakage data (i.e., due to high natural variability in the distribution of true leakages and not due to errors in the measurement method). The relatively small sample size used for the certification evaluations would not be adequate for a nonparametric statistical analysis. A nonparametric analysis would require a substantially larger panel to achieve the same statistical confidence level. This would unnecessarily create a substantially greater economic burden for respirator manufacturers.

NIOSH has determined that data from the entire 25-person test panel cannot be appropriately treated as a simple random sample from a large proportion (i.e., 95%) of the adult American working population. Approximately 5% of the adult American working population have extreme face sizes that will not be represented on the panel. Instead, NIOSH will consider the 25-person panel to constitute 10 separate random samples taken from within each of the 10 bivariate face-size ranges corresponding to the 10 sampling cells of the panel. For this statistical sampling model, NIOSH has developed the stepwise data analysis protocol outlined below for statistical analysis of data from the face-seal per-

formance tests. Detailed computing formulae for the indicated statistical significance tests are given in the proposed regulation.

Step 1—Conduct a preliminary statistical analysis to test for homogeneity of leakage distributions for three different data groups, denoted 1, 2, and 3. Preliminary statistical significance tests are first performed (per Steps 1a, 1b, and 1c below) to determine whether or not leakage distributions are significantly different between data groups.

Step 1a—Pool data from panel cells into three data groups. To have sample sizes that are large enough to permit valid statistical testing in Steps 1b and 1c, the 10 panel cells are first pooled into three larger data groups.

Step 1b—Compare the variances of the three data groups. The normalizing transformation, $X = \log[(1/L) - 1]$, of leakages (L) is used as the response variable in the statistical analysis. Homogeneity of variances of X in the three data groups is tested using Levene's Test. If the variances are statistically significantly different, omit Step 1c and proceed to Step 2. If the variances are not significantly different, proceed to Step 1c.

Step 1c—Compare means between data groups. This step is performed if the variances are not significantly different in Step 1b. Equality of means is tested using a one-way analysis of variance. Then proceed to Step 2.

Step 2—Conduct the main statistical analysis. The purposes of the main statistical analysis for a given facepiece and filter combination are:

(1) To compute a point estimate for the proportion, denoted P_t, of the 95% portion of the adult American working population with nonextreme face sizes

(i.e., those represented by the test panel subjects) who will obtain respirator leakages above a maximum allowable face-seal leakage (L_{max}) obtained from Table 1 of the Part and

(2) to account for the statistical uncertainty in the P_t point estimate, by computing a one-sided 95% upper confidence limit, denoted $UCL(P_t)$, for the true value of P_t.

Depending on the results of the statistical tests in Step 1, one or the other of two alternative protocols is used for the main statistical analysis (Step 2a or 2b below). If both means (Step 1c) and variances (Step 1b) are not significantly different, proceed to Step 2a. If either the means or the variances are significantly different, proceed to Step 2b.

In Step 2b, Plan I is used for the case of homogeneous variances. In this case, a pooled within-groups variance estimate is used in the analysis. Or, Plan II is used if Step 1b revealed significant differences between group variances. In this case, separate variance estimates for the three data groups are used in the analysis.

Step 2a—Conduct the main statistical analysis for the case when leakage distributions do not differ between data groups. In this case, face size is ignored as a factor and a leakage data set from an entire 25-person panel is treated as a simple random sample from the population of prospective wearers with nonextreme face sizes. Note that extreme face sizes lying outside the bivariate anthropometric range of the 10 basic panel cells constitute about 5% of facial sizes from prospective wearers in the adult American working population. A certifica-

tion test criterion (see Step 3 below) has been formulated that makes an appropriate allowance for their lack of representation on the 25-person panel. A higher proportion (i.e., 94.74%) of the working population represented by the panel is required to be adequately fitted compared with the 90% proportion required by the performance standard for the entire working population.

The proportion estimate P_t, with the t-subscript denoting "test panel," of those with excessive leakages is calculated as the tail area of a normal curve (i.e., the portion corresponding to leakages higher than L_{max}). In this case, the normal curve used for the calculation is fitted to X-values that are the normalized transformed values of the 25 leakages from the entire panel. P_t is a point estimate for the proportion who would have unacceptable (excessive) leakages (L exceeding L_{max}). This is equivalent to the left-tail area of the distribution of X-values. A 95% upper confidence limit for the true value of P_t is then computed for use in the accept/reject decision criteria of Step 3.

Step 2b—Conduct the alternative main statistical analysis for the case when leakage distributions differ between data groups. Proportions of wearers with excessive leakages are calculated separately for data groups 1, 2, and 3 by means of the general procedure discussed in Step 2a, but using separate normal distributions fitted to each group's leakage data. The point estimate for the proportion of nonextreme face sizes represented by the panel with excessive leakages (P_t) is then given by $P_t = (f_1P_1 + f_2P_2 + f_3P_3)$, where P_1, P_2, and P_3 denote proportions with excessive leakages within the three respective data groups, f_1, f_2, and f_3 denote relative frequencies of the 1, 2, and 3 data groups in the general

population of nonextreme face sizes and $(f_1 + f_2 + f_3) = 1.0$. A 95% upper confidence limit for the true value of P_t is then computed for use in the accept/reject decision criteria of Step 3. Note that different formulae are used to compute the UCL in Steps 2a and 2b.

Step 3—Perform the accept/reject decision test for the face-seal performance. $UCL(P_t)$, denoting the one-sided 95% upper confidence limit for the proportion of excessive leakages in the general population with nonextreme face sizes, is compared with the maximum permissible value for this proportion (1 − 0.9474 = 0.0526, as per the note in Step 2a). With respect to face-seal performance, the respirator is judged to be:

a) Not acceptable, if the UCL exceeds 0.0526, or

b) Acceptable, if the UCL is less than or equals 0.0526.

NIOSH invites comments, supported by suitable scientific rationale, for any alternative pooling of face-size-cell data compared with the three data groups proposed in Step 1a. NIOSH has made an attempt to strike a suitable balance between three factors:

(1) data group sample sizes (as large as possible),

(2) intragroup variances (as small as possible), and

(3) intergroup mean differences (as large as possible).

The criterion of 0.0526 for the maximum allowable proportion of excessive leakages in 95% of the adult American working population is conservative. This is because it assumes that all (100%) prospective respirator users with extreme face sizes (i.e., those in the 5% portion of the adult American working popula-

tion not represented on the 25-person panel) will have excessive leakages. In order to achieve the desired standard of having 10% or less of all prospective adult American wearers not being able to attain less than or equal to the maximum allowable face-seal leakage with the tested mask, no more than 5.26% of the 95% portion of facial sizes from the adult American working population represented by the panel can attain excessive leakages. Thus, 10% = [(0.05)(100%) + (0.95)(5.26%)]. The conservative assumed value of 100% in this equation reduces the standard from an allowable 10% (desired for the entire adult American working population) to the smaller value of 5.26% (required in the tested population). No other alternate method that is both valid and feasible is evident to NIOSH for obtaining a more reasonable point estimate of the proportion with excessive leakages (compared with 100%) for those prospective wearers with extreme face sizes.

As an alternative to the approach proposed by NIOSH, one method that might suggest itself would be to include a random sample of the 5% with extreme face sizes as an additional cell in the test panel. However, this is not feasible because such a cell would constitute only one or two people in a panel with cell sizes proportional to population numbers. A cell of extreme face sizes would not be a homogeneous group and could not be pooled with other cells of the panel. By itself, the cell would be too small to permit valid statistical analysis. Worse yet, a subpopulation of (all) "extreme face sizes" would itself require subdivision into more than one face-size cell. Otherwise, the leakage distribu-

tions of the new cell could have unusually high intracell variability and/or be multimodal.

The problems discussed here have led to NIOSH adopting a somewhat conservative method for setting a population standard that is to apply not only to the large majority of (sampled) prospective respirator wearers with typical face sizes, but also to the small portion with extreme face sizes who are too diverse to be sampled in adequate numbers. NIOSH welcomes any sound comments for improving the proposed solution to this statistical and public health problem.

The one-sided upper confidence limit for the point estimate P_t is calculated by use of classical statistical methods for propagation of errors. The point estimate P_t is based on the exact integral of a normal curve. NIOSH then estimated the variance of this point estimate by approximating the formula for P_t with a first-order Taylor series in the sample mean and standard deviation. Then the variance of this approximate quantity was determined and applied to the P_t point estimate. The estimate P_t was treated as approximately normally distributed. NIOSH considers this approximate treatment to be suitable, appropriate, and adequate for a statistical analysis of the panel data. The exact distributional form for the sample estimate is too complex for practical statistical analysis.

Subpart S—Self-Contained Breathing Apparatus. The function of Subpart S is to set forth the minimum performance requirements for the certification testing of self-contained breathing apparatus. NIOSH has added additional test require-

ments such as a diaphragm-overpressurization test, flammability test, a heat-exposure test, and a vibration test. These tests will better evaluate performance in typical applications such as firefighting, mining, and emergency egress situations.

§ 84.240—Self-contained breathing apparatus; descriptions. A commenter stated that OSHA has accepted buddy-breathing devices and that NIOSH should develop criteria for testing them. NIOSH is aware of the long controversy regarding the variety, availability, and use of these devices. In the fire service, particularly, it is possible for a firefighter to become trapped, disoriented or engrossed in life-saving as well as fire-fighting efforts to the extent that his air supply may be compromised or actually exhausted during those activities. In this situation it is very possible that a firefighter's ability or potential to effect a safe egress is significantly reduced, and additional support from other firefighters may be necessary. Traditionally this is accomplished by sharing air from one respirator between the donor and the receiver by utilizing a common facepiece and passing it back and forth while performing an egress.

Concern over these practices resulted in NIOSH sending out a "Letter to Interested Persons" dated July 24, 1984, requesting comments on the practicability, safety, and need for such a device and recommendations for performance criteria and suggestions for limitations on and conditions for safe use of such devices. After receipt and evaluation of those comments, NIOSH sent a "Letter to Interested Persons" dated July 23, 1985, stating that insufficient information was received on which to base certification of safe and practicable buddy-breath-

ing devices. This is still the NIOSH position, but NIOSH will continue to be receptive to the submission of other available research or information that would enable NIOSH to further consider this position.

§ 84.241—Interchangeability of oxygen and air prohibited; use of 100% oxygen near open flames or other ignition sources. NIOSH has concluded that the term "high heat" used in the original proposal for this section is not sufficient to cover additional sources of hazardous ignition. The intent of this requirement is to protect the user from increased risk as a result of wearing a closed-circuit breathing apparatus that generates high oxygen concentrations. This hazard results from leakage points such as at the facepiece seal and at the relief valve. Another risk results from respirator component contact with various levels of oxygen and saturation occurring to these components. Such contact lowers ignition temperatures of materials and increases the combustion propagation hazard for the wearer. Additionally, dead spaces such as head coverings as well as protective clothing are susceptible to such exposure. As a consequence there are many sources of ignition with sufficient levels of energy input capable of causing immediate combustion under these exposure conditions. In firefighting, open flame is a primary and prevalent ignition source. Other hazards include arcing, sparking, electrical, chemical, radiant and convective heat, and various levels of gases and their mixtures. Therefore, it is important to consider these prior to entry with a closed-circuit apparatus with oxygen facepiece concentrations exceeding 30%.

§ 84.241(b). Several commenters stated that there should not be a restriction on use and limitation of oxygen concentration for positive-pressure closed-circuit SCBA used in high heats and near open flames. NIOSH established additional performance criteria and recommendations of use for such SCBA because they were not addressed in the current regulations 30 CFR Part 11. In particular, the positive-pressure aspect was not covered. Safe use of such apparatus at various levels of oxygen concentrations was also investigated. This included extensive literature evaluation of materials and their oxygen level compatibilities. Consideration was also given to actual use, current research, and information obtained from the Lawrence Livermore Laboratory closed-circuit symposiums held on October 23–24, 1984. These considerations included knowledge of equipment and component deficiencies in fire-service compatibility and application, the lack of data demonstrating prior safe use of 100% oxygen SCBA and its relevance to the actual range of fire-fighting activities, and lack of research to substantiate safe use. These considerations and the fundamental Institute policy of prudent public health on any issue specific to the health and safety of workers were used to establish requirements for SCBA testing and certification.[69]

The oxygen concentration level has been limited to 30% and a recommendation on restricted use of 100% oxygen devices near open flames and other sources of ignition was established. This is based on the facts that most materials do not burn or support combustion at this level. In addition, there is still an

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[69]Federal Register, Volume 50, Number 222 (November 18, 1985).

advantage to be gained with regard to the ignition temperatures of materials that decrease as concentrations of oxygen increase. Although this is the current NIOSH position, NIOSH will continue to be receptive to the submission of future research or information that would enable the Institute to further consider its position on this matter.

§ 84.243 (formerly .244)—Pressure indicators and § 84.244 (formerly .245)—Timers and remaining-service-life indicators. One commenter had several suggestions specific to liquid-level gauges and timers. These included the use of timers visible to the wearer in lieu of liquid-level gauges, the deletion of a liquid-level gauge requirement, and allowing timers to be readable by either sight or touch rather than requiring both. This latter requirement was added because under certain conditions tactile sensitivity is reduced if gloves are worn. This could result in an inadvertent change of the setting.

NIOSH has concluded that because use varies with breathing apparatus, it is both technically advisable and practical to allow either a liquid-level gauge or timer or both to indicate remaining service time. This replaces the current 30 CFR Part 11 requirement for a gauge on all liquid-gas breathing apparatus. It is not prudent to totally exclude the use of liquid-level gauges because state-of-the-art permits such design while application may require such use and at the same time promote design diversification. It may also be necessary to read timers either by sight or by touch or by both methods. This choice should be made based on consideration of design and anticipated use or application.

§ 84.244(f) (formerly .245). Several commenters stated that reserve time alarms should be adjustable to user requirements because various job use applications may require different settings. Also, a 7-second alarm time is very short compared with the 20% to 25% of service time required for escape.

NIOSH recognizes that most open-circuit SCBA alarms sound during the entire 20% to 25% of the remaining service time. Generally, most closed-circuit devices that have longer service times than the open-circuit SCBA have alarms that sound for only very short periods of time. The volume of breathing gas is also approximately 80% less than that in open-circuit SCBA, thus it is important to limit gas leakage to activate the alarm. A trade off between alarm-time activation and resulting decrease in service time by gas loss is marginal. Therefore, it is necessary to limit alarm time with closed-circuit devices. It is also important to extend alarm time as long as possible to enhance safety. Thus NIOSH has concluded that it is necessary to extend the minimum alarm-time requirement to 30 seconds.

§ 84.245 (formerly .246)—Hand operated valves

§ 84.245(d, e) (formerly .246). Several commenters stated that two-way operation of a positive-pressure SCBA with a lever that allows a negative-pressure mode for donning should not be permitted because the SCBA might accidentally be used in this less protective mode. Also, the requirements for mainline and

by-pass valves are ill defined and may actually reduce overall safety and efficacy of a rebreather.

NIOSH maintains that elimination of this capability would limit design flexibility and could create a hazard for wearers. The result may be loss of vital breathing gas and a less than serious attempt by the wearer to obtain a good face-seal fit. A positive-pressure SCBA that can be switched to a negative-pressure operation mode may be switched to this mode prior to entry for donning purposes only, allowing user to adjust facepiece and SCBA fit. Actual use must involve proper training through an adequate respirator program and effective and efficient utilization of the manufacturer's instruction manual.

NIOSH has also concluded that not all SCBA designs require main-line and by-pass valves. Adequate SCBA performance depends on proper design and this is the manufacturer's responsibility. Each device must be individually tested and evaluated on its own merits. Therefore, in making the decision to approve an SCBA without such valves, it is necessary to simulate failures, conduct tests, and fully evaluate design and performance under such conditions. The final selection by the user must be based on knowledge of product, intended application, and specific hardware requirements.

§ 84.249 (formerly .248-2)—Compressed gas filters. Several commenters stated that the effective filter size downstream of the bottled gas of an SCBA should be specified and that the requirement that particles should be "effectively removed" is not adequately defined. NIOSH concludes that the filter size should

not be stipulated because this would constitute a design specification and hinder design innovation. Appropriate filter size should be designed, evaluated, and tested by the manufacturer. "Effectively removed" is dependent upon each specific design and certainly means that all or any injurious contaminants are an unacceptable exposure. The performance requirement has been changed to prohibit adverse effect to the respirator performance.

Former § 84.248-3—Breathing-bag test. Several commenters suggested that the gasoline-vapor test would be dangerous. NIOSH reviewed the breathing-bag-permeability test and agrees that it should be deleted from the performance test requirements for the following reasons: (1) the hazardous nature of the test, (2) the information obtained from the test is limited in nature because the data cannot be extrapolated to permeation of other gases and vapors to which the bag may be exposed; and (3) the test procedure required for this test is lengthy and detailed. Compared with the first proposal, the deletion of this test will reduce certification costs for respirator manufacturers.

§ 84.250 (formerly .248-4)—Weight markings. Several commenters said that the weight-marking requirement for an SCBA is not feasible because cylinder weight varies between types, accessory items cause variability, carbon dioxide scrubbers pick up varying amounts of moisture, there are many possible configurations of the same apparatus, and that weight is a design parameter. NIOSH has determined that the weight of accessories and weight variations during use cover a

wide range. This makes the task of weight markings for each model impractical, if not impossible. Therefore, NIOSH agrees and has changed this provision to require that only an initially fully charged SCBA unit without accessories should be weighed.

§ 84.251 (formerly .248-5)—Breathing-resistance test. Several commenters stated that the requirement regarding static pressure in the facepiece should be deleted because only the total exhalation pressure imposes the respiratory workload and is adequate as the performance limit requirement. NIOSH maintains that a performance requirement for static pressure exhalation differential is necessary to minimize potential performance defects and marginal respirator designs. For example, a static pressure set near the total exhalation pressure may fail by aspirating breathing gas and reduce service time. Also, if static drift is significant during the use period prior to maintenance and reset, the same effect could occur.

§ 84.252 (formerly .248-6)—Gas-Flow Test

§ 84.252(b) (formerly .248-6(b))—Closed-circuit apparatus. One comment stated that the minimum oxygen content for a closed-circuit SCBA should be set to some safe level below 19.5%. NIOSH maintains that the required minimum of 19.5% oxygen is necessary to eliminate any marginal apparatus that could create a hazard for the user. Also, any lower oxygen content will have marginal safety in high altitude usage.

§ 84.252(b)(4) (formerly .248-6(b)(4)). One comment stated that this paragraph implies that positive-pressure units must have a constant flow, although it is optional for negative-pressure devices. NIOSH agrees that this paragraph is unclear and that constant flow is not required for positive-pressure SCBA but may be optional as with the negative-pressure devices. Therefore, this section was revised to allow equivalent specifications for both types of devices, thereby giving increased flexibility in respirator design based upon respirator performance.

§ 84.255 (formerly .248-9)—Service-time test; closed-circuit apparatus. Several commenters stated that the service test time for closed-circuit SCBA should be set using a machine or metabolic simulator to set specific oxygen and carbon dioxide scrubber requirements. NIOSH has concluded that insufficient research exists to substantiate and correlate man/machine tests for setting service time. Additionally, the research, information, and data available, and its applications to all respirators, as well as its effective transfer and utilization as a replacement for the proposed service-time test, is unclear and will require further evaluation on a project basis.

§ 84.256 (formerly .248-10)—Test for carbon-dioxide in inspired gas; open- and closed-circuit apparatus; maximum allowable limits. A commenter stated that for the carbon dioxide performance test, the minute volume rate (total ventilation rate) should be changed from 10.5 to 40 L/min to give higher ventilations

and greater flushing of dead air space. Using information supplied in support of the comment, NIOSH has determined that if the ventilation is increased four times as suggested, then the additional carbon dioxide dead air space scrubbing of two times (approximately) would lower the average carbon dioxide level. The present method determines the highest possible level of carbon dioxide produced in the respirator, as demonstrated by the Bureau of Mines.[70]

A commenter suggested an upper limit of 1% carbon dioxide be required for all SCBA devices because increased respiration with increasing carbon dioxide results in a higher minute volume and decreased service time. NIOSH concludes that a level of 1% carbon dioxide maximum dead air space would unnecessarily limit design flexibility because carbon dioxide dead space is a direct function of mask size. The proposed change would mean that all SCBA devices would be required to have a nose cup even if design and other performance criteria did not require one. Therefore, this requirement has not been incorporated in this section.

§ 84.257 (formerly .248–11)—Tests during low-temperature operation. A commenter asked when, how, and what stressor samples are taken continuously, and if 0.05% carbon dioxide and the 19.5% oxygen limits are imposed during these tests. NIOSH agrees that this stressor information is necessary for closed-circuit

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[70]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).

SCBA devices and has added it to the proposed regulations as minimum performance criteria. These samples are not taken for open-circuit SCBA devices because carbon dioxide is removed on each exhalation and the oxygen level is determined by the oxygen concentration in the compressed-air cylinder and does not vary because exhaled gas is not recirculated.

§ 84.257(f) (formerly .248–11(f). Several commenters stated that cold temperature auxiliary components used on SCBA during cold tests must also be recommended by the manufacturer in addition to being commercially available. NIOSH agrees that only cold temperature auxiliary components recommended by the manufacturer may be used on a certified product. In fact these components must be furnished by the manufacturer and used during the tests and certified as part of the respirator.

§ 84.258 (formerly .248–12)—Vibration tests. Several commenters stated that the vibration standard MIL-STD-810D is not appropriate for testing respirators because it does not specify rubber tired vehicles, and the method is unclear. The mounting technique is not specified. A new method should be developed because it does not reflect provisions in the current MIL STD. Additionally, it does not specify respiration rate or tidal volume. The machine test is done at 60 L/min although the service-time test is performed at 40 L/min. This results in a testing disparity and inconsistency in the proposed regulation.

NIOSH agrees that regulatory revisions are necessary to clarify and improve test requirements. The following changes have been made:

a) Specifying MIL-STD- 810D, test I-3.2.1, Category 1-Basic transportation.[71]

b) Specifying test levels derived from common carrier spectra described in figures 514.3-1 through 514.3-3 of MIL-STD 810D, test I-3.2.1.

c) Requiring the test to simulate total transportation miles (24,000), during an 8-hour test period.

d) Specifying the mounting technique.

Additionally, a special vibration test has been performed for 30 CFR Part 11 certifications even though it is not specified. Although this test has not been validated, NIOSH concludes that self-contained self-rescuer (SCSR) equipment currently certified by NIOSH is superior to that which will be on the market if such a test is not performed. For example, this current test has shown the need to securely contain the chemical oxygen-generating material to prevent chemical abrasion and degradation and the need to fully weld rather than to spot weld screen-bed separators to maintain hardware canister integrity.

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[71]Military Standard, MIL-STD-810D, Military Test Methods and Engineering Guidelines, July 19, 1983.

§ 84.258(a) (formerly .248–12(a)). Several commenters stated that machine testing a respirator after exposure to the vibration test at 60 L/min, although service tests are done at 40 L/min (§§ 84.252(a)(2) and 84.254(a) respectively), results in inconsistencies. NIOSH agrees that the same 40 L/min machine test performed for breathing resistance and service time for SCBA should also be performed and the SCBA must meet the same requirements for this test. Therefore, 40 L/min replaces the 60 L/min test condition.

Former § 84.248–12(b). Several commenters stated that the shock test on SCBA should be eliminated due to inherent variability. NIOSH agrees that there is much inherent variability because there is no control over dropping orientation in the proposed shock test. After further consideration NIOSH concludes that additional research is necessary to quantify and establish a shock performance test requirement.

§ 84.258(d) (formerly .248–12(d)). Several commenters stated that NIOSH should eliminate the use of human subjects and conduct the test using a metabolic simulator. NIOSH concludes that the data collected during testing of human subjects is essential in order to validly test the performance of the whole device, rather than only a few specific characteristics as the simulator does.

§ 84.259 (formerly .248-13)—Use tests; purpose and requirements; general. Several commenters stated that the type of work performed in human subject tests does not represent the types of work found in the fire service and industry. NIOSH has concluded that the test activities are representative of activities found in fire-service use, underground mining, and general industry. Representative motions such as total body movement, walking, and running are included in the laboratory-performance tests. NIOSH recognizes that in a laboratory setting only a limited number of work activities may be incorporated in the test protocol. However, a ladder mill, an overcast, and weights for pulling and lifting as well as walking and running exercises are included in the performance-test protocol.

§ 84.260 (formerly .248-14)—Use tests 1, 2, 3, 4, and 5; purpose. One comment stated that NIOSH should quantify use tests by specifying the volume of oxygen, including a test for high performance to assure acceptable performance, considering human factors to ensure compatibility with the human body, use continuous monitoring during tests, set service time during the normal use test by using oxygen at a constant metabolic rate, and use a metabolic simulator for the first two quantitative tests to replace human test subjects.

NIOSH concludes that quantifying these tests in such a manner is not possible at this time because the translation and development of test methods from research data, if available at all, have not been done. Also, the applicability of the research available to all types of respirators is unknown.

§ 84.262 (formerly .248-16)—Use tests; requirements:

§ 84.262(b) (formerly .248-16(b)). Several commenters stated that facepiece fogging during use by test subjects should be defined on an objective or more quantitative basis. Because humans will wear SCBA, NIOSH concludes that human test subject input specific to vision is of vital concern and must be reflected in the final decision. Additionally, state-of-the-art respirator designs during the past several years have clearly demonstrated satisfactory solutions to this traditional problem.

§ 84.263 (formerly .248-17)—Flammability. Several commenters stated that the flammability test performed on a facepiece is unrepresentative, design restrictive, and should be modified to include whole-respirator exposure test. NIOSH maintains that this test is necessary because facepiece performance is critical and absolutely necessary for survival during fire-fighting use. However, NIOSH recognizes that SCBA are used for many applications other than firefighting and that flame-retardant facepieces may not be needed nor be suitable for other uses. Therefore, this test criterion will apply only to those SCBAs designated by the manufacturer as designed and intended for use by firefighters and mine rescue teams. Compared to the first proposal, this change should reduce costs for some respirator manufacturers and purchasers. Research to obtain criteria for whole SCBA exposure testing has not been conducted.

A commenter stated that the flammability test does not require respirators to operate during and after testing. NIOSH agrees that additional performance criteria should be listed to assure facepiece integrity after testing. Subsequently, all valves will be inspected to determine if they are operating properly. This is only a facepiece test and it must remain intact after the test, therefore, inspection points are adequate for test assessment. Consequently, testing an entire respirator is unnecessary.

§ 84.263(e, f) (formerly .248–17(e, f)). A commenter stated that the negative-pressure test during the flammability test is not appropriate for positive-pressure SCBA because the seal should prevent major escape of breathing gas to the surroundings. The negative-pressure test cannot assure this prevention. Visual inspection of sealing surfaces before and after testing should be considered sufficient for positive-pressure respirators. NIOSH considers significant any leakage from a facepiece in a positive-pressure device because such leakage can reduce the service time and compromise the intended high performance afforded by the SCBA. Therefore, NIOSH has added face-seal inspection points as well as valve-inspection points to the regulations.

One commenter stated that mouthpieces should not be used with escape SCBA because they will result in a product with marginal usefulness. NIOSH recognizes that all self-contained self-rescuers not only use mouthpieces but require them to make the devices small, light-weight, and easily-donned so they may be carried by each miner during an entire work shift.

Subpart T—Air-line Respirators. The function of Subpart T is to set forth the minimum performance requirements for the certification testing of air-line respirators. These devices are not to be used in IDLH atmospheres because air supplies may be interrupted and hoses may be severed. The performance requirements detailing maximum allowable air pressures, maximum allowable hose lengths, minimum and maximum air-supply volume to the facepiece, and maximum resistance in the facepiece are necessary to ensure that these respirators are safe and effective.

§ 84.272 (formerly .251-1)—Air-line respirators; demand and pressure demand and § 84.273 (formerly .251-2)—Air-line respirators; continuous-flow. Several commenters stated that paragraph (b) (that stipulates a maximum air pressure of 125 psig) should be removed from both sections and that paragraph 1(a) (that allows the manufacturer to specify hose length and pressure) should apply to both regulated and continuous-flow air-line respirators. NIOSH agrees that these sections need to be extensively revised to achieve consistency as recommended by commenter. Therefore, § 84.272(a) is included in both sections for regulated and continuous-flow class respirators. The performance requirement for maximum pressure of 125 psig is given in both sections.

§ 84.274 (formerly .251-3)—Air-supply-line tests

§ 84.274(a) (formerly .251-3(a))—Length of hose. Several commenters stated that the maximum hose length and the number of hose-length multiples for air--line respirators should be deleted because this requirement is unclear and does not appear to present a hazard to the user. NIOSH agrees that this requirement is a design restrictive specification. The provision has been revised to allow multiple hose lengths. However, a maximum hose length of 300 feet is specified to minimize possible safety related hazards.

§ 84.274(b)(1, 2) (formerly .251-3(b)(1, 2)). Several commenters stated that demand and pressure demand air-line respirators should not be limited to a flow of 425 L/min because SCBA are not limited to this flow rate. Also, continuous-flow, air-line respirators should not be limited to a maximum airflow. NIOSH has determined that there is no supporting information offered to justify the change requested by the commenters other than demand and pressure-demand flow should be same for air-line respirators and SCBA. The 425 L/min limitation is believed to have been initially listed incorrectly in current 30 CFR Part 11 requirements. This flow limitation applies only to continuous-flow respirators and should not limit demand or pressure-demand regulator capabilities. These regulators are designed to meet peak inspiratory flows on a physiological basis because many of these air-line respirators do not operate on a constant flow basis. Such a restriction could make it unsafe or not give maximum protection. Additionally, for continuous-flow air-line respirators there are physiological rea-

sons making such a limit desirable, such as prevention of eye irritation, skin drying, and dehydration.

Several commenters stated that the minimum flow rate should be increased for continuous-flow respirators to assure positive pressure is maintained, and give maximum protection. NIOSH has concluded that the current minimum airflow requirement is adequate. However, the Institute is considering bilevel performance certifications for continuous-flow, air-line respirators (refer to the discussion earlier in this preamble). Class I would be for tight-fitting facepieces providing between 115 and 170 L/min and loose-fitting hoods and helmets providing between 170 and 230 L/min. Class II would be for tight-fitting facepieces providing at least 170 L/min and loose-fitting hoods and helmets providing at least 230 L/min. The Class II devices should provide higher user protection than that of the Class I devices. However, the Institute is not attempting to or intending to make the protection offered by continuous-flow, air-line respirators equivalent to the protection offered by positive-pressure, air-line respirators. These are two distinct classes of respiratory protection. If a manufacturer wishes a continuous-flow, air-line respirator certified as a positive-pressure device, the air-line respirator may be submitted for this type of certification if the device meets the criteria in this Part.

§ 84.274(c) (formerly .251-3(c)). Several commenters said that NIOSH should establish regulator cycling requirements for SCBA devices as well as air-line respirators because they can be used in immediately dangerous to life and health (IDLH) environments. NIOSH has not observed problems with new certifications or field problems as a result of not cycling SCBA regulators. During routine maintenance in most use conditions, SCBA regulators and diaphragms are inspected more frequently than air-line respirators. Also, SCBA respirators have a by-pass mode to accommodate any regulator failure or a fail-safe operation. Air-line respirators typically are used for longer periods of time on a routine basis and subject to an increased frequency or potential failures. Additionally, if a respirator is submitted as a combination air-line/SCBA respirator, the regulator is tested to the air-line requirement because the combination respirator must meet all applicable requirements for each type.

Several commenters wanted to know the justification for testing an air-line respirator regulator with a 100,000-cycle test and requested changing the test conditions to a reduced number of test cycles. NIOSH has concluded that a 100,000-cycle test is realistic and representative of actual use conditions because it represents 2 weeks of continuous use. Certification experience under the current 30 CFR Part 11 substantiates this conclusion with the absence of observed field usage problems in this area.

§ 84.275 (formerly .251-4)—Harness test

§ 84.275(a) (formerly .251-4(a)). A commenter stated that the harness-load performance test should be doubled from the proposed 300-pound test to account for sudden load strain. NIOSH agrees that the load-strain performance test should be increased from 300 pounds to 600 pounds to increase safety margin to the user. Additionally, NIOSH has certified respirators with life lines that far exceed the proposed load strain. Where life lines are attached to harnesses, the harness is the weak link and must function satisfactorily to provide safe and effective performance.

§ 84.279 (formerly .251-8)—Airflow-resistance test; air-line respirator, positive-pressure class. In relation to the airflow-resistance performance test for positive-pressure air-line respirators, several commenters stated that the resistance values should be consistent with SCBA requirements except for hoods/helmets. NIOSH concludes it is not necessary to impose equivalent performance requirements for both air-line respirators and SCBA because air-line respirators cannot be used in IDLH atmospheres.

Subpart U—Air-Purifying Respirators; General Requirements. The function of Subpart U is to set forth the generic safety and efficacy requirements for certification of air-purifying respirators. These requirements have been consolidated into one subpart for conciseness and clarity. Descriptions of the several classes of air-purifying respirators have also been incorporated for clarity.

§ 84.282 (formerly .262)—Filters used with canisters and cartridges; location; replacement

§ 84.282(a) (formerly .262(a)). Several commenters suggested that the wording in paragraph (a) should be revised as follows:

"Particulate filters used with a gas and vapor canister or cartridge shall be located so that a gas- and vapor-removing element is located downstream of the particulate filter. In some cases, it may be necessary to place an additional gas- or vapor-removing element at the inlet side to protect the particulate filter."

NIOSH has revised this provision to incorporate the suggestion of allowing an additional gas or vapor element placed at the inlet side of the filter, to protect the filter media when necessary. This revision will permit increased design flexibility and innovation. It will allow a respirator manufacturer to design a safer and more effective respirator for those instances where the contaminant gas or vapor may degrade the filter media.

§ 84.283 (formerly .263)—Powered air-purifying respirators flow requirements

§§ 84.283(a, b, c) (formerly .263(a, b, c)). Several commenters suggested raising the minimum flow rate for continuous-flow respirators and performing the tests with a breathing machine to assure positive pressure. One of the commenters suggested a minimum airflow of 6 cfm for tight-fitting powered air-purifying respirators (PAPR). These respirators are used in non-IDLH atmospheres and NIOSH concludes the proposed performance criteria are adequate for these

applications. However, NIOSH is considering two certification categories for powered air-purifying respirators (see discussion earlier in this preamble).

Subpart V—Particulate Air-Purifying Respirators. The function of Subpart V is to set forth the minimum performance requirements for the certification testing of particulate air-purifying respirators. NIOSH has concluded that the current test methods in 30 CFR Part 11 do not adequately distinguish between lower and higher efficiency filters. For example, the current 30 CFR Part 11 test methods produce time-integrated values for filter-media penetration. As a result, filter performance is not measured at different times during the service life of a filter. The proposed regulation incorporates a performance requirement for instantaneous penetration. This requirement is essential for evaluating filter effectiveness because certain filter media initially have adequate efficiencies and others may initially have inadequate efficiencies that then increase with usage due to loading effects.[72]

It is not feasible to test filters for the entire range of use conditions that may affect their protection performance. Thus, for performance testing NIOSH has selected aerosol-test criteria representing severe-use conditions to ensure adequate filter safety and efficacy. The proposed filter-efficiency performance tests require the use of an aerosol in the size range 0.10 to 0.25 micrometer count median diameter. Research has shown this aerosol size range to be one of the

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[72]Hinds, W. C.: Filtration in Aerosol Technology Properties, Behavior, and Measurement of Airborne Particles, John Wiley & Sons, Inc., (1982), pp. 164–186.

most-penetrating for most types of filter media.[73,74,75,76,77,78,79,80] NIOSH has con-

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[73]Thomas, J. W., and R. E. Yoder: Aerosol Size for Maximum Penetration Through Fiberglass and Sand Filters, A. M. A. Arch. Ind. Health 13:545 (1956).

[74]Rimberg, D.: Penetration of IPC-1478, Whatman 41, and Type 5G Filter Papers as a Function of Particle Size and Velocity, Am. Ind. Hyg. Assoc. J. 30(4):394–401 (1969).

[75]Stafford, R. G. and H. J. Ettinger: Filter Efficiency as a Function of Particle Size and Velocity, Atmos. Environ. 6:353–362 (1972).

[76]Liu, B. Y. H. and K. W. Lee: Efficiency of Membrane and Nuclepore® Filters for Submicrometer Aerosols, Environ. Sci. Technol. 10:345–350 (1976).

[77]Lee, K. W. and B. Y. H. Liu: On the Minimum Efficiency and the Most Penetrating Particle Size of Fibrous Filters, J. Air. Pollut. Control Assoc. 30(4):377–381 (1980).

[78]Liu, B. Y. H. and B. Fardi: A Fundamental Study of Respirator Air Filtration, Progress Report for NIOSH Grant #1 R010H01485–01A1, University of Minnesota, St. Paul, MN (1985), p. 38.

[79]Liu, B. Y. H. and K. L. Rubow: Air Filtration by Fibrous Media, Fluid Filtration: Gas, Volume I, ASTM STP 975, R. R. Raber, Ed, Philadelphia, PA (1986), pp. 1–12.

[80]Stevens, G. A. and E. S. Moyer: "Worst Case" Aerosol Testing Parameters: (continued...)

cluded that test aerosols in this size range are the best evaluator of filter performance under severe-use test conditions available with current state-of-the-art aerosol generation and detection systems designed for filter evaluation. Also, it should be technically feasible for manufacturers to develop filter media that comply with these test requirements.

NIOSH has determined that commercially-available instrumentation is suitable for conducting the required tests. For example, TSI models 8110, 8160, and 8150 can be used for both the solid and liquid aerosol tests. The Air Techniques, Inc. model Q127, which is currently used for testing high-efficiency filters against Part 11 requirements, can be used to perform the oil-mist test in this Part. The Sibata AP-6310G generator together with the AP-364A test unit can also be used to perform the solid-aerosol test. Note that the mention of any company or product does not constitute endorsement by NIOSH.

NIOSH recognizes that the most-penetrating aerosol size varies as a function of filter type, particle size, and flowrate.[81,82,83] NIOSH also recognized that an

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[80](...continued)
I. Sodium Chloride and Dioctyl Phthalate Aerosol Filter Efficiency as a Function of Particle Size and Flow Rate, Am. Ind. Hyg. Assoc. J. 50(5):257-264 (1989).

[81]Ibid.

[82]Brosseau, R. M., J. S. Evans, and M. J. Ellenbecker: Collection of Monodisperse Aerosols by Electrostatic Respirator Filters, presented at the 1989 American Industrial Hygiene Conference, St. Louis, MO (May 1989).

alternative and more-desirable performance test would evaluate each filter at several different aerosol sizes (e.g., 0.05, 0.10, 0.15, 0.20, and 0.25 μm), determine the most-penetrating size for each tested filter, and conduct subsequent penetration testing at that size. However, to conserve testing time and reduce test costs, filter loading could be accomplished with any aerosol size $\leq$ 0.25 μm. Initial and final instantaneous filter penetration could be measured with the most-penetrating aerosol size. All other test criteria (e.g., filter preconditioning, aerosol neutralization, filter loading, test temperature, filter efficiencies) would remain the same as in Subpart V.

NIOSH is considering this alternative procedure for the Final Rule. Presently there are limited data on the combined effects of "worst-case" aerosol size, flowrate, preconditioning, and aerosol charge neutralization.[84,85,86] In addition to

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[83](...continued)
[83]Liu, B. Y. H. and B. Fardi: A Fundamental Study of Respirator Air Filtration, Progress Report for NIOSH Grant #1 R010H01485-01A1, University of Minnesota, St. Paul, MN (1985), p. 38.

[84]Stevens, G. A. and E. S. Moyer: "Worst Case" Aerosol Testing Parameters: I. Sodium Chloride and Dioctyl Phthalate Aerosol Filter Efficiency as a Function of Particle Size and Flow Rate, Am. Ind. Hyg. Assoc. J. 50(5):257-264 (1989).

[85]Moyer, E. S. and G. A. Stevens: "Worst Case" Aerosol Testing Parameters: II. Efficiency Dependence of Commercial Respirator Filters on Humidity Pretreatment, Am. Ind. Hyg. Assoc. J. 50(5):265-270 (1989).

these other severe-use test conditions, any adverse effects on filter penetration due to filter loading during use are not completely known. NIOSH invites comments on: (1) the technical feasibility of the alternative test method discussed above, (2) the availability of test equipment for the alternative performance test, and (3) the feasibility of producing filters, other than high-efficiency filters, that could pass the alternate type of performance test.

The proposed tests require the use of a solid aerosol for solid-aerosol certification and an oil aerosol for liquid-aerosol certification. For liquid-aerosol performance testing, NIOSH intends to use an oil mist, such as dioctyl phthalate (DOP), that represents severe-use conditions. Oil mists such as DOP degrade some filter media. Any adverse effects due to storage and use at high humidities are evaluated by requiring filter preconditioning at 85% relative humidity and 38 degrees Celsius for 24 hours prior to testing (see discussion for § 84.292(c)).

Lastly, a neutralized aerosol will be used for the filter-efficiency tests. This also represents severe-use conditions with regard to different types of aerosol charge distributions that may occur in the workplace (see discussion for § 84.293(c)).

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[86](...continued)
[86]Moyer, E. S. and G. A. Stevens: "Worst Case" Aerosol Testing Parameters: III. Initial Penetration of Charged and Neutralized Lead Fume and Silica Dust Aerosols through Clean, Unloaded Respirator Filters, Am. Ind. Hyg. Assoc. J. 50(5):271-274 (1989).

Using severe-use test conditions to evaluate particulate respirators not only helps to assure that respirator users will receive adequate protection, but also will make it easier for respirator program managers to correctly select particulate respirators. A 42 CFR Part 84 certification will require only that the user know the concentration of the particulate, the exposure limit or applicable exposure standard, and the physical nature of the particulate hazard (i.e., solid, liquid, or mixture of solid and liquid particulates).

This new classification method will replace the current 30 CFR Part 11 certification classes that are based on restrictive design specifications such as single-use and reusable respirators. The new certification classifications are based on performance requirements that will permit substantial design flexibility and innovation by respirator manufacturers. The current 30 CFR Part 11 certifications are also based on restrictive testing classifications that are application-specific (e.g., for dusts, fumes, mists). Thus, the user also needs to take into consideration factors such as particle size, aerosol charge distribution, and workplace conditions (e.g., relative humidity).

Because of the above mentioned changes to NIOSH performance tests, it is necessary to reclassify particulate air-purifying respirators based on their filtration performance and the physical nature of the aerosol they are to be used against (solid, liquid, or combination). The three new filter performance classes are:

(1) Type I with a filtration efficiency of at least 90% under the test conditions

(2) Type II with a filtration efficiency of at least 99% under the test conditions

(3) Type III with a filtration efficiency of at least 99.97% under the test conditions

§ 84.290 (formerly .270)—Particulate air-purifying respirators; description. A comment was received that there is no provision in the proposed regulations for specific application certifications such as for acid mists, oil mists, paint sprays, or pesticides. Another comment stated that deleting the current application-specific test classifications will be confusing.

Toxic properties of pesticides and paint sprays vary greatly. No laboratory test could cover the entire range of variables needed for specific test classifications. For example, the current 30 CFR Part 11 certifications for pesticides are not recommended for pesticides with poor warning properties or that are carcinogenic.

The objective of the proposed requirements is to base particulate respirator certifications on aerosol-performance tests representing severe-use conditions rather than to test for all conceivable usage conditions and hazardous particulates. Filters will be classified according to performance efficiency and not on the general type of aerosol used for testing (i.e. dust, fume, mist).

§ 84.290(a) (formerly .270(a)). Many commenters suggested changing this paragraph to read "solid- and/or liquid-particulate test." NIOSH agrees with the intent of this suggestion and has incorporated wording to allow certification of respirators with filters for use against solid, liquid, or both solid and liquid particulates. The wording in § 84.290(b) has been revised to reflect this change.

NIOSH concludes that filters tested against the proposed solid aerosol will adequately protect users exposed only to solid particulates. One commenter noted that only a small percentage of particulate respirator users are exposed to liquid oil mists. Requiring a liquid-particulate test may unnecessarily increase breathing resistance for the majority of those users. Thus NIOSH is creating three certification classes for particulate respirators that are based on the physical nature of the contaminant. Compared with the first proposal, this revision will substantially reduce costs for both respirator manufacturers and purchasers. It will also permit design flexibility and innovation to better protect respirator wearers.

§ 84.290(c) (formerly .270(c)). Several commenters suggested using a classification system with filtration efficiency designations of Types I, II, III, and IV instead of "low, medium, and high" efficiencies. It was claimed that certification performance classes should be based on 80%, 90%, 99%, and 99.97% filtration efficiencies that will be consistent with international standards. Another commenter stated that the filter-efficiency requirements must be supported by research and claimed that no testing was done to support 42 CFR Part 84 filtra-

tion performance requirements. A comment made reference to the British Standards Institution respirator standards and European Standard for respirators that permit lower filtration efficiencies. The comment also supported the elimination of particulate tests in 30 CFR Part 11.

NIOSH agrees with the comment on renaming the filtration efficiency classifications. The new filtration performance classes are designated as Types I, II, and III. This eliminates the negative connotation of naming a filter a low efficiency filter. Performance requirements for class efficiencies have been revised as well. Type I filters must now demonstrate at least 90% efficiency. NIOSH research[87] indicates that this is technologically feasible. The currently certified dust, fume, and mist filters provide initial point efficiencies of between 91% and 93% when tested against aerosol sizes of 0.01 to 0.30 μm count median diameter. The recommendation to create a certification class for filter efficiencies of 80% or higher is rejected by NIOSH because the overall protection afforded by such a filter respirator would be unacceptably low.

§ 84.291 (formerly .271)—Particulate air-purifying respirators; performance requirements; general. A comment was received stating that particulate filters should be color coded. NIOSH recognizes that color coding might aid users in the identification of filter types. However, requiring color codes for filters with-

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[87]Moyer, E. S.: "Respirator Filtration Efficiency Testing," Fluid Filtration: Gas, Volume I, ASTM STP 975, R. R. Raber, Ed., American Society for Testing Materials, Philadelphia, PA, (1986), pp. 167–180.

out permanent filter housings may not be feasible. Wording has been incorporated requiring Type I, II, or III to be printed on the filters and requiring Type III filters that have a "cartridge style housing" to be color coded magenta. In addition, all filters must be marked as to whether they are certified for solid, liquid, or solid and liquid particulates. This requirement for 42 CFR Part 84 is analogous to what is currently used in 30 CFR Part 11.

§ 84.293 (formerly .273)—Particulate instantaneous-penetration filter tests. Many commenters requested changing the regulations to allow for "certification for solid and/or liquid particulates or both." Commenters claimed that filters designed to meet the proposed requirements will be hot, heavy, hard to breathe through, and uncomfortable. Several commenters claimed that high-efficiency filters, which have a higher breathing resistance than electrostatic filters, would be the only filters to pass the new requirements.

NIOSH has concluded that it is appropriate to change the test requirements to reflect the proposed certification classifications (§ 84.290). Oil-mist-filtration performance tests will be required only when the applicant requests certification for liquid particulates or both solid and liquid particulates. Certain filters currently certified under 30 CFR Part 11 may not meet these new requirements. However, as previously stated the filter technology is available. NIOSH research indicates that currently-certified dust, fume, and mist filters could potentially meet the new Type I efficiency requirements. Additionally, high-efficiency filters will meet the most stringent requirements for Type III filters.

Several commenters suggested that the test aerosol should be chemically and physically inert and the chemical nature of the aerosol be stated. One commenter suggested using paraffin oil instead of oils such as DOP. NIOSH has not incorporated the recommendation that performance test aerosols be chemically and physically inert. One objective of a liquid-particulate performance test is to identify filters that may physically degrade in contact with liquid aerosols and reduce the respirator wearer's protection. Oils commonly found in the workplace can adversely affect respirator filter performance. NIOSH did agree with a comment that test aerosols be better defined. Refer to the discussion at the beginning of Subpart V.

§ 84.293(c) (formerly .273(b)). One commenter stated that a dynamic-preconditioning test is more stringent and more desirable than static preconditioning. NIOSH selected the 24-hour static-preconditioning test condition on the recommendation of the ANSI Ad Hoc Respirator Committee.[88] Filter-media performance studies have been conducted with static preconditioning because this type of preconditioning best simulates filter storage conditions experienced by users.

The adverse effects on filter performance due to high temperatures and humidity during filter storage and use in high humidities have been described by

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[88]American National Standards Institute Z88 Committee for Respiratory Protection, Ad Hoc Subcommittee for Respirator Test and Approval, undated letter from Donald P. Wilmes of the 3M Company.

several investigators during the last decade.[89,90,91,92] Possible degradation of filter performance during storage will be evaluated by requiring a 24-hour preconditioning at 85% relative humidity and 38 degrees Celsius prior to performance testing. In addition, neutralized aerosols will be used for filtration-efficiency testing. NIOSH research indicates that "neutralizing" the test aerosol can significantly decrease filter efficiency (i.e., reduce wearer protection).[93] Thus, humid-air preconditioning and neutralized-aerosol testing are severe-use test conditions

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[89]Held, B. J., et al.: Respirator Studies for the National Institute for Occupational Safety and Health, July 1, 1973, through June 30, 1974, Los Alamos Scientific Laboratory Report LA-5825-PR, Los Alamos, NM (December 1974).

[90]Ackely, M.W.: Degradation of Electrostatic Filters at Elevated Temperature and Humidity, paper presented at the World Filtration Congress III, Downington, Pennsylvania, pp. 169-176 (September 14, 1982).

[91]Ortiz, L. W., S. C. Soderholm, and F. O. Valdez: Penetration of Respirator Filters by an Asbestos Aerosol, Am. Ind. Hyg. Assoc. J. 49(9):451-460 (1988).

[92]Moyer, E. S. and G. A. Stevens: "Worst Case" Aerosol Testing Parameters: II. Efficiency Dependence of Commercial Respirator Filters on Humidity Pretreatment, Am. Ind. Hyg. Assoc. J. 50(5):265-270 (1989).

[93]Moyer, E. S. and G. A. Stevens: "Worst Case" Aerosol Testing Parameters: III. Initial Penetration of Charged and Neutralized Lead Fume and Silica Dust Aerosols through Clean, Unloaded Respirator Filters, Am. Ind. Hyg. Assoc. J. 50(5):271-274 (1989).

that are representative of conditions typically encountered in actual filter respirator use.

§ 84.293(e) (formerly .273(d)). Four commenters recommended that NIOSH test respirator penetration at only one airflow rate. NIOSH previously proposed two airflow rates for performance testing because filter penetration is a function of the face velocity through the filter.[94,95] However, after further review of the requirements for particulate instantaneous penetration, NIOSH has concluded that a single flow rate is adequate for filter performance evaluations. Both the cited research studies and 17 years of NIOSH experience with filter testing under 30 CFR Part 11 indicate that for a given aerosol size a higher flow rate will normally yield a higher penetration than will a lower flow rate. Therefore NIOSH has selected 85 liters per minute as the most appropriate test flow rate. Use of a single flow rate will substantially reduce certification testing costs for filter respirator manufacturers.

However, NIOSH is concerned that there may be use conditions or filter designs that could result in higher filter penetrations at flow rates less than

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[94]Rimberg, D.: Penetration of IPC-1478, Whatman 41, and Type 5G Filter Papers as a Function of Particle Size and Velocity, Am. Ind. Hyg. Assoc. J. 30(4):394 (1969).

[95]Stevens, G. A. and E. S. Moyer: "Worst Case" Aerosol Testing Parameters: I. Sodium Chloride and Dioctyl Phthalate Aerosol Filter Efficiency as a Function of Particle Size and Flow Rate, Am. Ind. Hyg. Assoc. J. 50(5):257-264 (1989).

85 L/min. NIOSH requests that this possibility be considered and commented on by interested parties.

§ 84.293(f) (formerly .273(e)). Several commenters recommended deleting the breathing-machine test for powered air-purifying respirators (PAPRs). Another recommended that a PAPR be tested at the flow rate of its blower and clarifying the term "cycle" that implies that air is not inhaled and exhaled through the respirator. NIOSH has concluded that PAPRs should be tested in their normal operating mode because flow rates vary over time as the filters load and batteries discharge. A powered air-purifying respirator with a tight-fitting facepiece may require an initial flow rate of 400 L/min to meet the final minimum required flow rate of 115 L/min. Because filter penetration is a function of face velocity, this test will measure filter efficiency under normal usage conditions.

One commenter stated that this provision is irrelevant to the testing of PAPRs. NIOSH has reviewed and revised this paragraph. The challenge concentration has been increased to 2,000 mg/m^3 for PAPRs. This value is based on typical flow rates of PAPRs and filter loading during the current lead-fume testing in 30 CFR Part 11.

§ 84.293(g) (formerly .273(f)). Several commenters requested information on why sodium chloride is required in the proposal in place of the silica-dust and lead- fume tests used in 30 CFR Part 11. Commenters made the assumption that sodium chloride is intended by NIOSH for solid-aerosol performance test-

ing. However, the former § 84.273(f) did not mention a specific compound. Upon review, NIOSH determined that additional aerosol specifications are appropriate for the performance test to avoid confusion and to help assure test procedure standardization. Sodium chloride is specified as the solid test aerosol. The liquid test aerosol must be generated with an oil (e.g., dioctyl phthalate) that is a liquid at room temperature (20 degrees Celsius) and that has a density of 0.91 to 0.99 g/cm^3. NIOSH invites comments on whether or not these additional specifications will hinder the future development and implementation of different test aerosols.

NIOSH concludes that the current 30 CFR Part 11 certification tests have substantial deficiencies in that they:

1) measure time-integrated average performance rather than instantaneous penetration, and thus are not representative of typical respirator usage
2) do not adequately consider the adverse effects of particle size, face velocity, or aerosol type on filter penetration
3) lack sensitivity and are non-reproducible
4) do not consider the adverse effects of typical use conditions, such as high temperatures and high relative humidities.

Several commenters requested that a time period be specified to conduct tests after preconditioning the filters for specific time periods. NIOSH has incorporated an 8-hour time period after filter preconditioning. This is a reasonable amount of time to initiate testing without suffering an excess loss of water absorbed during the preconditioning.

One commenter stated that it is not clear what "100 ± 5 mg of the aerosol has contacted the filter" means, and if it means respirator filter, then the test is too short. Another commenter suggested that NIOSH delete the requirement to run the test until there is no further increase in penetration. NIOSH has changed this provision to indicate that it is the respirator filter that the challenge aerosol must contact. In addition, the test loading has been increased to at least 200 mg in response to the comment that "the test is too short." The new challenge of 200 mg is based on the loading currently used in testing filters against lead fume in 30 CFR Part 11. This change has also eliminated the need for tests to be run "until there is no further increase in penetration."

§ 84.293(h) (formerly .273(g)). One commenter stated that an "aerodynamic mean diameter" does not exist, that it should be AMMD. NIOSH has now given the test condition aerosol requirement as the count median diameter (CMD), and the maximum permitted value for geometric standard deviation of the aerosol has been increased to 1.8. The latter requirement can be met using current technology that is commercially available (refer to earlier discussion for Subpart V).

Subpart W—Gas and Vapor Air-Purifying Cartridge Respirator. The function of Subpart W is to set forth the minimum performance requirements for the certification testing of gas and vapor air-purifying cartridge respirators. The proposed regulation incorporates several new requirements to replace several

proposals that have been deleted. Cartridges will be tested at three humidities to better represent actual use conditions. This new requirement is necessary because relative humidity can substantially reduce cartridge service life. A shelf-life disclosure requirement has been added. NIOSH has concluded that a shelf-life requirement is necessary because commonly occurring storage conditions such as high and low temperatures and humidities can also reduce service life in a manner that can not be readily detected by the respirator user or purchaser.

§ 84.300 (formerly .280)—Gas and vapor air-purifying cartridge respirators; description

§ 84.300(a) (formerly .280(a)). Several comments questioned why NIOSH proposed lowering the maximum use concentration (MUC) of methylamine to 75 ppm and stated that it should remain at 100 ppm because the NIOSH Respirator Decision Logic lists the MUC of methylamine as 100 ppm. OSHA may change permissible exposure limits (PELs) for gases, and then NIOSH limits will conflict with OSHA policy. Because exposure limits for substances change as new information is learned about their toxicity, maximum use concentrations (MUC) have been redefined as 10 times the NIOSH Recommended Exposure Limit (REL) or other applicable exposure limit, whichever is lower. In addition, because regulatory agencies govern the use of respirators in the workplace and because exposure limits may change as more is learned of substances' toxicity, the nonregulatory MUC information has been moved to Appendix A and listed

as a NIOSH recommendation. Thus, the MUC will change as exposure limits change.

Several commenters suggested that NIOSH include performance requirements for certification of chlorine dioxide, hydrogen sulfide, and elemental mercury vapor respirators. These devices are currently certified under 30 CFR Part 11 using the special gas and vapor respirator test requirements. NIOSH has incorporated these requirements in 42 CFR Part 84, using the performance criteria developed for such devices under 30 CFR Part 11.

§ 84.303 (formerly .283)—Breathing-resistance test

§ 84.303(a) (formerly .283(a)). Several commenters recommended deleting final breathing resistance as was first proposed for particulate filters. NIOSH has deleted the final breathing-resistance requirement because breathing resistance changes minimally after testing with a gas or vapor. This deletion will permit design flexibility and innovation. Compared with the first proposal, the deletion might also reduce costs for both respirator manufacturers and purchasers.

§ 84.304 (formerly .284)—Gas and vapor cartridge service-life test

§ 84.304 (formerly .284(b)(3)). Several commenters claimed that no currently produced organic-vapor chemical cartridge will meet the 85% relative humidity preconditioning and 50-minute service-life performance requirement in the proposal. Unsubstantiated assertions were also received that a respirator that will meet these requirements will be hot, cumbersome, uncomfortable and at least

2 1/2 to 4 times larger than cartridges currently certified under 30 CFR Part 11. In addition, commenters stated that users have not expressed a need for longer service life. One commenter cited five studies on effects of high humidities on organic-vapor cartridges. Two manufacturers claimed that cartridges lasting from 75 to 100 minutes, under 30 CFR Part 11 test conditions, lasted only 21.8 and 18.3 minutes when tested in accordance with the original proposal. They also stated that sorbent technology is increasing but this requirement is beyond feasibility and that NIOSH will be judged arbitrary and capricious.

Essentially all of the claims regarding the initial proposal for this section were not supported with test data or other substantial evidence. The intent of the original proposal was to evaluate cartridges under severe-use and storage conditions that frequently occur in the workplace. In particular, the severe adverse effects of high humidity during storage and use were to be evaluated by the preconditioning requirement.

After consideration of the objectives and possible effects of the initial performance requirement, NIOSH has deleted the cartridge-preconditioning test requirement and replaced it with a requirement to disclose cartridge shelf life. The new proposal for § 84.304(h) requires the respirator to retain at least 90% of the required service life of this Part throughout the shelf life period stated by the manufacturer. Knowledge of shelf life for respirator sorbent elements is crucial for safe and effective respirator use. Substantial reductions in sorbent capacity during storage or use cannot be detected before use by a respirator wearer. These capacity reductions can create a hazard for the wearer when the

cartridges are used because they reduce the service life of the sorbent. Several studies have shown that high humidity conditions during storage and use can substantially affect sorbent service life.[96,97,98,99]

Replacing the preconditioning requirement with the shelf-life labeling requirement should provide the same safety and efficacy to the user because high humidity during storage is one of the most important conditions that a manufacturer must consider when establishing shelf life for a cartridge. The revised requirement still considers the adverse effects of high humidity during use because it requires cartridges to be tested at low, medium, and high humidities.

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[96]Nelson, G., A. Correia, and C. Harder: Respirator Cartridge Efficiency Studies VII: Effects of Relative Humidity and Temperature, Am. Ind. Hyg. Assoc. J. 37(5):280–288 (1976).

[97]Jonas, L. A., E. B. Sansone, and T. S. Ferris: The Effect of Moisture on the Adsorption of Chloroform by Activated Carbon, Am. Ind. Hyg. Assoc. J. 46(1):20–23 (1985).

[98]Wood, G. O.: Effects of Air Temperatures and Humidities on Efficiencies and Lifetimes of Air-Purifying Chemical Cartridges Tested Against Methyl Iodide, Am. Ind. Hyg. Assoc. J. 46(5):251–256 (1985).

[99]Hall, T., P. Breysse, C. Corn, and L. A. Jonas: Effects of Adsorbed Water Vapor on the Adsorption Rate Constant and the Kinetic Adsorption Capacity of the Wheeler Kinetic Model, Am. Ind. Hyg. Assoc. J. 49(9):461–465 (1988).

NIOSH has concluded that the revised provision will assure the same protection to the user.

This revised provision will provide respirator manufacturers with considerable design flexibility for cartridges and suitable cartridge packaging. It will permit innovation for design of cartridges and their packaging containers. Additionally, manufacturers will have maximum flexibility in establishing cartridge shelf lives and, if necessary, appropriate storage conditions to assure the stated shelf life. The new provision will permit manufacturers to design and sell respirator sorbent cartridges that best meet the needs of their customers and respirator users. Compared with the first proposal, this revision will lead to lower certification costs for respirator manufacturers and could lead to lower costs for respirator purchasers.

NIOSH does not expect a manufacturer to test the service life of every gas and vapor cartridge respirator under all conceivable storage conditions. However, manufacturers must be able to provide customers and users with service-life information on those chemicals their NIOSH-certified respirators are capable of providing adequate protection against.

§ 84.304(e) (formerly .284(b)(3) and (c)). Because of the difficulty in maintaining a relative humidity of 85% during canister and cartridge testing, NIOSH has revised the test-condition requirement from 85% to 80% relative humidity. To maintain equivalent severity of test conditions, the test temperature has been increased from 25 degrees to 30 degrees Celsius. The higher test temperature,

which is representative of conditions encountered during actual respirator use, will ensure that a cartridge is challenged with a test atmosphere that contains as much or greater moisture than the originally proposed test conditions.

§ 84.304(g) (formerly .284(f)). One commenter stated that it is not clear why "combination" cartridges should be only one-half as good as regular cartridges. NIOSH has no data on which to base a revision of this requirement. Thus, it has not been changed from the current 30 CFR Part 11 requirement. This lower service life is permitted because different sorbents are needed for the different types of gases and vapors. A sorbent mix in combination cartridges is used and service life is decreased for both types of contaminants if cartridge size is to remain the same. Requiring the same service life for these "combination" cartridges as for single gas or vapor types will require that all cartridges be larger, bulkier, and harder to breathe through. Additionally, note that the indicated penetration values in Table 10 (and Tables 12, 13, and 14) should not be confused with permissible exposure levels (PELs) set by regulatory agencies such as OSHA. Several commenters suggested that NIOSH include performance requirements for chlorine dioxide, hydrogen sulfide, and elemental mercury vapor respirators. These devices are currently certified under 30 CFR Part 11 using the special gas and vapor respirator test requirements. NIOSH has incorporated these requirements in 42 CFR Part 84, using the performance criteria developed for such devices under 30 CFR Part 11.

Subpart X—Gas and Vapor Air-Purifying Canister Respirators. The function of Subpart X is to set forth the minimum performance requirements for the certification testing of gas and vapor air-purifying canister respirators. Subpart X incorporates the same three test humidities and shelf-life requirements that are specified for gas and vapor air-purifying cartridges in Subpart W. The current 30 CFR Part 11 test classifications for canister respirators are design- and application-specific (e.g., chin style, front-mounted, escape canisters). In contrast, this proposal creates a certification classification system based solely on adsorption capacity performance for a limited number of contaminants. Canister respirators will receive certifications as either low- or high-performance canisters for hazards such as ammonia, chlorine, and sulfur dioxide.

§ 84.310 (formerly .290)—Description and classification

§ 84.310(a) (formerly .290(a)). Several commenters said that the statement in the proposal that a half-facepiece canister respirator can be used only for escape purposes is unclear as to whether it refers to both IDLH and non-IDLH environments and needs clarification. Escape canister respirators can be used for escape from both IDLH and non-IDLH atmospheres. Revised wording to reflect this change has been incorporated.

§ 84.310(b) (formerly .290(b)). One commenter suggested that NIOSH test the entire PAPR during the service-life test to evaluate the effect of gases and vapors on respirator parts and that the service life be increased. NIOSH performance test concentrations are much higher than typical use concentrations for these devices. NIOSH has concluded that testing the entire unit at these concentrations may not be indicative of use degradation of PAPR components at lower use concentrations. In addition, corrosion and degradation from exposure to chemical and physical agents to which respirators are likely to be exposed is covered under § 84.220(a).

§ 84.315 (formerly .295)—Canister service-life test. Several commenters stated that the requirement to test within 8 hours of preconditioning is impractical for testing and adds nothing of significance to the test. It was requested that the 30 CFR Part 11 requirements for preconditioning and testing should be retained. Another commenter stated that the minimum service-life requirement is too stringent for equilibrated canisters if they are to be tested at 64 L/min. Further, it was claimed that these requirements make the respirators bulkier and heavier and will not be conducive to the wearers' comfort.

In response to these comments, NIOSH has reviewed and completely rewritten the canister performance test portions of the regulations for the reasons stated for § 84.304. Most importantly, preconditioning of canisters has been deleted. A new requirement has been added (§ 84.315(g)), stating that a manufacturer must determine and mark the shelf life on each canister. The claimed

shelf life must be based on data reflecting the effect of high storage humidities on the canister. See the discussion under § 84.304 for the intent and intended effects of this provision. Additionally, the test conditions for the service-life performance testing have been revised to 30 degrees Celsius at 25%, 50%, and 80% relative humidity.

Several commenters suggested that NIOSH include performance requirements for hydrogen sulfide in 42 CFR Part 84 because these devices (for escape only) have been and are certified in the special gas and vapor category of 30 CFR Part 11. NIOSH has incorporated the current performance requirements for hydrogen sulfide in this section, using the performance criteria developed for escape-only usage canisters under 30 CFR Part 11.

Because of the difficulty in maintaining a test relative humidity of 85% during canister testing, NIOSH has revised the test condition from an 85% to 80% relative humidity. To maintain equivalent severity of test conditions, the test temperature has been increased from 25 degrees to 30 degrees Celsius. The higher test temperature, which is representative of conditions encountered during actual respirator use, will ensure that a canister is challenged with a test atmosphere that contains as much or greater moisture than the originally proposed test conditions.

§ 84.315(j) (formerly .295(f)). One commenter suggested that NIOSH not certify the carbon monoxide canister because the service-life indicator is a moisture indicator. The commenter also said that "b" and "d" footnotes of Table 6 cannot apply to the same line of the table and questioned why there are no pretest conditions for carbon monoxide.

NIOSH notes that the carbon monoxide canister has been in use for many years and there are still industrial and mining applications where it is needed. An indicator that responds to moisture is appropriate because the active canister agent (hopcalite) is also adversely affected by moisture.

NIOSH has eliminated preconditioning for all types of canisters. It is not required because the performance testing for carbon monoxide canisters will be performed at a relatively high humidity of 95%. NIOSH considers the combination of high-humidity and low-temperature test at 0 degrees Celsius to be severe-use test conditions for the performance testing of carbon monoxide canisters. In Table 11 (formerly Table 6) the footnotes of the first proposal have been corrected.

Subpart Y—Organic Vapor Gas and Vapor Air-Purifying Cartridge and Canister Respirators. The function of Subpart Y is to set forth the minimum performance requirements for the certification testing of nonspecific gas and vapor organic vapor cartridges and canisters. Subpart Y incorporates the same three test humidities and shelf-life requirements that are specified for other cartridges and

canisters in Subparts W and X. These requirements are particularly relevant to organic vapor cartridge and canister evaluations.

A user information requirement has been added requiring manufacturers to provide the user with a list of organic vapor(s) and gas(es) hazards against which they recommend their respirators be used. This information can be given as part of the label or user instructions or both. It is the position of NIOSH that this information is vital to the correct selection and use of organic vapor respirators. Manufacturers have a responsibility to provide this information so that respirator users will receive safe and effective respiratory protection.

§ 84.320 (formerly .300)—Description and limitations. One commenter stated that air-purifying respirators can only be used if a certification is granted for a new substance. For a Premanufacturing Notice (PMN) substance, the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV®) and any warning properties are unknown. The comment claimed that this will place substantial burden on new chemical manufacturers. NIOSH notes that EPA regulates use of respirators for PMN substances. NIOSH cannot certify respirators for new chemicals for which the Institute has no information. EPA receives information on these substances from which they can base decisions. If EPA approves use controls, then air-purifying respirators can be utilized.

§ 84.321 (formerly .301)—Organic gas and vapor air-purifying cartridge respirators. One commenter stated that it is unjustifiable to use the single value of 1,000 ppm as the maximum use concentration (MUC) for these types of cartridges in view of varying toxicities and sorption efficiencies. NIOSH agrees with the comment and has eliminated MUCs as a condition of certification. NIOSH will now consider MUCs as assumed conditions of use and has moved them to Appendix A. NIOSH will assume that gas and vapor cartridges will not be used in concentrations exceeding the lowest of the following: (1) a contaminant's IDLH, (2) 10 times the NIOSH-recommended exposure limit (REL) for contaminant, and (3) an exposure limit established by an applicable regulatory agency. This is consistent with changes made throughout the cartridge portions of the regulations.

§ 84.323 (formerly .303)—Labeling requirements. Several comments were received on the labeling requirements claiming that:

(1) It will be extremely difficult for manufacturers to indicate all organic vapors and gases for which their respirators will provide adequate protection. Such a provision will create numerous problems. First, it will take manufacturers many years to test even the most common chemicals (the number of common chemicals in the workplace far exceeds 1,000) for their respirators. This will therefore leave certain end users without any protection for that period of time. Second, there are many chemicals that are not widely used but for which an organic vapor respirator may be useful. Those chemicals will not normally

be used as a test challenge medium by the manufacturer, yet they might have been tested and successfully used by end users. Under the proposed labeling requirement, the end user might be left without a reasonable alternative because the user could not use such a respirator without the manufacturer's approval.

(2) Nearly all organic vapors and gases occur as mixtures and to test against only one of the components provides little useful information.

(3) The best method for evaluating a cartridge's performance against a specific organic vapor and gas is in the workplace where the mixtures and environmental conditions in which they will be used are present. This is best done by the user.

(4) NIOSH must delete the requirement to label these respirators with a list of all the organic vapors and gases having good warning properties for which the respirator is effective. This places an unnecessary burden on the manufacturer to test and certify respirator performance in this manner because those substances with good warning properties can notify the wearer (assuming the wearer has passed an odor-sensitivity test) of contaminant breakthrough. However, for those substances without good warning properties, specific field tests should be required and so labeled by the manufacturer.

(5) When the manufacturer's list is printed and is in the hands of the end user, there is no protection for the manufacturer if OSHA changes a permissible exposure limit (PEL), thereby redefining the warning properties of the substance.

(6) Including a list as part of the label will turn the label into a book. OSHA regulation 29 CFR Part 1910.1000, Tables Z-1 and Z-2, includes an al-

phabetical listing of airborne contaminants including organic vapors. These tables are several pages long. Just listing the chemicals in these tables will require an extraordinarily long certification label.

NIOSH maintains that respirator manufacturers have important responsibilities to their customers and respirator users to provide adequate information on the proper selection and use of respirators. One of these is the critical obligation to identify those organic gases and vapors against which their respirators will provide safe and effective protection. Correct respirator selection is a critical element of effective respirator protection. Providing this type of information to the prospective purchaser and user is essential to ensure that the correct respirator is matched to the workplace hazard.

Although NIOSH will require such information be provided with each respirator (§ 84.50), NIOSH will not require that this information be submitted for review and concurrence by NIOSH. Compared with the first proposal, this approach will reduce certification costs for manufacturers of organic vapor respirators.

There are several means for manufacturers to obtain the required information. These include the field experience of customers and users, research data available from professional societies, NIOSH, independent laboratories, customer laboratories, and respirator manufacturer laboratories. Additionally, responsible consideration of the similarity of the chemical sorption responses of gases and vapors with similar chemical activity may be used by a manufacturer. Prudent use of data on homologous series of vapors and on other available sorbent

materials might be used to predict expected levels of respiratory protection. NIOSH solicits comments and suggestions regarding this requirement or alternative ways of accomplishing the same objective.

NIOSH does not expect manufacturers to test all organic vapor respirators against every conceivable organic vapor. However, manufacturers must be able to provide customers and users with information on the specific organic chemicals their NIOSH-certified respirators are capable of providing adequate protection against. This information is particularly vital to purchasers and users because the certification performance tests will use only a single organic vapor—carbon tetrachloride. Numerous articles in the professional literature clearly demonstrate that organic vapor cartridges and canisters can yield widely varying service lives and levels of protection depending on the organic vapor they are used against.

§ 84.327 (formerly .307)—Particulate tests; canisters and cartridges containing filters. Several commenters stated that a provision for combination escape respirators using an air-purifying mode should be included because NIOSH has certified these devices under the current regulation. An air-line respirator, used in an air-purifying mode only for escape, should not have to meet resistance requirements as an air-purifying respirator. Instead, the applicable breathing-resistance requirements of Subpart T should apply. NIOSH has added a combination respirators requirements as a new § 84.315. These are performance re-

quirements that have been developed as "in-addition-to" tests under the current 30 CFR Part 11 regulation.

§ 84.328 (formerly .308)—Service-life test. One commenter stated that:

(1) Testing equilibrated cartridges and canisters within 8 hours is too time constraining. Testing within 24 hours will be more reasonable, and it will still maintain the same level of performance. If there is supporting evidence for this change it should be published for review and comment;

(2) Minimum life requirements are too stringent for equilibrated cartridges and canisters if they are to be tested at 64 L/min. The public has not stated the need for respiratory protection exceeding the current performance levels. The result of these requirements will be larger, bulkier respirators that will not be conducive to the end users' comfort. The technical justification for the change in required performance level must be stated. This information must be made available for comment; and

(3) Test concentrations and penetrations require tolerance limits. There is a certain amount of error in these tests that should be defined.

Several commenters stated that:

(1) The proposed requirement that the cartridges be tested within 8 hours of preconditioning is impractical to comply with and adds nothing of significance to the test (see comments on § 84.301) and

(2) They also strongly recommended maintaining the following performance requirements: Test at 25 ± 1 degree Celsius and 50% ± 2% relative humidity

at a flow rate of 32 L/min for preconditioned samples or 64 L/min for as-received samples. This includes preconditioning at 25 ± 1 degrees Celsius and at 25% or 85% ± 2% relative humidity.

(3) It was claimed that no organic vapor chemical cartridge currently available in the United States will meet this requirement. It was claimed that organic vapor chemical cartridges will have to be made about four times bigger to meet this requirement with today's technology. It was stated that respirator users have not expressed the need for longer service life organic vapor cartridges.

In response to these concerns, NIOSH has eliminated organic gas and vapor cartridge preconditioning for the same reasons it has been eliminated in §§ 84.304 and 84.315.

One commenter said that NIOSH should require desorption testing for organic vapor cartridges and canisters and should use the Nelson and Harder method of service-life testing.[100] NIOSH concludes that although desorption can be studied on a case-by-case basis, no test has been developed that can predict desorption for a class of compounds such as organic vapors. Therefore, NIOSH has concluded that retaining "generic wording" in the regulations that allows flexibility by respirator manufacturers is the safest procedure.

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[100]Nelson, G. O. and C. A. Harder: Respirator Cartridge Efficiency Studies V. Effect of Solvent Vapor, Am. Ind. Hyg. Assoc. J., 35:391–410 (1974).

Subpart Z—Gas and Vapor Air-Purifying Respirators for Unlisted Contaminants. The intent of Subpart Z is to set forth the minimum performance requirements for the certification testing of specialty respirators designed for protection against toxic gas(es) and vapor(s) not specified in previous Subparts. NIOSH experience with respirator certification under 30 CFR Part 11 indicates that there is a need for a systematic procedure to certify gas and vapor respirators for specific contaminants as the need develops in the workplace or as the manufacturers believe is necessary. The current 30 CFR Part 11 does not specify tests and performance criteria for the evaluation of gas and vapor specialty respirators. Thus, over the last 15 years NIOSH developed "in addition to criteria" test procedures that assure that each specialty respirator application is properly and consistently evaluated. These criteria have been used in this Subpart as the basis for performance tests for these devices. NIOSH maintains that each submission for certification of specialty gas and vapor respirators must be reviewed as to safety and efficacy provided by the device. The scientific merit of the application, test data, and any applicable field experience must all be considered.

§ 84.332 (formerly .312)—General test requirements

§ 84.332(a) (formerly .312(a)). One commenter stated that all requirements for the certification application must be stated in this provision. The commenter also stated that there are not always studies or data available on the warning properties of all chemicals. If there are no OSHA PELs or ACGIH TLV®s for

a substance, it is not possible to determine if the substance has adequate warning properties.

Because this Subpart deals with substances not specifically listed elsewhere in the regulation, it is difficult to predict all of the information NIOSH might need to adequately evaluate the safety and efficacy of a respirator for these substances. The alternative would be to not allow specific certifications, but this would not benefit respirator manufacturers or users.

§ 84.334 (formerly .314)—Requirements for end-of-service-life indicators. Several commenters stated that listing requirements that an end-of-service-life indicator (ESLI) must meet is premature and should be deleted. Few, if any, indicators are in existence today. Pre-existing limitations in the requirements will stifle product innovation. For instance, the requirement that the wearer be able to see a passive ESLI is not necessarily of value. For example, if the cartridge service life is sufficiently long to assure that during its use the respirator will be removed, the wearer will be able to see the indicator long before breakthrough occurs. An example of this would be a cartridge with a service life of 200 hours. If its indicator changes at 90% of the service, the user will have the remaining service life of 20 hours to view the indicator change before breakthrough occurs.

NIOSH recognizes that although there are only a few ESLIs currently certified, permitting them to be certified under 42 CFR Part 84 permits and encourages future ESLI innovations. Most cartridges will not have service lives of 200

hours. Therefore NIOSH concludes that requiring an indicator to change at 10% of the remaining service life is a safe procedure that cannot be eliminated because of a few exceptions to the rule.

§ 84.334(a) (formerly .314(a)). One commenter stated that this contradicts cases where MSHA or OSHA allows the use of a respirator without ESLI against a contaminant without adequate warning properties. NIOSH agrees that this comment is correct. The proposed wording is for NIOSH certification purposes. Regulatory agencies can allow their use in the workplace. Wording to this effect has been added to Appendix A.

§ 84.334(b) (formerly .314(b)). It was suggested that NIOSH should set specific test parameters for evaluating ESLI instead of stating high and low temperatures, relative humidity, etc. NIOSH has proposed general test parameters because this section permits certification of respirators and ESLI developed in the future. Thus, flexibility in the requirements allows NIOSH and the manufacturers to review on a case-by-case basis the procedures needed to ascertain the safety and efficacy of a respirator.

§ 84.334(b)(1) (formerly .314(b)(1)). One commenter stated that there must be guidelines for contaminant concentrations if no ACGIH TLV®s or OSHA PELs exist. NIOSH has concluded that, if no NIOSH REL, OSHA PEL, ACGIH TLV®, etc. exists, there is insufficient information available concerning the toxici-

ty of the chemical to make an informed selection of an air-purifying respirator. Guidelines for testing will be worthless in this case.

§ 84.334(b)(3) (formerly .314(b)(3)). Several commenters stated that the manufacturer cannot anticipate all use conditions in the workplace. It was stated that this requirement must be removed because it is not feasible to comply. In § 84.334(b)(3), NIOSH does not require a manufacturer to anticipate all use conditions. However, in order to design a safe and effective respirator, a manufacturer must have knowledge of use conditions that can be reasonably expected. Therefore, NIOSH has concluded that this is not an unreasonable requirement.

§ 84.334(c) (formerly .314(c)). One commenter recommended deleting this requirement that all passive ESLI shall be visible to the wearer and shall be detectable to people with physical impairments such as color blindness. It was stated that color blindness is a physical impairment preventing use of this type of respirator and not a reason for restricting design. It was claimed that the requirement for the ESLI to be visible to the wearer restricts design innovation. NIOSH requires reference colors that enable color blind people to discern the difference in shades. NIOSH concludes that this requirement does not restrict product design or innovation.

§ 84.335—Combination air-line and air-purifying respirators. A new § 84.335 has been added to provide performance requirements for combination air-line and air-purifying respirators.

Appendix A. During the development of 42 CFR Part 84, NIOSH recognized that many of the requirements in 30 CFR Part 11, such as breathing-gas purity levels, were more the responsibility and under the authority of the several regulatory agencies. Therefore, NIOSH incorporated, as "assumed conditions of use" in 42 CFR Part 84, many such existing requirements from the current 30 CFR Part 11. The comments on 42 CFR Part 84 pointed out several other requirements of the same nature, such as maximum use concentrations for air-purifying respirators, and these were also included in Appendix A.

Commenters stated that Appendix A, paragraph (f), is incorrect, in that it stated gas and vapor cartridge respirators will be used in concentrations in excess of the maximum use concentration specified in this Part. NIOSH has corrected this statement by adding the word "not" so that it reads "gas and vapor cartridge respirators will not be used in concentrations in excess of the maximum use concentrations recommended by NIOSH." Paragraph (f) also is revised to discuss the relationship between NIOSH recommendations and regulatory requirements.

Regulatory Impact Analysis

Under Executive Order 12291, the Department must prepare a "preliminary regulatory impact analysis" for any proposed rule that has an annual effect on the economy of $100 million or more, has certain other effects, or is categorized as a "major rule" by the Office of Management and Budget. Under the Regulatory Flexibility Act (P.L. 96-353, 94 Stat. 1164 [5 U.S.C. 601 et seq.]), the Department must prepare an "initial regulatory flexibility analysis" for any proposed rule that has a significant economic impact on a substantial number of small entities, including small businesses. Because of the substantial concerns of the respirator manufacturing industry and the public, the Department has voluntarily prepared a preliminary regulatory impact analysis (PRIA) and initial regulatory flexibility analysis (IFRA). Together with the main body of the Preamble to the second NPRM, the Preliminary Regulatory Impact Analysis prepared by NIOSH constitutes both a PRIA and an IRFA for 42 CFR Part 84.[101]

After extensive analysis, NIOSH has concluded that the proposed rule, if implemented, would create significant health benefits for up to 6.6 million users of NIOSH-certified respirators. This number could grow to as high as 10 million by the mid-1990s. Additionally, Part 84 will provide significant economic and

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[101]National Institute for Occupational Safety and Health: Preliminary Regulatory Impact Analysis: 42 CFR Part 84, Second Notice of Proposed Rulemaking–Revision of Tests and Requirements for Certification of Respiratory Protective Devices, (September 1989).

other benefits to 32 domestic respirator manufacturers, owners of about 7 million nondisposable respirators, and those employers who annually purchase over 110 million disposable respirators. In general these benefits cannot be quantified.[102] However they will be obtained at reasonable economic cost to respirator owners, purchasers, and manufacturers.[103] The health and economic benefits would be primarily of two types. First, users of respirators will directly because of both major and minor improvements in respirator performance, safety, and reliability. Even small improvements in respirator performance would be significant in the aggregate because of the large number of person-years of exposure involved. The total incremental effect for all respirators would depend on how many respirator failures would be prevented and how many ineffective or marginally performing devices are eliminated. NIOSH expects that significant incremental reductions in both chronic and acute exposures to harmful substances would occur over time. Second, the use of performance rather than specification standards would substantially increase the flexibility of manufacturers in designing and marketing new and improved respirator designs. While the specific innovations that might be made cannot be predicted, they could be both performance-enhancing and cost-reducing.

For the potential incremental recurring costs of complying with the new Part 84 requirements, NIOSH's best estimate is about $6 million annually for 32

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[102]Ibid., Section C.

[103]Ibid., Sections D and E.

domestic respirator manufacturers. Additionally, NIOSH's best estimate is that some respirator owners will incur potential costs of $8 million annually for a period confined to the first 5 years after promulgation of Part 84. However, since data were not available to make a multitude of offset adjustments for non-quantifiable benefits to both respirator manufacturers and owners, these best estimates substantially overestimate the actual potential costs.

The potential cost for manufacturers is slightly greater than 1% of estimated industry retail revenues of about $650 million a year and about 2% of direct revenues to manufacturers. While some manufacturers might face a cost increase of more than 1%, others might have no increase at all. Regardless, NIOSH has concluded that cost increases of this magnitude would not create significant impacts on a substantial number of manufacturers, purchasers, or users.

NIOSH determined that the only provision contributing to potential costs for respirator owners is the Sunset Clause (§ 84.2(b)(1)) for antiquated Part 11 certifications. Based on cost analyses conducted with the spreadsheet model developed for this PRIA and a reanalysis of the benefits created by each regulatory Subpart, NIOSH substantially revised the Sunset Clause to 5-, 6-, and 8-year expiration periods instead of the single 5-year expiration period proposed in the first NPRM. Potential total costs due to the original Sunset Clause were reduced by over $56 million with no significant reduction in protection for wearers.

Owners of entry-SCBA respirators used in firefighting applications will incur essentially all potential costs resulting from the revised Sunset Clause. Over the

entire population of approximately 400,000 firefighter SCBAs in 1990,[104] the potential total nonrecurring costs over the 5-year Sunset Clause period will average about $95 per firefighter-SCBA user ($19/wearer/year) and about $95 for each Part 11 SCBA used in firefighting ($19/respirator/year), where the average cost for a new firefighter SCBA is $1,600.

NIOSH concludes that the owners of more than 80% of the atmosphere-supplying respirators in 1990 (i.e., over 1.3 million supplied-air, nonfirefighting entry-SCBAs, and escape-only SCBAs[105]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as the new 6- or 8-year phase-out periods for Part 11 respirators provided for these devices under the revised Sunset Clause in this NPRM. NIOSH also concludes that the owners of most air-purifying respirators in 1990 (i.e., over 5 million nondisposable, non-powered, air-purifying respirators and PAPRs[106]) will incur no potential costs due to the Sunset Clause because the average service lives of these devices are the same as their 5-year phase-out period. The only air-purifying respirator owners affected by the Sunset Clause will be those owning 380,000 gas masks in 1990.[107] The 5-year nonrecurring cost impact over this respirator population will average about $5.30 per gas mask respirator (a bit over

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[104]Ibid., Table XVIII.

[105]Ibid.

[106]Ibid.

[107]Ibid.

$1/respirator/year) and about $10.70 per respirator user (a bit over $2/user/-year).

As discussed in the Preamble to this second Notice of Proposed Rulemaking (NPRM), there are a considerable number of regulatory alternatives at the provision-by-provision level that NIOSH has considered, proposed, and revised in many cases. In determining which particular provisions and performance tests to propose, NIOSH has sought to minimize unnecessary costs while assuring or improving product performance and safety. The Institute particularly welcomes comments on changes that would make the proposed standards even more cost-effective while providing the same or increased protection to respirator wearers as that given in the second NPRM.

For the PRIA, potential benefits and potential costs are considered to be the incremental benefits and costs created by the proposal above and beyond the benefits and costs of the current regulation. Additionally, the potential costs are considered to be the incremental time, effort, or financial resources required to bring currently certified respirators into compliance with the proposed 42 CFR Part 84 requirements. Typical incremental costs would include those specific costs necessary to bring certified devices into compliance (e.g., incremental costs to develop, redesign, modify, construct, or assemble any materials or new test or manufacturing equipment, incremental costs to conduct additional tests, inspections, observations). For the PRIA, note that current costs or activities of respirator owners and manufacturers incurred or performed in the normal course of their maintenance, manufacturing, and sales activities, whether or not

required by the current 30 CFR Part 11, are not considered to be potential costs that will be created by the proposed regulation.

Copies of the complete PRIA may be obtained from the NIOSH Docket Officer, National Institute for Occupational Safety and Health, Division of Safety Research, Room S-112, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505. The telephone number of the NIOSH Docket Office is (304) 291-4597. NIOSH requests comments and additional information on (1) assumptions used in the preliminary analysis, (2) methods of analysis, and (3) conclusions reached. NIOSH also welcomes any alternative suggestions designed to achieve the objectives of Executive Order 12291 at lower costs while providing the same or increased protection to respirator users as that given in this second proposal.

Paperwork Reduction Act

Under provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35, 5 CFR 1320) (the Act), NIOSH shall not engage in a collection of information without obtaining Office of Management and Budget (OMB) approval of such information collection and displaying a valid OMB control number. NIOSH prepared a detailed Supporting Statement to supplement the Institute's request to OMB for approval to collect certain essential information required to properly conduct respirator certification activities under the proposed 42 CFR

Part 84 regulation for respirator certification by the U.S. Government.[108] Under the Act a "collection of information" includes, but is not limited to, such agency activities as reporting, notification, recordkeeping, and labeling requirements. The Supporting Statement identifies the impact of this proposal on the current reporting, record keeping, disclosure/notification, and labeling requirements for industrial respirator manufacturers. The purpose of the Supporting Statement is to demonstrate that NIOSH has taken every reasonable effort to ensure that:

❶ The information collection requirements in Part 84 are the least burdensome necessary for the proper performance of NIOSH's functions to comply with legislative and statutory requirements and achieve program objectives associated with respirator certification;

❷ The information collection does not duplicate information otherwise accessible to NIOSH;

❸ The information collection has practical utility; and

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[108]National Institute for Occupational Safety and Health: Supporting Statement for Request to OMB for Approval of a Collection of Information Under the Paperwork Reduction Act of 1980: 42 CFR Part 84, Second Notice of Proposed Rulemaking–Revision of Tests and Requirements for Certification of Respiratory Protective Devices, (September 1989).

❹ NIOSH has sought to minimize the cost to itself of the collecting, processing, and using the required information, but has not done so by shifting disproportionate costs or burdens to the 32 domestic respirator manufacturers.

The following ten sections of Part 84 contain reporting requirements: §§ 84.11, 84.20(d), 84.21(a, b), 84.24, 84.25(b, c), 84.30, 84.32(c), 84.331, 84.332, and 84.334(b). The following six sections contain notification requirements: §§ 84.20(f)(3), 84.21(c), 84.22, 84.23, 84.50, and 84.51. The following three sections contain recordkeeping provisions: §§ 84.20(c), 84.20(g), and 84.232(g). The following five sections contain labeling requirements: §§ 84.40, 84.41(b, c), 84.224, 84.323, and 84.332(e)(6). NIOSH has submitted a request for OMB approval of these proposed collections of information.

NIOSH estimates that the Institute program for reviewing and maintaining the information collected from respirator manufacturers under the proposed 42 CFR Part 84 will annually require 5 person-years of effort (three existing positions, one new position to review laboratory test reports, and one new position for processing interim certifications). NIOSH estimates an annual personnel cost for 42 CFR Part 84 of $210,000 in 1991. In addition, NIOSH estimates an annual travel cost of $15,000 and an annual office supplies cost of $1,500 in 1988 dollars. Thus, the total annual cost to the Federal Government for infor-

mation collected under 42 CFR Part 84 is estimated as the annual personnel cost plus the cost for travel and supplies, which is $230,000/year in 1991.

For respirator manufacturers, the costs due to the information collection provisions, 3-year average estimates were computed and reported in the Supporting Statement. The total average annual cost for each of the 32 domestic manufacturers was estimated as $99,000. For the purposes of 5 CFR 1320, the total annual cost burden averaged over the first 3 years of 42 CFR Part 84 for the domestic industry of 32 respirator manufacturers was then estimated as $99,000/manufacturer) times (32 manufacturers), which is $3.2 million/year.

The potential cost burden associated with Part 84 information collection requirements is about $3.2 million/year for 32 domestic respirator manufacturers. This "burden" is slightly less than 1/200 of estimated industry retail revenues of about $650 million/year and about 1/100 of direct annual revenues to respirator manufacturers. While some individual manufacturers might face a burden of more than 1% of sales, others might have no increase at all. Regardless, NIOSH has concluded that any burden increases of this magnitude would not create significant impacts on a substantial number of manufacturers, purchasers, or users.

For 9 of the 24 information collection provisions in 42 CFR Part 84, NIOSH cost estimates were based either on estimates in the 1986 Report from the DISC Corporation[109] or over 17 years of NIOSH experience with the present

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[109]Decision Information Systems Corporation, Final Report=Cost Impact Study of 30 CFR 11 Revisions, Washington, DC (September 5, 1986).

30 CFR Part 11. Of the $3.2 million estimate for total annual cost burden for all 32 domestic respirator manufacturers, over 97% of the total cost estimate was derived from survey data or more than 17 years of NIOSH experience.

For 15 of the 24 information collection provisions, NIOSH lacked survey cost estimates or similar information. Thus the estimates for 15 provisions were based on NIOSH professional judgment. However, the 3-year average cost estimates for these 15 provisions total only $2,900/yr/mfr, which is less than 3% of the estimated $99,000 total average annual cost per manufacturer. Thus even if the NIOSH cost assumptions for all 15 of these provisions were grossly in error (e.g., actual values were 500% higher), use of improved cost estimates would have only a moderate effect on the total annual cost burden for all domestic manufacturers (e.g., increase of 12% or less).

For the burden hours to respirator manufacturers due to the information-collection provisions, the estimated total average annual burden per manufacturer over a 3-year period was 4,600 hours. For the purposes of 5 CFR 1320, the total annual burden averaged over the first 3 years of 42 CFR Part 84 for the domestic industry of 32 respirator manufacturers was then estimated as 4,600 hours/manufacturer) times (32 manufacturers), which is 150,000 hours.

For 9 of the 24 information-collection provisions, NIOSH burden estimates were derived from either estimates in the 1986 DISC Report[110] or from NIOSH experience with the present 30 CFR Part 11. Of the 150,000 hours estimate for

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[110]Ibid.

total annual burden for all 32 domestic respirator manufacturers, 97.0% of the total hours of burden is derived from survey data or NIOSH experience.

For 15 of the 24 provisions, NIOSH lacked survey estimates or similar information. Thus the annual burden estimates for these 15 provisions were based on NIOSH professional judgment. However, the 3-year estimates of average burden for these 15 provisions total only 131 hrs/yr/mfr, which is 3.0% of the estimated 4,600 hours total average annual burden per manufacturer. Thus even if the NIOSH burden assumptions for all 15 of these provisions were grossly in error (e.g., actual values were 500% higher), use of improved burden estimates would have only a moderate effect on the total annual burden for all domestic manufacturers (e.g., increase of 12% or less).

Under the current 30 CFR Part 11, the annual average burden for respirator manufacturers to prepare new certification applications was estimated as about 1,300 hr/mfr. Thus the average change in the total paperwork burden resulting from the proposed regulation is estimated as 4,600 hr/yr/mfr) minus 1,300 hr/-yr/mfr), which is an average increase of 3,300 hr/yr/mfr.

Copies of the complete Supporting Statement may be obtained from the Docket Officer, National Institute for Occupational Safety and Health, Division of Safety Research, 944 Chestnut Ridge Road, Morgantown, West Virginia 265-05, telephone (304) 291-4597. NIOSH requests comments and additional information on all assumptions used in the Supporting Statement as well as any alternative suggestions designed to achieve the objectives of the Paperwork Reduction Act of 1980 at lower costs while providing the same or increased protection

to respirator users as given in the proposal. Comments should also be sent to the Reports Clearance Officer (Attention: PRA), U. S. Public Health Service, Hubert Humphrey Building, Room 721-H, 200 Independence Avenue, SW, Washington, DC 20201 and to the Office of Regulatory Affairs (Attention: Desk Officer for HHS/PHS/CDC/NIOSH), Office of Management and Budget, New Executive Office Building (Room 3208), Washington, DC 20503.

List of Subjects in 42 CFR Part 84

Occupational safety and health respirators, 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:

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Assistant Secretary for Health

Approved:

_____

Secretary

Part 84—RESPIRATORY PROTECTIVE DEVICES; TESTS AND REQUIREMENTS FOR CERTIFICATION

Subpart A—General Provisions

Sec.

Subpart B—Application Procedure

Subpart C—Quality Assurance

Subpart D—Respirator Testing

Subpart E—NIOSH-Certification Label

Subpart F—Maintenance and Instructional Materials

Subpart R—Face-Seal Leakage

Subpart S—Self-Contained Breathing Apparatus

Subpart T—Air-Line Respirators

Subpart U—Air-Purifying Respirators; General Requirements.

Subpart V—Particulate Air-Purifying Respirators

Subpart W—Gas and Vapor Air-Purifying Cartridge Respirators

Subpart X—Gas and Vapor Air-Purifying Canister Respirators

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

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

Appendix A—Assumed Conditions of Use

Appendix B—Major Respirator Components

Appendix C—Protection of Human Test Subjects and Laboratory Personnel

Appendix D—Performance Requirements from 30 CFR Part 11

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 respirator certification by the U.S. Government as conducted and administered by the National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control (CDC).

§ 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 report described in § 84.30 of this Part, and by conducting

selected tests of each respirator submitted. NIOSH, for cause, may perform additional tests not specified in this Part.

(b) Expiration of manufacturers' certificates issued under 30 CFR Part 11 and recertification under this Part.

(1) NIOSH/MSHA certificates, granted for respirators certified as meeting 30 CFR Part 11 performance requirements, shall expire in accordance with the timetable set forth in this paragraph:

(i) for self-contained breathing apparatus designed, intended, or marketed for use in nonfirefighting environments (approval numbers TC-13F-XXX), 8 years from the effective date of this Part.

(ii) for self-contained breathing apparatus designed, intended, or marketed for use in firefighting environments (approval numbers TC-13F-XXX), 5 years from the effective date of this Part.

(iii) for supplied-air (air-line) respirators (approval numbers TC-19C-XXX), 6 years from the effective date of this Part.

(iv) for all chemical cartridge respirators (approval numbers TC-23C-XXX) and all particulate respirators (e.g., dust, fume, mist, high efficiency) (approval numbers TC-21C-XXX), 5 years from the effective date of this Part.

(v) for all gas masks (canister respirators) (approval numbers TC-14C-XXX), 6 years from the effective date of this Part.

(2) A manufacturer may request a NIOSH certification under this Part for a respirator previously certified by NIOSH/MSHA under 30 CFR Part 11 by

submitting an application for certification as specified in §§ 84.10 and 84.11 of this Part.

(3) A manufacturer may request a NIOSH certification under this Part for a respirator, previously certified by NIOSH/MSHA under 30 CFR Part 11, that has been upgraded to meet the requirements of this Part, by submitting an application for an upgrade kit as specified in §§ 84.10 and 84.11 of this Part.

(4) Certifications shall be issued for complete respirators or upgraded complete respirators only.

(5) Pursuant to the provisions of Subpart H of this Part, NIOSH/MSHA certificates issued under 30 CFR Part 11 can be withdrawn prior to the expiration dates given in § 84.2(b)(1) of this Part.

(6) Respirators certified as meeting 30 CFR Part 11 performance requirements shall be approved for use until the expiration dates given in § 84.2(b)(1) of this Part provided they are maintained in an approved condition in accordance with 30 CFR 11.2(a).

§ 84.3 Administrative definitions.

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

"Critical characteristic" means a feature capable of adversely affecting product conformity with the general construction or technical requirements of this Part.

"Director" means Director of NIOSH.

"Major Modification" is any modification that affects the performance of a certified respirator, as related to the general construction or technical requirements of this Part.

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

"Minor Modification" is any modification that has been demonstrated by the manufacturer not to affect the performance of a certified respirator, as related to the general construction or technical requirements of this Part.

"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 to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.

"Upgraded respirator" means a respirator previously certified under 30 CFR Part 11 that has been retrofitted as specified by the manufacturer to bring it within the minimum requirements of this Part, and certified by NIOSH under this Part.

Subpart B—Application Procedure

§ 84.10 Submission of an application.

An application to NIOSH for certification of a respirator, an upgraded respirator, or 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.

§ 84.11 Required contents of an application to NIOSH.

(a) An application to NIOSH for certification of a respirator shall be written in English and shall contain:

(1) a letter of transmittal from the applicant to NIOSH requesting certification of a respirator;

(2) a test report as described in § 84.30 of this Part;

(3) 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 that will meet both the minimum requirements and the objectives set forth in § 84.20 of this Part;

(4) a minimum of six respirators or six upgraded respirators with no operation included that was not included on the respirators tested by the applicant or his agent and with no operation included that will not be incorporated in regular production processing;

(5) a copy of the applicant's proposed user instructions and a sample of the packaging materials;

(6) top assembly drawings and drawings of the applicable components specified in Appendix B of this Part;

(7) a parts list, including at a minimum, the applicable components specified in Appendix B of this Part that may be replaced during the life of the respirator;

(8) marking of all documents submitted under items (6) and (7) of this paragraph that are deemed to be "confidential," "trade secrets," or "privileged" information;

(9) for upgraded respirators, an upgrade kit including components, modification instructions and revisions to user instructions;

(10) a check or money order for the required fee determined in accordance with the provisions of Subpart J (the fee schedule is available from the Certification Branch, Division of Safety Research, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505);

(11) written assurance that the applicant will comply with the provisions set forth in Appendix C of this Part during any testing required under §§ 84.255, 84.257, 84.259, 84.260, 84.261, and 84.262 in Subpart S of this Part that involves human subjects;

(12) if applicable, a statement that the submitted respirator is designed for mine rescue, firefighting, or other mine emergency.

(b) an application to NIOSH for certification of a major modification of a certified respirator shall be written in English and shall contain all of the applicable contents as described in paragraph (a) of this section. Only those portions of the application affected by the major modification shall be included.

§ 84.12 Withdrawal of an application.

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

(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.

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.

Subpart C—Quality Assurance

§ 84.20 Quality assurance.

Manufacturers 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) Maintain control drawings and specifications so that the product is manufactured as certified;

(d) Report to NIOSH in accordance with § 84.22 of this Part any knowledge of a product distributed with critical characteristics not in accordance with the certification specifications;

(e) For quality assurance inspections and tests, instrument calibrations, and drawing and specification control as they affect certified respirators manufactured and shipped to purchasers, permit a representative(s) of NIOSH to:

(1) conduct without notice routine in-plant audits or

(2) conduct without notice post-certification, in-plant audits for cause;

(f) Perform all applicable certification tests at least every three years for each certified respirator or component, to determine continued conformance with this Part.

(1) The manufacturer shall randomly select a sample of each respirator that has been in production since either the initial certification tests or the last audit tests and test the complete respirator as prescribed in this Part, or sample and test the respirator component as permitted in section (2) of this paragraph.

(2) Where a respirator component is used on two or more similar respirators in a class of respirators, a representative sample of that component, from a respirator certified under the same class of respirator, shall be obtained and tested.

(3) The manufacturer shall notify NIOSH, as specified in § 84.21 of this Part, of any failure of compliance with this Part;

(g) Maintain a record of all minor modifications to a certified respirator for the duration of the certification; and

(h) Make available to NIOSH, upon request, within one week, the record of such minor modifications. The record of such minor modifications shall be made

available for inspection by NIOSH personnel during in-plant audits prescribed in paragraph (e) of this section.

(i) Provide to NIOSH, without charge, sufficient respirators as requested by NIOSH for examination and testing when NIOSH has reasonable cause to believe that the certified respirator may not comply with the requirements of this Part.

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

Any manufacturer who discovers that any respirator released by the manufacturer for sale or distribution, fails to comply with an applicable requirement contained in this Part shall:

(a) In accordance with § 84.22 of this Part, notify NIOSH within one work day of discovery of the failure to comply, if such failure poses the potential of 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, not to exceed 30 days, after discovery in accordance with § 84.22 of this Part, and

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

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

(2) The purchaser of such potentially defective 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, Division of Safety Research, Certification Branch required by § 84.21 of this Part shall be by telephone or telegram that 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 produced that have been judged acceptable by the manufacturer's quality control program, and the approximate number of such respirators that 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) A reasonable evaluation of the effect the defect or the failure to comply with the applicable requirement may have on the safety and efficacy of any user's respiratory protection;

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

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

(h) Any other relevant information that 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) of this Part shall be made within 14 days from the receipt of such directive from NIOSH and shall include, in writing, the following:

(1) In clear and nontechnical terms, the information prescribed in § 84.22 of this Part, paragraphs (a), (d), (e), and (h) and instructions with respect to use of the potentially defective or noncomplying respirator pending the correction of the potential defect or noncompliance; and;

(2) A statement such as the following:

The manufacturer will remedy the potential defect or bring the respirator into compliance with each applicable requirement contained in Federal regulation 42 CFR Part 84 in accordance with a plan to be approved by NIOSH. Further information on the corrective action for your potentially defective or noncomplying respirator 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 potentially defective or non-

complying 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 potentially defective or noncomplying respirator and to subsequent transferees, where known to the manufacturer; 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.

(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 determines through testing, inspection, research, or examination of reports or other data that any respirator does not comply with an applicable requirement contained in this Part then,

(1) if such failure poses an immediate and significant threat of serious injury or death, NIOSH shall within one work day notify the manufacturer of the respirator in writing of the information contained in paragraph (3) of this section or

(2) if such failure to comply does not pose an immediate and significant threat of serious injury or death, NIOSH shall within a reasonable time notify the manufacturer of the respirator in writing specifying the information contained in paragraph (3) of this section; and

(3) the written NIOSH notification shall specify:

(i) the respirator or respirators involved;

(ii) the defect in the respirator or the manner in which the respirator fails to comply with the applicable requirements contained in this Part;

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

(iv) 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 poses 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, not to exceed 30 days.

(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(c) of this Part 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

§ 84.30 Laboratory testing by applicant.

(a) The applicant shall conduct all of the applicable laboratory tests and expert evaluations set forth in Subparts Q through Z of this Part.

(b) The applicant shall submit a written laboratory test report to NIOSH that shall include four separate sections with the following:

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

(2) a detailed description of the test procedures or reference to previously submitted 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; and

(4) a statement that the respirator meets the general construction requirements specified in § 84.220 of this Part. The statement shall include considerations and reasons as to why the respirator meets such requirements.

§ 84.31 NIOSH evaluation of respirator performance.

(a) 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 Q through Z of this Part;

(2) is free from defects or characteristics that make it unsafe or ineffective for its anticipated use.

(b) NIOSH will conduct selected tests on each respirator submission for the purpose of substantiating the test results or conclusions included in the applicant's test report.

(c) In addition to the requirements of this Part, as a further condition of certification, NIOSH may require additional documentation or tests reasonably necessary to evaluate the quality, safety, or effectiveness of the respirator sub-

mitted to NIOSH for certification. NIOSH will notify the respirator manufacturers in writing of these additional requirements, stating specifically the reasons for such requirements.

§ 84.32 Issuance of certification; denial of certification.

(a) NIOSH will issue a certification if NIOSH concludes that the applicant's test report provides sufficient evidence of compliance with this Part and the respirator passes NIOSH substantiation testing.

(b) NIOSH will issue a denial of certification if

(1) the respirator has failed NIOSH substantiation testing or if

(2) NIOSH's initial evaluation concludes that the applicant's report does not provide sufficient evidence of compliance with this Part and the manufacturer then fails to supply requested additional information or analysis of test results to NIOSH within 30 days.

(c) A denial of certification 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 of this Part.

(d) In the event NIOSH denies a certification based on NIOSH testing as specified in this section, before NIOSH will accept a resubmittal the applicant shall provide NIOSH with a report detailing the reason for failure, a resolution of the discrepancy in test results, and any applicable revised documentation. NIOSH will evaluate the report and will provide a written response to the appli-

cant of the acceptance or denial of this report. NIOSH may also, at its discretion, require and conduct a review of the applicant's test facility.

§ 84.33 Availability of respirator test results.

NIOSH will make available, for public review, all results of laboratory 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 NIOSH shield shown in Figure 1 of this Part and the following words: "Certified for the U. S. Government by the National Institute for Occupational Safety and Health under 42 CFR Part 84.";

(4) the certification number assigned by NIOSH;

(5) the date on which the respirator was certified;

(6) any conditions or limitations specified by NIOSH; and

(7) the following statement:

Figure 1–NIOSH shield for certification label [42 CFR 84.40(a)(3)].

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

(b) The certification labels for mine rescue and emergency respirators as defined in Subpart K of this Part shall also display the MSHA official emblem shown at 30 CFR 1.1 and any conditions or limitations specified by MSHA.

(c) Abbreviated certification labels permitted on cartridges and filters shall contain at a minimum:

(1) The name of the manufacturer;

(2) The certification number assigned by NIOSH; and

(3) The certification classification of the cartridge or filter.

§ 84.41 General label and marking requirements.

(a) Legible reproductions or abbreviated forms of the certification label acceptable to NIOSH for mounting 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 carrier assembly and canister (where applicable)
Gas and vapor air-purifying canister respirator	Entire	Respirator container and canister
Air-line respirator	Entire	Respirator container and user instructions
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, each component specified in Appendix B of this Part, and each 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) For chemical-cartridge respirators and canister respirators, an expiration date that is based on shelf life determined by the requirements of §§ 84.304(h) and 84.315(g) of this Part shall be marked on each cartridge/canister or on each cartridge/canister container.

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

Subpart F—Maintenance and Instructional Materials

§ 84.50 User instructions.

Each respirator shall be provided with user instructions that contain information covering at least, but not limited to, the following subjects:

(1) the principles of operation,

(2) limitations of use,

(3) procedures for selecting facepiece size,

(4) donning instructions,

(5) fit-test instructions for both respirator selection and point-of-use fit checks before each donning,

(6) proper operation and use procedures,

(7) storage recommendations,

(8) preventive maintenance including trouble shooting, routine repair procedures and testing to be routinely performed by users,

(9) component parts list including spare parts,

(10) reproduction of the NIOSH-certification label, and

(11) cleaning and disinfecting recommendations.

84.51 Maintenance manual.

When maintenance is required beyond routine maintenance performed by users, comprehensive maintenance manuals shall be available for manufacturer-authorized maintenance personnel.

Subpart G—Modification of MSHA/NIOSH-Certified Respirators

§ 84.60 Major modification of MSHA/NIOSH-certified respirators.

(a) If an applicant submits to NIOSH a proposed major modification of a respirator that holds a NIOSH/MSHA certification issued under 30 CFR Part 11, the proposed major modification shall meet the performance standards

prescribed in Appendix D of this Part. NIOSH, at its discretion, may test or evaluate the respirator and substantiate the applicant's data.

(b) NIOSH will issue the applicant a certificate indicating NIOSH/MSHA certification of the major modification if NIOSH concludes that the applicant's test report and any results from discretionary NIOSH testing or evaluations meet the relevant minimum performance requirements of Appendix D of this Part. Such certification will not exceed the time period specified in § 84.2(b)(1) of this Part.

(c) NIOSH will issue a denial of certification for major modification if

(1) the respirator has failed any discretionary NIOSH testing or evaluations or

(2) NIOSH's initial evaluation concludes the respirator as modified fails to meet the relevant NIOSH performance standards in effect on the date of the original certification, NIOSH then requests additional documentation or analysis of test results, and the applicant fails to supply the requested information to NIOSH within 30 days.

(d) A written denial of certification of major modification 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 I of this Part.

Subpart H—Withdrawal of Certification

§ 84.70 Withdrawal of certification for cause.

NIOSH may withdraw the NIOSH-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 that meets the objectives and requirements set forth in § 84.20 of this Part;

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

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

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

(e) Failure of a manufacturer to maintain the records required in § 84.20(g) and (h) of this Part 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) Willful release for sale or distribution of respirators that do not meet all applicable requirements of this Part or that are unsafe or ineffective for their anticipated use;

(h) A determination by NIOSH that an applicant's test report upon which certification was based is invalid; or

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

§ 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 its intent to withdraw certification, state the reasons for the proposed withdrawal of certification, and state 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.

(c) If, within 30 working days, the manufacturer fails to file an appeal on the proposed withdrawal or certification, the Director shall notify the manufacturer that certification is withdrawn.

(d) If, within 30 working days, the manufacturer files an appeal to the Director, 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. Upon receipt of a notice of appeal, the Director 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 based upon relevant material and reliable evidence of record. Within 30 days after receiving the recommendation of the Administrative Law Judge, the Director will revise, reverse or affirm the original NIOSH determination.

Subpart J—Certification Service Fees

§ 84.90 Purpose and scope of fees.

(a) Subpart J establishes a system under which NIOSH shall charge fees for services performed for respirator manufacturers in connection with the Federal certification of respirators such as, but not limited to, application processing,

product evaluation, substantiation testing, post-certification product audits, and any quality assurance audits conducted for cause. Included in this Subpart is the basis for the fees.

(b) The NIOSH certification services for which fees are charged include—

(1) Application processing by professional staff, technicians, and other specialists (investigators), including administrative review of applications, analysis of drawings, technical evaluation, substantiation testing, test set up and tear down, consultation on applications, routine post-certification product audits, and any post-certification, in-plant, quality-control audits conducted by NIOSH for cause;

(2) Clerical services, computer tracking and status reporting, records control and security and document preparation directly supporting application processing;

(3) A proportionate share of management, administration, and operation of the NIOSH Division of Safety Research and of the Institute itself that is in support of certification activities; and

(4) Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing and the granting of certifications.

(c) Fees are not charged for—

(1) Technical assistance not related to processing a certification application;

(2) Respirator research programs conducted by NIOSH;

(3) NIOSH participation in research conducted by other government agencies or private organizations; and

(4) Regulatory review activities, including NIOSH participation in the development of health and safety standards, regulations, and legislation.

§ 84.91 Fee calculation.

(a) A flat-rate, documentation review fee shall be charged for initial administrative review of each certification application. This fee shall be calculated based on the hourly compensation cost to conduct the review. The review fee shall be nonrefundable. However, payment shall be fully credited against subsequent charges for services rendered.

(b) A flat-rate, device-specific fee shall be charged for evaluating, testing, certifying, and any routine post-certification auditing of each respirator submitted for certification. This fee shall be calculated based on the costs of the services provided to respirator manufacturers under § 84.90 of this Part. Direct costs shall be based on current compensation and benefit costs for professional and support personnel directly involved in providing the service. Indirect costs shall be based on a proportionate share of the cost of activities that support the certification service, including management, administration, and operation of the NIOSH Division of Safety Research and of the Institute itself; facility operating costs; and amortization and depreciation of facilities and equipment.

(c) A variable-rate fee shall be charged the holder of NIOSH respirator certification for the actual costs of any post-certification, in-plant, quality assurance audit conducted by NIOSH for cause under § 84.20(e)(2) and (3). This fee shall

be based on the hourly compensation cost to conduct the necessary audit, consultation with manufacturer during the audit, and any actual travel expenses incurred by the auditor(s) where required to conduct the audit.

§ 84.92 Fee administration.

(a) As provided for in § 84.11(a)(10) an applicant shall submit all applicable flat-rate fees with the certification application.

(b) Services for which variable fees are charged shall be billed by NIOSH for the fee when processing of the action is completed. Invoices will contain specific payment instructions.

§ 84.93 Fee revisions.

Each fee schedule for Federal certification services conducted by NIOSH shall remain in effect for at least one year and be subject to revision at least once every three years.

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 certification 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 certification. No respirator intended for emergency use in mines shall be certified without concurrence by MSHA.

Subparts L—N [Reserved]

Subpart O—Technical Definitions

§ 84.200 Definitions as used in this Part.

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

"Adequate Warning Properties" means that the gas or vapor has physiological effects in humans (e.g., odor, taste, eye irritation, respiratory irritation) that have been demonstrated as being capable of providing respirator wearers with timely,

consistent, persistent, and reliable warning of gas or vapor concentrations at or below the established exposure limit.

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

"Atmosphere-Supplying Respirator" means a respirator that provides the wearer with air, oxygen-enriched 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 that contains the sorbent and/or catalyst that removes specific contaminants from the air drawn through it.

"Compressed Breathing Gas" means oxygen, oxygen-enriched air, or air stored in a compressed state that is 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 an ANSI Type II sound level meter using slow response.

"End-of-Service-Life Indicator" (ESLI) means an indicator or warning device on a respirator that 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 any other sources of inward leakage. Face-seal leakage is given by (C_i/C_o), where C_i is the inhaled concentration and 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 $[1 - (C_p/C_c)]$, where C_c 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_c), where C_c is the concentration of challenge aerosol and 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 that is in a gaseous state at standard temperature and pressure.

"Gas and Vapor Respirator" means an air-purifying respirator that 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.

"Hood" or "Helmet" is a respirator component that 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): Acute respiratory exposures that:

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

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

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

"Loose-Fitting Facepiece" means a facepiece that is not designed to provide a gas-tight seal with the wearer's face, but that 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 that relies on negative pressure in the facepiece due to wearer's inspiration to provide respirable breathing gas.

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

"Noseclip" is a device that provides a gas-tight seal for the nostrils.

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

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

"Powered Air-Purifying Respirator" (PAPR) means an air-purifying respirator that 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" (SCBA) means an atmosphere-supplying respirator in which the source of air, oxygen-enriched 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 that is designed to provide an 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. Non-powered particulate respirators

are further classified in terms of the efficiency of their filter elements as either Type I, Type II, or Type III filters and by the type of aerosol (solid particulate, liquid particulate, or both solid and liquid particulate) for which they provide protection. Powered particulate respirators are further classified in terms of the efficiency of their filter elements as either Type II or Type III filters and by the type of aerosol (solid particulate, liquid particulate or solid and liquid particulate) for which they provide protection.

(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 min-

utes, 30 minutes, 45 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or other service times as may be prescribed by NIOSH.

(v) Classifications of self-contained breathing apparatus may be further classified by the type of breathing gas.

(2) Air-line respirators are further classified 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

Type I

Type II

Type III

Powered Particulate

Type II

Type III

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 that are combinations of any two or more of the basic classifications described in § 84.210 of this Part and can be used in either mode on a routine basis, will be classified by the type of respirator in the combination that provides the least protection to the user. Those combinations that may be used in only one mode on a routine basis, such as air-line with escape-only particulate filter respirators, will be classified in accordance to the mode that is used on a routine basis, unless otherwise specified by NIOSH.

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 such as, but not limited to, toxic vapors or toxic particles released from the respirators or corrosion damage to respirator parts that affects performance.

(b) Respirators shall be constructed of materials that 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 that 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) A manufacturer may request optional certification for impact and penetration resistance for a respirator with eyepiece(s) or window(s), such as a full-facepiece respirator or a helmeted, powered air-purifying respirator. If the manufacturer applies for such certification, the respirator shall provide the following levels of impact- and penetration-resistant performance. When mounted on a horizontally-positioned headform, the respirator eyepiece or window shall be capable of withstanding, without fracturing or dislodging, the impact of a 25.4-millimeter (1.00 inch) diameter steel ball, with a mass of 68 ± 1 grams that is dropped from 1.25 ± 0.01 meters. When mounted as above, the respirator window or eyepiece shall also be capable of withstanding, without fracturing, piercing through, or dislodging, a pointed projectile consisting of a Singer No. 25 or equal size 135 x 17 needle fastened into a holder weighing 44.2 ± 0.1 grams dropped from a height of 1.25 ± 0.01 meters. Respirators with eyepieces or windows that have not been optionally certified as meeting these requirements shall be legibly and permanently marked with the words: "Does not provide impact or penetration-protection criteria specified in ANSI Z87.1" on the eyepiece(s) or window(s).

(f) All respirators shall permit the wearer adequate vision and be designed to permit the wearing of safety glasses 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 that are securely attached to the mouthpiece or respirator and provide a gas-tight seal at the nostrils.

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

(i) Escape-only, closed-circuit, self-contained breathing apparatus with mouthpieces or halfmask facepieces shall be equipped with eyepiece goggles that meet the requirements of § 84.200 of this Part and paragraph (e) of this section.

§ 84.221 Combination respirators.

Combination respirators described in § 84.211 of this Part shall, as applicable, meet all minimum requirements for all individual respirator classes that have been combined.

§ 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/noseclips, hoods, or helmets; and

(c) Accidental 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, the 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) For self-contained breathing apparatus designated by the manufacturer as designed, intended, and marketed for use by firefighters or mine-rescue teams, body harnesses shall remain functional and shall not melt when exposed to a temperature of 500 degrees F for 5 minutes.

§ 84.224 Respirator containers.

(a) Respirators shall be packaged for shipment and sale in a durable container bearing markings that show the manufacturer's name, the type and commercial designation of the respirator it contains, and all appropriate labels as prescribed in §§ 84.40(a), 84.40(b), 84.41(b), and 84.41(c) of this Part.

(b) Containers may provide for storage of more than one respirator; however, such containers shall prevent contamination of respirators that 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 Testing tolerances.

Unless otherwise specified in this Part, the operating tolerances for all quantitative test condition parameters of this Part shall be ± 5% of the nominal specified value.

§ 84.226 Inhalation and exhalation valves.

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

(b) Where exhaled air can adversely affect cartridges, canisters and filters, inhalation valves shall be required.

(c) If a respirator is equipped with an exhalation valve, such valve shall be protected against damage and external influence.

§ 84.227 Exhalation-valve-leakage test.

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

(b) Leakage between the valve and valve seat shall not exceed 10 milliliters per minute.

§ 84.228 Noise levels; hoods, and helmets.

Noise levels generated by the respirator shall be measured inside the hood or helmet at maximum obtainable airflow within pressure and hose length requirements and shall not exceed, except as indicated below, 80 dBA when the respirator is worn in accordance with the user instructions provided by the manufacturer. 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 user instructions.

§ 84.229 Statistical procedure for analysis of performance test results.

(a) Unless otherwise specified in this Part, all performance tests that produce quantitative results shall at a minimum be analyzed for compliance with the relevant performance specification using the method of acceptance sampling by variables to control percent defective.

(b) For a given performance test, test 6 components or devices. For the 6 results, first compute the sample arithmetic mean (m). Then compute the sample standard deviation (s) using an (n − 1) divisor.

(c) For the sample of 6 to demonstrate acceptable performance against a performance specification representing a maximum acceptable limit for some measured performance characteristic, calculate the test statistic U = [m + (2.9624)(s)], that shall be equal to or less than the maximum acceptable limit. For the sample of 6 to demonstrate acceptable performance against a performance criterion representing a minimum acceptable limit for some measured performance characteristic, calculate a the test statistic L = [m − (2.9624)(s)] that shall be equal to or greater than the minimum acceptable limit.

Subpart R—Face-Seal Leakage

§ 84.230 Applicability.

All non-powered air-purifying respirators and all negative-pressure, atmosphere-supplying respirators except those of each type utilizing a mouthpiece shall be tested and evaluated for face-seal leakage in accordance with the provisions of this Subpart.

§ 84.231 General.

In this Subpart the term "face-seal leakage" refers to the total inward leakage of contaminant into the respirator wearer's breathing zone. Face-seal leakage therefore includes the leakage that occurs at the interface of the respirator and the wearer's face plus any filter penetration. It is assumed that for a well-designed respirator all other sources of leakage (e.g., hose couplings, exhalation valves, lens seals) 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 data analysis.

§ 84.232 Non-powered air-purifying, particulate respirators..

(a) Filter Selection. Air-purifying particulate respirator facepieces shall be tested for face-seal leakage when fitted with the highest-efficiency particulate filters available for that respirator.

(b) Panel Selection. Each facepiece style shall be tested on a panel of 25 adult individuals having facial dimensions that represent 95% of the facial sizes in the adult American population. Panel members shall have a bivariate distribution of face lengths (Menton-Nasal Root Depression Lengths) and face widths (Bizygomatic Breadths) approximately equal to that of the 10-cell anthropometric panel[1] shown in Figure 2 of this Part. Individuals having unshaven facial hair, deep scars, unusually deep wrinkles, or unusual facial deformity that would lie between the facepiece and the wearer's face, shall not be included in the panel.

(c) Pretest Fitting. From the facepiece sizes available for the facepiece style being evaluated, each test subject shall select the appropriate facepiece size by following the written sizing instructions to be provided as part of the user instructions and included as part of the application. Each test subject shall be asked to follow the written donning and fitting instructions recommended by the applicant in the user instructions. 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

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[1]Hack, A., et al.: Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes, Los Alamos Scientific Laboratory Report LA-5488, Los Alamos, NM (1974).

test supervisor shall intervene and assist in fitting the respirator in accordance with the applicant's user 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 user instructions. The waiting period may be reduced or eliminated for short-duration respirators (e.g., short-duration escape respirators).

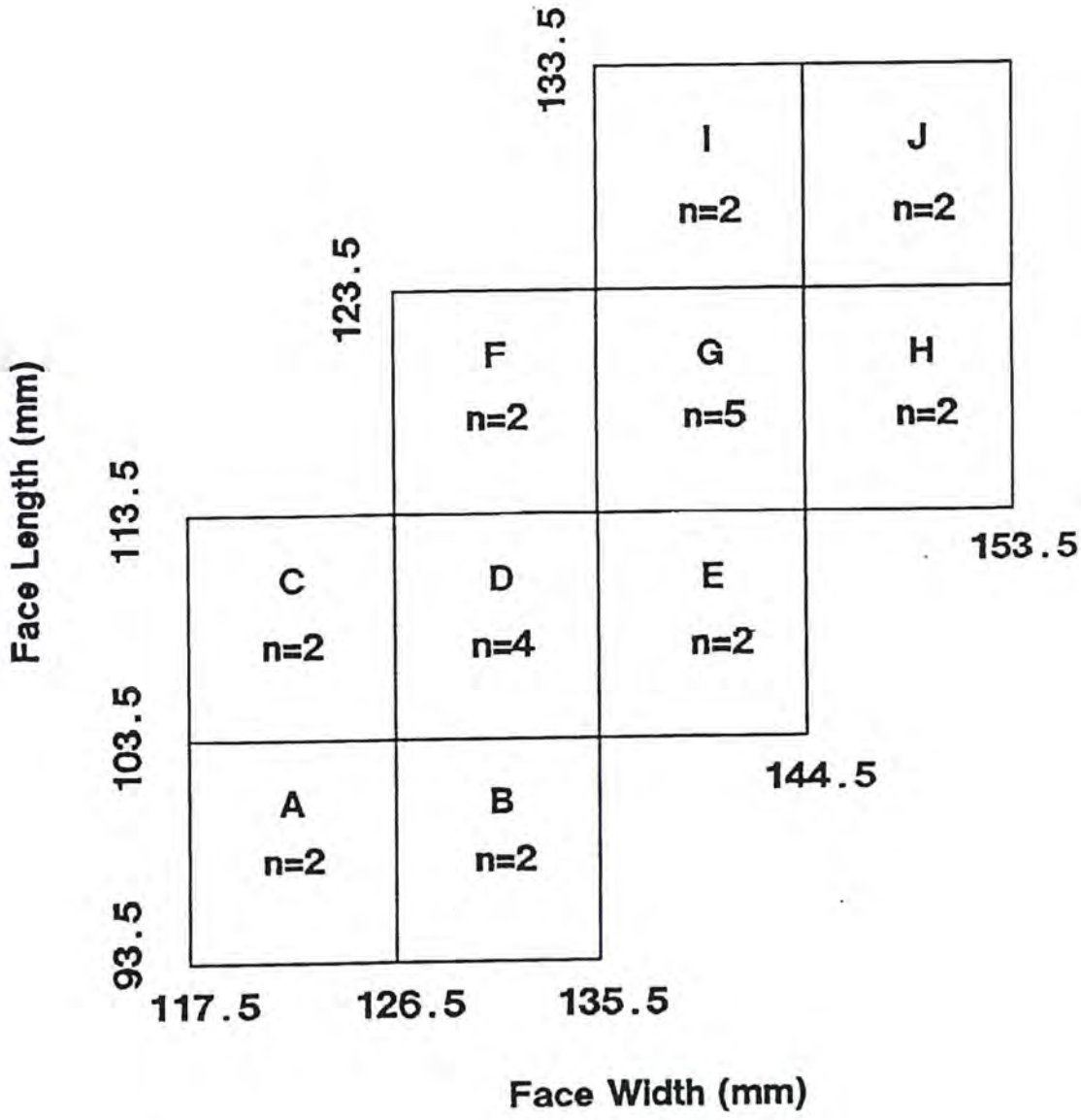

Figure 2–Anthropometric test panel specifications for face-seal performance testing [42 CFR 84.232(b)].

(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. Such safety spectacles shall be the generic type recommended by the respirator manufacturer in the user instructions.

(e) Test Hardware. The facepiece shall be leak tested on each panel member using an appropriate nontoxic aerosol such as crystalline sodium chloride or oil mist. The aerosol shall have a mass median aerodynamic diameter (MMAD) 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. In those test systems where the challenge concentration and the inhaled concentration are not measured simultaneously, the challenge aerosol concentration shall not vary more than ± 10 percent in the time interval between sampling the challenge concentration and sampling inhaled concentration. The aerosol detector shall be linear within ± 10 percent at least throughout the range of face-seal leakages from 0.02 to 1.0 times the maximum allowed face-seal leakage for the respirator type being tested. All facepieces shall be probed to obtain an aerosol sample representative of the inhaled aerosol concentration. In order to minimize particle loss at the inlet of the probe, the shape and dimension of the probe shall be that of the Liu probe shown in Figure 3 of this Part. In order to minimize sampling bias associated with incomplete mixing of contaminant within

the facepiece cavity, the probe shall be positioned with the probe inlet 10 to 15 millimeters in front of the center of the upper lip as shown in Figure 3 of this Part. The probe shall be designed to minimize the risk of injury to the subject if the facepiece is bumped during the test. Sampling rate shall be approximately 2 ± 0.5 liters/minute.

(f) Exercise Regimen. During the quantitative-leak testing, the test subject shall breathe primarily through the mouth and perform an exercise regimen equivalent to or more severe than the following regimen (i.e., a regimen that always yields UCL(P_t) values, as computed by § 84.232(h), equal to or exceeding those resulting from use of the following regimen):

(1) Normal breathing with head motionless for 1 minute;

(2) Deep breathing (simulating that during hard work) with head motionless for 30 seconds. Do not prolong this exercise because of the danger of hyperventilation;

(3) Turning head slowly side to side while breathing normally, pausing for at least two breaths before changing direction. Continue for at least 1 minute;

(4) Moving head slowly up and down while breathing normally, pausing for at least two breaths before changing direction. Continue for at least 1 minute;

(5) Reading from a prepared text, slowly and clearly, and loudly enough to be heard and understood by the test operator. Continue for 1 minute;

(6) Normal breathing with head motionless for at least 1 minute.

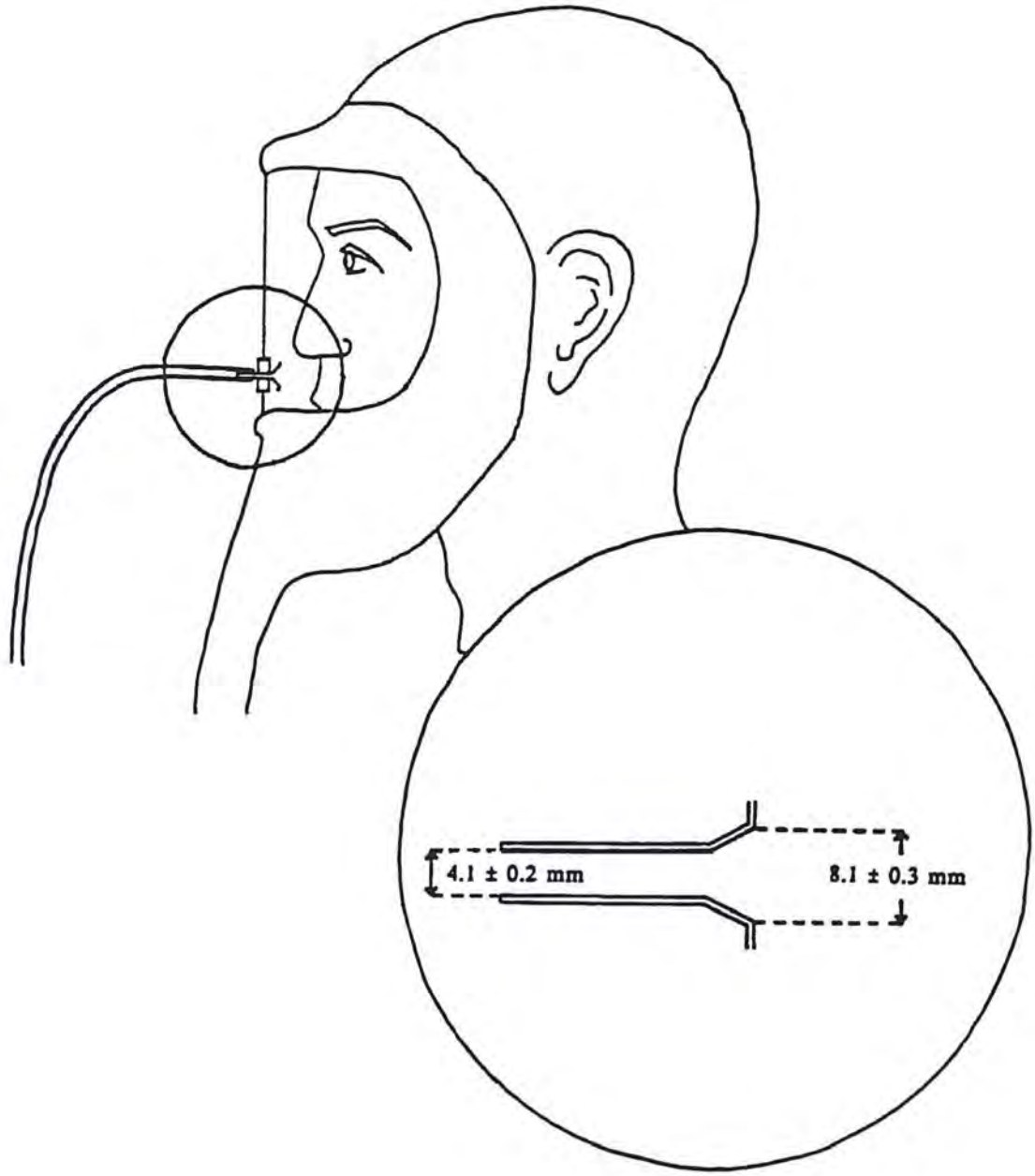

Figure 3–Facepiece probe specifications for face-piece performance testing [42 CFR 84.232(e)].

(g) Data. Face-seal leakage, denoted by L, shall be measured as the ratio $L = C_i/C_o$, where C_i denotes the inhaled challenge concentration sampled from inside the facepiece and C_o denotes the concentration of challenge aerosol outside the facepiece. Face-seal leakage is therefore expressed as a dimensionless number between zero and one. The time-averaged face-seal leakage for each exercise shall be recorded. The average face-seal leakage for the six exercises, L, shall be computed. In addition, a permanent recording that shows the instantaneous leakage as a function of time for the entire test shall be retained for documentation.

(h) Performance Criteria and Statistical Data Analysis. The following statistical analyses shall be used to determine if the face seal under evaluation has a high probability (at least 95%) of providing the required performance, as stated in Table 1 of this Part, to at least 90% of the adult American working population.

Table 1—Maximum allowed face-seal leakage (L_{max}) for respirator facepiece and test-filter combinations.

(42 CFR 84.232(h))

	Filter used for face-seal test		
Facepiece	Type I	Type II	Type III
Quarter or Half	0.15	0.06	0.05
Full	0.10	0.02	0.01

(1) Step 1—Preliminary statistical analysis to test for homogeneity of leakage distributions in different data groups. The raw performance data are time-averaged face-seal leakages, denoted by L, meeting the requirements of paragraphs (a) through (g) of this section. Tabulate L for each subject in the 25-person panel of § 84.232(b) of this Part. The variable to be analyzed is X = log[(1/L) − 1]. Calculate X for each value of L and tabulate.

(i) Step 1a–Forming pooled data groups. Pool values of X into three data groups by pooling the 10 cells of the basic panel as follows:

Data group 1: Panel cells A, B, and C; sample size of 6,

Data group 2: Panel cells D, E, F, and G; sample size of 13, and

Data group 3: Panel cells H, I, and J; sample size of 6.

(ii) Step 1b—Comparing variances within different data groups. Perform Levene's Test as follows.

(A) Compute $m_X(1)$, $m_X(2)$, and $m_X(3)$, the sample means of X in each of the three data groups.

(B) For each data group, compute and tabulate values of D, the absolute value of the difference between an X-value and the mean of X for that data group:

$$D = \text{abs}(X - m_X)$$

Tabulate values of D for each of the 1, 2, and 3 data groups. Denote data group sample sizes by N_1, N_2, and N_3, respectively (i.e., 6, 13, and 6, if all panel members have been tested). Compute $N_t = N_1 + N_2 + N_3$, where the subscript, t, denotes "tested panel," with N_t usually equal to 25. Compute the three data group sample means of D (absolute differences), denoted by $m_D(1)$, $m_D(2)$, and $m_D(3)$, and also compute the sample variances of D, denoted by $V_D(1)$, $V_D(2)$, and $V_D(3)$ of D for the 1, 2, and 3 data groups, respectively. Compute unbiased variance estimates by using the appropriate data group value of $(N_i - 1)$ as the divisor (for data group i = 1, 2, and 3). Compute the grand sample mean absolute difference, $m_D(T)$, of D for the N_t subjects in the total panel, denoted by (T).

(C) Perform a one-way analysis of variance (ANOVA) of values of the D differences. The test statistic is a variance ratio, denoted by F_D for this data, of two mean squares that are computed as follows:

$$\text{MS(Between)} = (1/2)[N_1(m_D(1)-m_D(T))^2 + N_2(m_D(2)-m_D(T))^2 + N_3(m_D(3)-m_D(T))^2]$$

$$\text{MS(Within)} = [1/(N_t-3)][(N_1-1)(V_D(1)) + (N_2-1)(V_D(2)) + (N_3-1)(V_D(3))]$$

F_D = [MS(Between) / MS(Within)], with 2 and (N_t-3) degrees of freedom, where $N_t = N_1 + N_2 + N_3$ will usually be 25.

(D) Compare F_D to its critical value, $F(.01; 2,N_t-3)$, for a test at the 0.01 probability level. For example, for a full panel of 25 subjects, the critical value is $F(.01; 2,22) = 5.72$. If F_D exceeds its critical value, decide that the amount of intersubject variability of D and hence of X is not equal within all three data groups. In this case, omit Step 1c (paragraph (h)(1)(iii)) and proceed to Step 2b (paragraph (h)(2)(ii)(B)). If F_D does not exceed its critical value, decide that within-group variances are homogeneous. In this case, proceed to Step 1c (paragraph (h)(1)(iii)).

(iii) Step 1c–Comparing means between data groups. Perform a one-way analysis of variance (ANOVA) for the three data groups of pooled X-values that were formed in Step 1a (paragraph (h)(1)(i)). Proceed as follows.

(A) Tabulate values of X for each of the 1, 2, and 3 data groups. Denote data group sample sizes by N_1, N_2, and N_3, respectively (i.e., 6, 13, and 6, if all panel members have been tested). Compute $N_t = N_1 + N_2 + N_3$, where the subscript, t, denotes "tested panel," with N_t usually equal to 25. Compute the three data group sample means, $m_X(1)$, $m_X(2)$, and $m_X(3)$, and the sample variances, $V_X(1)$, $V_X(2)$, and $V_X(3)$ of X for the 1, 2, and 3 data groups, respectively. Compute unbiased variance estimates by using the appropriate data group value of $(N_i - 1)$ as the divisor (for data group i = 1, 2, and 3). Compute the grand mean, $m_X(T)$, of X for the N_t subjects in the tested panel, denoted by (T).

(B) The test statistic is a variance ratios, denoted F_X for this data, of two mean squares that are computed as follows:

$$\text{MS(Between)} = (1/2)[N_1(m_X(1) - m_X(T))^2 + N_2(m_X(M) - m_X(T))^2 + N_3(m_X(3) - m_X(T))^2]$$

$$\text{MS(Within)} = [1/(N_t - 3)][(N_1 - 1)(V_X(1)) + (N_2 - 1)(V_X(2)) + (N_3 - 1)(V_X(3))]$$

F_X = [MS(Between) / MS(Within)], with 2 and $(N_t - 3)$ degrees of freedom, where $N_t = N_1 + N_2 + N_3$ will usually be 25.

(C) Compare F_X to its critical value, $F(.05; 2, N_t - 3)$, for a test at the 0.05 probability level. For example, for a full panel of 25 subjects, the critical value is F(.05; 2,22) = 3.44. If F_X exceeds its critical value, decide that the averages of X are not equal within all three data groups. In this case, proceed to Step

2b (paragraph (h)(2)(ii)(A)). If F_X does not exceed its critical value, decide that the averages of X are equal within all three data groups and that within-group distributions of X are homogeneous. Note that the variances were already found to be homogeneous as tested in Step 1b (paragraph (h)(1)(ii)) before entering Step 1c (paragraph (h)(1)(iii)). In this case, proceed to Step 2a (paragraph (h)(2)(i)).

(2) Step 2—Main statistical analysis. Depending on the results of the statistical tests in Step 1 (paragraph (h)(1)), one or the other of two alternative statistical protocols shall be used for the main statistical analysis (Step 2a or Step 2b in this section). The purposes of the main statistical analysis are: (1) to compute the point estimate for the proportion, P_t, of the adult American working population with nonextreme face sizes who will have leakages above L_{max}, the maximum allowed face-seal leakage, for the facepiece and filter combination, and (2) to compute a one-sided 95% upper confidence limit, denoted by $UCL(P_t)$, for the true value of the point estimate P_t in order to account for its statistical uncertainty (i.e., margin of error).

(i) Step 2a—Main statistical analysis for the case when leakage distributions do not differ between data groups. In this case, face size is ignored as a factor. The entire panel of N_t subjects (usually 25) is treated as a single random sample or data group.

(A) Compute the mean, $m_X(T)$, and variance, $V_X(T)$, of the N_t values of X. Compute the unbiased variance estimate using $(N_t - 1)$ as the divisor.

(B) Compute the standard deviation of X for the entire panel as:

$$s_X(T) = \text{sqrt}[V_X(T)]$$

(C) Transform L_{max}, the maximum allowed face-seal leakage for the face-piece and filter combination given in Table 1 of this Part, to the corresponding minimum allowed value of the response variable, denoted X_{min}:

$$X_{min} = \log[(1/L_{max}) - 1]$$

(D) Compute z_t, the standard normal deviate that corresponds to X_{min} for the entire panel:

$$z_t = (X_{min} - m_X(T))/(s_X(T))$$

(E) Using a table of the standard normal distribution, obtain the ordinate, f_t, and left-tail area, P_t, that correspond to z_t. For example, with $z_t = -2.43$, $f_t = 0.0208$ and $P_t = 0.0075$. Or with $z_t = 0.82$, $f_t = 0.2850$ and $P_t = 0.7939$. Note that P_t is a point estimate for the proportion of the adult American working population with nonextreme face sizes (i.e., those represented on the panel) who will have excessive leakages (L greater than L_{max}). This corresponds to the proportion with $X \leq X_{min}$ (i.e., the left-tail area of the distribution of X-values).

(F) Compute the standard error of the point estimate P_t:

$$S.E.(P_t) = f_t \text{ sqrt}[(1/N_t) + ((z_t)^2/(2(N_t-1)))]$$

(G) To account for the statistical uncertainty (margin of error) associated with the P_t estimate, compute the one-sided 95% upper confidence limit for the true value of P_t:

$$UCL(P_t) = P_t + [t(.95; N_t-1)][S.E.(P_t)]$$

where $t(.95; N_t-1)$ is the 95th percentile of a Student's-t statistic with N_t-1 degrees of freedom, obtained from a standard statistical table. For example, with $N_t = 25$, $t(.95; 24) = 1.711$. Proceed to Step 3 (paragraph (h)(3)) for accept/reject-decision criteria based on $UCL(P_t)$.

(ii) Step 2b—Alternative main statistical analysis for the case when leakage distributions differ between data groups. This Step estimates proportions of wearers with excessive leakages, computed separately for each of the data groups 1, 2, and 3. The three point estimates of proportions are then combined into a weighted estimate of the proportion of excessive leakages in the population whose face sizes are in the bivariate range represented by the panel members. A one-sided 95% upper confidence limit is then calculated for the true value of the latter proportion. Two alternative statistical protocols are given below for Step 2b (paragraph (h)(2)(ii)). Use Plan I (paragraph (h)(2)(ii)(A)) if Step 1b (paragraph (h)(1)(ii)) showed no significant difference between data group vari-

ances but Step 1c (paragraph (h)(1)(iii)) showed significant differences between the data group means. In this case, a pooled within-groups variance estimate will be used in the calculations. Use Plan II (paragraph (h)(2)(ii)((B)) if Step 1b (paragraph (h)(1)(ii)) showed significant differences between group variances. In this case, separate variance estimates for the respective data groups will be used in the calculations.

(A) Plan I. Use this analysis protocol when the within-group variances are statistically homogeneous. Perform the following calculations.

(1) Compute the sample means, $m_X(1)$, $m_X(2)$, and $m_X(3)$, and the sample variances, $V_X(1)$, $V_X(2)$, and $V_X(3)$ of X for the 1, 2, and 3 data groups, respectively. Compute unbiased variance estimates by using the appropriate data group value of (N_i-1) as the divisor (data group i = 1, 2, and 3).

(2) Compute the pooled within-groups variance:

$$V_X(W) = [1/(N_t-3)][(N_1-1)(V_X(1)) + (N_2-1)(V_X(2)) + (N_3-1)(V_X(3))]$$

Compute the pooled within-groups standard deviation of X:

$$s_X(W) = \text{sqrt}[V_X(W)]$$

(3) Transform L_{max}, the maximum allowed face-seal leakage for the facepiece and filter combination given in Table 1 of this Part, to the corresponding minimum allowed value of the response variable, denoted X_{min}:

$$X_{min} = \log[(1/L_{max}) - 1]$$

(4) Perform the operations, in paragraphs (5), (6), and (7) immediately following, separately for each of the three data groups. The formulae given below are given in the notation for the first data group. Replace the data group notation (1) in the formulae with (2) or (3) when repeating the operations for the second and third data groups, respectively. After completing the next three paragraphs for each of the three data groups, proceed to paragraph (8) immediately following in this paragraph.

(5) Compute z_1, the standard normal deviate that corresponds to X_{min} for the first data group:

$$z_1 = (X_{min} - m_x(1))/(s_x(W))$$

(6) Using a table of the standard normal distribution, obtain the ordinate, f_1, and left-tail area, P_1, that correspond to z_1. For example, with $z_1 = -2.43$, $f_1 = 0.0208$ and $P_1 = 0.0075$. Or with $z_1 = 0.82$, then $f_1 = 0.2850$ and $P_1 = 0.7939$. Note that P_1 is a point estimate for the portion of the adult American working population represented by the first data group on the panel who will have excessive leakages (L greater than L_{max}). This is equivalent to the proportion with $X \leq X_{min}$ (i.e., the left-tail area of the distribution of X-values).

(7) Compute $V(P_1)$, the variance of the P_1 estimate:

$$V(P_1) = (f_1)^2[(1/N_1) + ((z_1)^2/(2(N_t-3)))]$$

(8) Select numerical values for f_1, f_2, and f_3, the relative frequencies (proportions) of the 1, 2, and 3 data groups, respectively, within the adult American working population with nonextreme face sizes. Use the relative frequencies employed in the panel: $f_1 = 6/25 = 0.24$, $f_2 = 13/25 = 0.52$, and $f_3 = 6/25 = 0.24$.

(9) Compute P_t, the point estimate for the proportion of excessive leakages within the population of nonextreme face sizes (i.e., those represented by the panel members):

$$P_t = f_1P_1 + f_2P_2 + f_3P_3$$

(10) Compute the variance of the point estimate P_t:

$$V(P_t) = (f_1)^2V(P_1) + (f_2)^2V(P_2) + (f_3)^2V(P_3)$$

(11) Compute the standard error of the P_t estimate:

$$S.E.(P_t) = \text{sqrt}[V(P_t)]$$

(12) Compute the one-sided 95% upper confidence limit for the true value of the proportion P_t:

$$UCL(P_t) = P_t + [t(.95; (N_t-3))](S.E.(P_t))$$

where $t(.95; N_t-3)$ is the 95th percentile of a one-sided Student's-t statistic with (N_t-3) degrees of freedom, obtained from a standard statistical table. For example, with $N_t = 25$, $t(.95; 22) = 1.717$. Continue to Step 3 (paragraph (h)(3)) for accept/reject-decision criteria based on $UCL(P_t)$.

(B) Plan II. Use this protocol when the within-group variances are not statistically homogeneous. Separate variance estimates for each of the three data groups will be computed. Perform the following calculations.

(1) Compute the sample means, $m_X(1)$, $m_X(2)$, and $m_X(3)$; the sample variances, $V_X(1)$, $V_X(2)$, and $V_X(3)$; and the sample standard deviations (square root of each respective variance), $s_X(1)$, $s_X(2)$, and $s_X(3)$ of X for the 1, 2, and 3 data groups, respectively. Compute unbiased variance estimates by using the appropriate data group value of (N_i-1) as the divisor (data group i = 1, 2, and 3).

(2) Transform L_{max}, the maximum allowed face-seal leakage for the facepiece and filter combination given in Table 1 of this Part, to the corresponding minimum allowed value of the response variable, denoted X_{min}:

$$X_{min} = \log[(1/L_{max}) - 1]$$

(3) Perform the operations, in paragraphs (4), (5), and (6) immediately following, separately for each of the three data groups. The formulae given below are given in the notation for the first data group. Replace the notation (1) in the formulae with (2) or (3) when repeating the operations for the second and third data groups, respectively. After completing the next three paragraphs for each of the three data groups, respectively. After completing the next three paragraphs for each of the three data groups, proceed to paragraph (7) immediately following in this paragraph.

(4) Compute z_1, the standard normal deviate that corresponds to X_{min} for the first data group:

$$z_1 = (X_{min} - m_X(1))/(s_X(1))$$

(5) Using a table of the standard normal distribution, obtain the ordinate, f_1, and left-tail area, P_1, that correspond to z_1. For example, with $z_1 = -2.43$, $f_1 = 0.0208$ and $P_1 = 0.0075$. Or with $z_1 = 0.82$, then $f_1 = 0.2850$ and $P_1 = 0.7939$. Note that P_1 is a point estimate for the portion of the adult American working population represented by the first data group on the panel who will have excessive leakages (L greater than L_{max}). This is equivalent to the proportion with $X \leq X_{min}$ (i.e., the left-tail area of the distribution of X-values for the first data group).

(6) Compute $V(P_1)$, the variance of the estimate P_1:

$$V(P_1) = (f_1)^2[(1/N_1) + ((z_1)^2/(2(N_1-1)))]$$

(7) Select numerical values for f_1, f_2, and f_3, the relative frequencies (proportions) of the 1, 2, and 3 data groups, respectively, within the adult American working population with nonextreme face sizes. Use the relative frequencies employed in the panel: $f_1 = 6/25 = 0.24$, $f_2 = 13/25 = 0.52$, and $f_3 = 6/25 = 0.24$.

(8) Compute P_t, the point estimate for the proportion of excessive leakages within the population of nonextreme face sizes (i.e., those represented by the panel members):

$$P_t = f_1P_1 + f_2P_2 + f_3P_3$$

(9) Compute the variance of the point estimate P_t:

$$V(P_t) = (f_1)^2V(P_1) + (f_2)^2V(P_2) + (f_3)^2V(P_3)$$

(10) Compute the standard error of the P_t estimate:

$$S.E.(P_t) = \text{sqrt}[V(P_t)]$$

(11) Compute d.f., the effective degrees of freedom for $S.E.(P_t)$:

$$d.f. = [V(P_t)]^2 / \{[(f_1)^4(V(P_1))^2 / (N_1-1)] + [(f_2)^4(V(P_2))^2 / (N_2-1)] + [(f_3)^4(V(P_3))^2 / (N_3-1)]\}$$

(12) Compute the one-sided 95% upper confidence limit for the true value of P_t:

$$UCL(P_t) = P_t + [t(.95; d.f.)][S.E.(P_t)]$$

where t(.95; d.f.) is the 95th percentile of a one-sided Student's-t statistic with d.f. degrees of freedom, obtained by linearly interpolating in a standard statistical table. For example, with d.f. = 15.62, t(.95; 15.62) = 1.753 + (0.62)(1.746 − 1.753) = 1.753 + (−0.004) = 1.749. Continue to Step 3 (paragraph (h)(3)) for accept/reject-decision criteria based on $UCL(P_t)$.

(3) Step 3—Accept/reject-decision criteria for face-seal performance. $UCL(P_t)$, that was obtained in either Step 2a (paragraph (h)(2)(i)) or Step 2b (paragraph (h)(2)(ii)) of this section, is the 95% upper confidence limit for the true proportion of excessive leakages in the portion of the adult American working population represented on the 25-person panel. Compare $UCL(P_t)$ to the maximum permissible value for this proportion, 0.0526. With respect to face-seal leakage performance, the respirator is judged to be:

Not acceptable, if $UCL(P_t)$ exceeds 0.0526, or

Acceptable, if $UCL(P_t)$ is less than or equal to 0.0526.

§ 84.233 Non-powered gas and vapor respirators.

(a) Except for the provisions outlined below, non-powered gas and vapor respirators will be evaluated for face-seal performance using the procedure given above for non-powered particulate respirators.

(b) The performance criteria of § 84.232(h) of this Part for non-powered particulate respirators equipped with Type III filters shall apply to all non-powered gas and vapor respirators.

(c) Non-powered gas and vapor respirators will be evaluated for face-seal performance when fitted with Type III particulate filters available for those respirators that are of similar weight and shape. If a Type III particulate filter of appropriate weight and shape is not available for the respirator, such a filter may be improvised for the purpose of the face-seal performance test. If it is not possible to improvise such a particulate filter, a challenge gas or vapor appropriate for the respirator being evaluated may be substituted for the aerosol challenge agent specified in § 84.232(e) of this Part.

(d) Non-powered gas and vapor cartridge respirators need not be evaluated for face-seal performance if (1) they incorporate a facepiece that is a component of a particulate respirator that has previously met the requirements of this subpart using a type III filter and (2) the weight and shape of the cartridge is similar to that of the particulate filter with which it was evaluated.

(e) Non-powered canister respirators that are available in different configurations (such as a facepiece mounted canister and a remote canister connected

with a breathing tube) shall be tested in each configuration for which certification is sought.

§ 84.234 Negative-pressure, atmosphere-supplying respirators.

Negative-pressure, atmosphere-supplying respirators shall be evaluated for face-seal performance as prescribed in § 84.232 of this Part for negative-pressure, air-purifying particulate respirators. The maximum allowed face-seal leakage for a negative pressure, air-supplied respirator shall be 0.01 if equipped with a full facepiece and 0.05 if equipped with a half facepiece. Caution should be exercised when testing closed-circuit SCBA to assure that the test system is compatible with oxygen.

§ 84.235 Regulator preconditioning.

All negative-pressure, open-circuit, self-contained breathing apparatus shall be preconditioned with the regulator overpressurization procedure of § 84.264 of this Part prior to conducting the face-seal performance 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-enriched 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) Compressed, oxygen-enriched air;

(iii) Chemical oxygen; or

(iv) 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 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.

(b) In carrying out any tests in §§ 84.255, 84.257, 84.259, 84.260, 84.261, and 84.262 of this Subpart that involves human subjects the manufacturer shall comply with the protection of human subjects provisions of Appendix C of this Part.

§ 84.241 Interchangeability of oxygen and air prohibited; use of 100 percent oxygen near open flames or other ignition sources.

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

(b) Certifications may be issued for self-contained breathing apparatus using oxygen as described in nonmandatory Appendix A of this Part, paragraph (j) of this Part. Such apparatus shall not be certified as suitable for use near open flames or other ignition sources.

§ 84.242 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 49 CFR §§ 100–178.

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

(c) Containers normally removed from apparatus for refilling shall be equipped with an indicating gauge that 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, CGA V-1, 1987 standard.

§ 84.243 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) Dial-indicating gauges shall be accurate to within ± 5 percent of full-scale when tested both up and down the scale at each of 5 equal intervals. 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 user instructions, whichever is less.

(e) 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. 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. 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 690 kPa (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 (Z) of breathing gas 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:

$$Z = X - 1.75Y$$

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

(j) Apparatus using liquefied breathing gas, except apparatus classified for escape-only, shall be equipped with either gauges visible to the wearer that indicate the remaining liquid content in the container or timers visible to the wearer

that indicate the remaining service life of the apparatus. 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.

§ 84.244 Timers; remaining service-life indicators.

(a) Timers shall be provided for apparatus with chemical oxygen sources, except apparatus classified for escape only.

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

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

(d) Timers shall be equipped with automatically preset alarms that will warn the wearer for a period of 30 seconds or more when 20 to 30 percent of service life is remaining.

(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 when the remaining service life or cylinder pressure of the apparatus is reduced to between 20 to 30 percent of the rated service time or full-cylinder pressure. There shall be no degrading of performance by the remaining service-life indicator at 20 to 30 percent of full-cylinder pressure.

(g) If a manual shut off is not used for a remote gage, then the alarm shall activate at 25 to 30 percent of rated service pressure or time.

(h) Audible remaining-service-life indicators and preset timer alarms shall be clearly and distinctly detectable and be between 80 dBA and 100 dBA at both ears.

(i) Remaining-service-life indicators or warning devices shall warn the wearer for a period of 30 seconds or more after the alarm is initiated.

§ 84.245 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 operated 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 by-pass systems designed and constructed to permit the wearer to breathe and conserve the 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, by-pass system, valve control shall be colored red. For closed-circuit apparatus, the by-pass valve shall be designed to close automatically if not being held open by the wearer.

(h) A main-line or by-pass valve system is not 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 a pressure of 13 ± 0.5 millimeters (0.5 inch) of water-column height above the minimum pressure required to fill the breathing bag, within the breathing-resistance requirements for the apparatus.

(2) With the facepiece or mouthpiece attached in a normal manner to the breathing machine, and operated as described in § 84.251 of this Part, the facepiece or mouthpiece pressure shall not exceed 540 millimeters (21 inches) of water-column height when tested in each of the following modes:

Mode 1—with the first-stage reducer in a "failed-open" mode, i.e., with the pneumatic system subjected to the pressure of a fully-charged cylinder container;

Mode 2—with the by-pass valve in a locked-open position; and

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

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

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

§ 84.246 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 that are flexible and resistant to gases and vapors.

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

§ 84.247 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 through 84.264 of this Part.

§ 84.248 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.

§ 84.249 Compressed gas filters.

All self-contained breathing apparatus using compressed gas shall have a filter downstream of the gas source to remove particles that may adversely affect respirator performance.

§ 84.250 Weight markings.

All self-contained breathing apparatus excluding optional accessories shall have the completely assembled and fully charged weights or range of weights permanently and legibly marked on the apparatus.

§ 84.251 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 with 24 res-

pirations per minute and a minute-volume of 40 liters at a work rate of 100 watts (622 kp-m/min).[2]

(2) The facepiece pressure of positive-pressure, open- and closed-circuit equipment shall remain positive during the entire inhalation cycle, while the breathing apparatus is operated with the breathing machine with 24 respirations per minute, a minute-volume of 40 liters and a cam with a work rate of 100 watts (622 Kp- m/min.).

(3) Inhalation resistance for open- or closed-circuit apparatus with positive or negative pressure shall comply with the requirements as specified in Table 2 of this Part.

(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 airflow shall be measured in the facepiece or mouthpiece with a breathing machine at a work rate of 100 watts.

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[2]Silverman, L., G. Lee, T. Plotkin, L. Amory, and A. R. Yancy: Fundamental Factors in Design of Protective Equipment, OSRD Report No. 5732 (April 1, 1945). The breathing machine cam dimensions are available from NIOSH upon request.

(3) Exhalation resistance for open- or closed-circuit apparatus with positive or negative pressure shall comply with the requirement as specified in Table 2 of this Part.

Table 2—Maximum allowable breathing resistance
in millimeters of water-column height
(42 CFR 84.251)

Apparatus	Inhalation	Exhalation
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 millimeters of water-column height.

[b]Including the pressure required to fully open the relief valve, if applicable.

§ 84.252 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 millimeters (2 inches) of 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 shall be achieved:

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

§ 84.253 By-pass gas-flow test.

(a) Open-circuit apparatus.

(1) The by-pass gas-flow test shall be performed on open-circuit apparatus equipped with a by-pass valve as prescribed in § 84.245 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 by-pass valve shall be fully opened.

(3) The breathing-gas container valve shall be fully opened and the airflow shall be measured at 345 kPa (500 psi) gauge decreasing increments until 25 percent of the service pressure remains.

(4) Except as prescribed in subparagraph (5) of this paragraph, at any pressure, an adjustable by-pass valve shall provide a minimum flow rate of 130 liters per minute in the fully-open position.

(5) Any by-pass valve on a self-contained breathing apparatus for escape only shall provide a minimum flow rate of 85 liters per minute.

(6) Any constant-flow by-pass valve shall provide a minimum flow rate of 85 liters per minute and a maximum flow rate of 130 liters per minute.

(b) Closed-circuit apparatus.

(1) The by-pass gas-flow test shall be performed on closed-circuit apparatus equipped with a by-pass valve as prescribed in § 84.245 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 by-pass 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 rate shall be measured at 345 kPa (500 psi) gauge decreasing increments until 25 percent of the service pressure remains.

(4) At any pressure, the by-pass valve shall provide a minimum flow rate of 30 liters per minute.

§ 84.254 Service-time test; open-circuit apparatus.

(a) Service time shall be measured with a breathing machine operated as described in § 84.251 of this Part.

(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.

§ 84.255 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 7 of this Part.

(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.

§ 84.256 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.[3]

(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.

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[3]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 Investigation 6865 (1966).

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

(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 limits given in Table 3 of this Part.

Table 3—Maximum allowable average concentration of carbon dioxide

(42 CFR 84.256(c))

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 4, 5, 6, and 7 of this Part. 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.

§ 84.257 Tests during low-temperature operation.

(a) The manufacturer shall specify the minimum temperature for safe operation and test subjects 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 (8.5 inches) high at a rate of 30 cycles per minute. During each rest period, samples shall be taken from all closed-circuit self-contained breathing apparatus, to determine carbon dioxide and oxygen levels. Such levels shall meet the requirements in § 84.256(d) and definitions in § 84.200 of this Part.

(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 respirators, the air-line shall be briefly connected to determine proper functioning, then disconnected.

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

§ 84.258 Vibration tests.

Vibration, and machine tests shall be conducted on four apparatus. The leak test recommended by the applicant shall be performed for apparatus sealed against moisture following the vibration, and machine tests. Following these tests, one apparatus shall be disassembled and inspected prior to testing the three remaining apparatus on human subjects according to the use tests described in §§ 84.259 through 84.262 of this Part.

(a) A vibration test shall be conducted in accordance with the Military Standard MIL-STD 810D test I-3.2.1 Category 1—Basic transportation.

(1) The test levels shall be derived from the common carrier spectra described in figures 514.3-1 through 514.3-3 of Military Standard MIL-STD 810D test I-3.2.1.

(2) The common carrier spectra given in figures 514.3-2 through 514.3-3 have a test duration of 60 minutes per 1,000 miles. To simulate total miles of expected transportation of 24,000 miles, the duration of the test shall be 8 hours on each axis.

(3) The test setup shall consist of mounting each apparatus in its transport configuration on the vibration fixture/table using restraints and tie downs typical of those used during actual transport. Testing excitation shall be applied to each three dimensional axis from an original reference position as specified by the applicant. The equipment shall not be operated during this test. The apparatus shall be independently monitored for vibration during the test to ensure the test equipment was functioning properly.

(b) Following the vibration testing, the apparatus shall be machine tested at 40 liters per minute and shall meet the resistance requirements listed in § 84.251 of this Part. The low air-supply warning device shall function within 10 percent of the required range specified in this Part.

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

(d) After completion of the tests described in paragraphs (a) through (c) of this section, one of the four apparatus shall be disassembled and inspected for significant damage that is likely to cause the apparatus to fail to provide the required protection to the user. If no serious damage is noted upon disassembly, the remaining three apparatus shall be accepted for testing on human sub-

jects according to the use tests described in §§ 84.259 through 84.262 of this Part.

§ 84.259 Use tests; purpose and requirements; general.

(a) The use tests described in Tables 4, 5, 6, and 7 of this Part are designed to represent typical workload performed by a person wearing the apparatus.

(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. The wearer's pulse and respiration rate shall be recorded during each 2-minute sample period prescribed in use tests 1, 2, 3, and 4.

(d) Use tests 1, 2, 3, 4, and 5 shall be conducted on each respirator. Each respirator shall be worn by a different subject.

§ 84.260 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 4, 5, 6, and 7 of this Part, 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.

Table 4—Duration and sequence of specific activities for test 1, in minutes (42 CFR 84.260, et seq.)

	Service Time in Minutes[a]						
Activity	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]For 2–, 3–, or 4–hour apparatus, repeat 1–hour test 2, 3 or 4 times, respectively.

Table 5 - Duration and Sequence of Specific Activities for Test 2, in Minutes

(42 CFR 84.260, et seq.)

Activity	Service Time							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	60 minutes	2, 3, and 4 hours
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 km. (3 miles) 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 km. (3 miles) per hour			2			2	3	
Climbs vertical treadmill (or equivalent)						1	1	
Carries 20 kg. (45 pound) mass and walks at 4.8 km. (3 miles) per hour	1						2	
Walks at 4.8 km. (3 miles) 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 6 - Duration and Sequence of Specific Activities for Test 3, in Minutes

(42 CFR 84.260, et seq.)

Activity	Service Time							
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	60 minutes	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 2-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 7 - Duration and Sequence of Specific Activities for Test 4, in Minutes

(42 CFR 84.260, et seq.)

Activity	Service Time									
	3 minutes	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes	60 minutes	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			
Samplings 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 1-hour tests).

(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 lie face downward for a one-quarter full charge of liquefied breathing gas.

(4) The test described in subparagraph (3) 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.

§ 84.261 Use-transfer test.

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

(b) Each test subject trained in accordance with the applicant's user instructions shall don the complete 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 respi-

rator until reduction or loss of external air supply alerts the test subject that the external air supply has been terminated.

(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.

§ 84.262 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 degrees Celsius,

the maximum temperature of inspired air recorded during use tests shall not exceed the requirements given in Table 8 of this Part, after correction for deviation from 24 degrees Celsius:

Table 8—Maximum allowed inspiration temperature

(42 CFR 84.262(c))

Where service life of apparatus is:	Where percent relative humidity of inspired air is:	Maximum allowed temperature of inspired air shall not exceed:	
		degrees F	degrees 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]

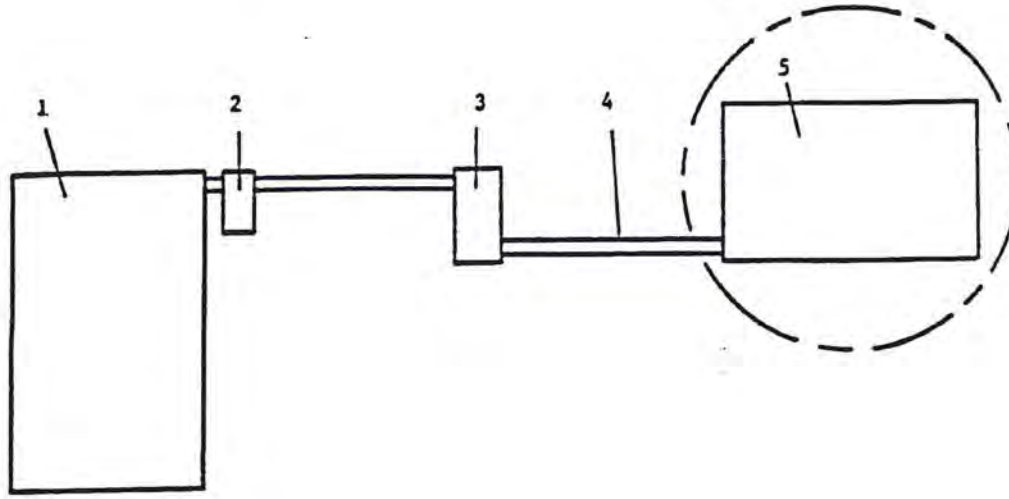
[a]Where percent relative humidity is 50–100 and apparatus is designed for escape only, these maximum allowed temperatures will be increased by five Celsius degrees.

§ 84.263 Flammability test for firefighter and mine-rescue SCBA.

(a) For self-contained breathing apparatus designated by the manufacturer as designed for and intended for use by firefighters or mine-rescue teams, full facepieces shall be tested for flammability for a short period with a test apparatus as shown on Figures 4 through 6 of this Part. 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 as shown in Figures 5 and 6 of this Part, and a metal dummy head that pivots vertically and horizontally as shown in Figure 5 of this Part.

(b) The test rig shall be adjusted as follows: The distance between facepiece and burner tips shall be 250 millimeters (Figure 5 of this Part). The pressure reducer shall be adjusted to a flow of 60 liters per minute using air at 1.25 kPa (18.1 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 at the facepiece shall be 950 ± 50 degrees Celsius.



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.

Figure 4–Test system schematic for flammability performance test of a fullface mask [42 CFR 84.263].

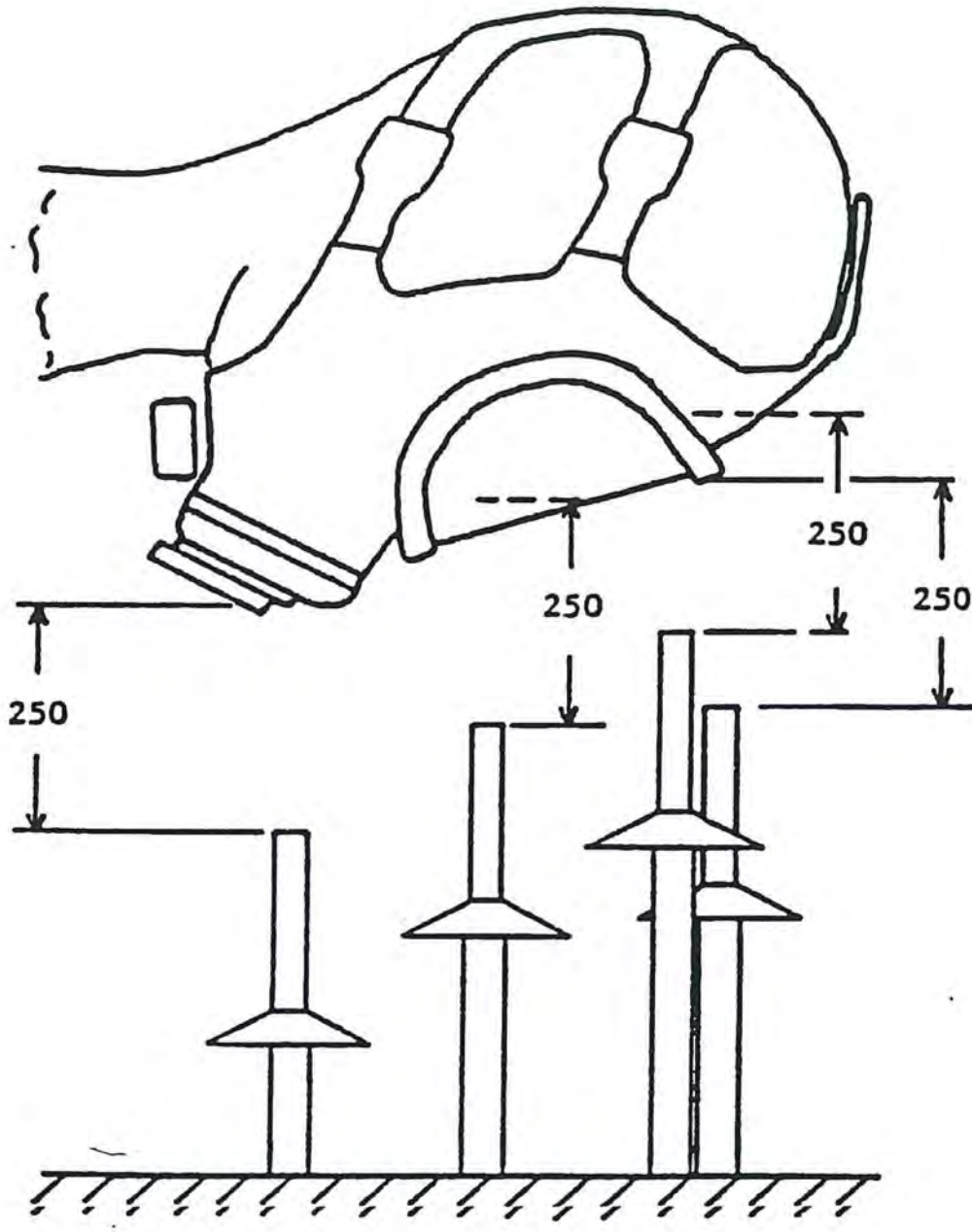


Figure 5–Elevation view, propane burners for flammability performance test of a fullface mask, dimensions in millimeters [42 CFR 84.263].

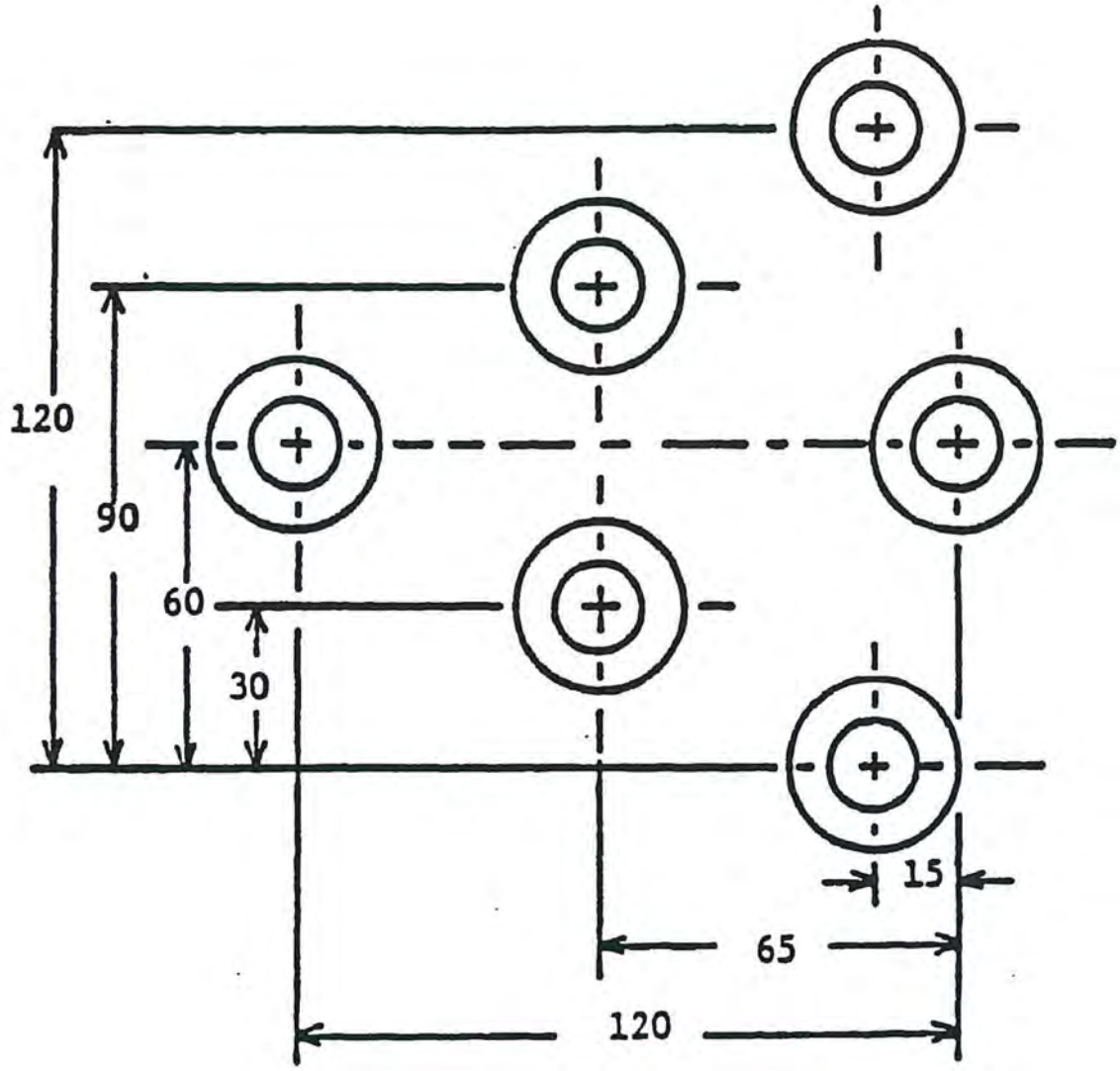


Figure 6–Plan view, propane burners for flammability performance test of a fullface mask, dimensions in millimeters [42 CFR 84.263].

(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 −10 mbar (−0.145 pounds per square inch) gauge shall be created in the cavity of the mask. All valves and facepiece-sealing surfaces shall be visually inspected.

(f) The facepiece passes the test 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 −10 mbar gauge initial pressure within the cavity of the mask does not exceed 1 mbar gauge per 60 seconds, and all valves are operating properly and all facepiece sealing surfaces appear intact.

§ 84.264 Regulator-overpressurization test.

(a) Regulators for all open-circuit self-contained breathing apparatus 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 by-pass 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 a sequence of 20 simulated

blocking attempts. Following the simulation blocking cycles, the regulator diaphragm shall be inspected and shall be found free of damage.

(b) Negative-pressure, open-circuit, self-contained breathing apparatus regulators shall be tested and evaluated as set forth in paragraph (a) prior to evaluating the respirator in the face-fit test of Subpart R.

Subpart T—Air-Line Respirators

§ 84.270 Air-line respirators; description.

Air-line respirators are atmosphere-supplying respirators that use a stationary source of compressed air delivered through a hose. Air-line respirators are available as negative-pressure, positive-pressure, and continuous-flow configurations.

§ 84.271 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 §§ 84.272 through 84.279 of this Part.

§ 84.272 Air-line respirator; demand and pressure-demand.

(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 86.2 kPa (125 pounds per square inch) gauge.

(c) The pressure at the inlet of the hose connection shall not exceed 86.2 kPa gauge.

§ 84.273 Air-line respirator; continuous-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 86.2 kPa (125 pounds per square inch) gauge.

(c) The pressure at the inlet of the hose connection shall not exceed 86.2 kPa gauge.

(d) Where the pressure at any point in the supply system exceeds 86.2 kPa gauge, the compressor or air-delivery system shall be equipped with a pressure-release mechanism that will prevent the pressure at the hose connection from exceeding 86.2 kPa gauge under any conditions.

§ 84.274 Air-supply-line tests.

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

(a) Length of hose. Hoses may be supplied in single or multiple lengths not to exceed 91.2 meters (300 feet).

(b) Airflow.

(1) Continuous-flow respirators shall permit a continuous flow of not less than 115 liters per minute to tight fitting facepieces and a continuous flow not less than 170 liters per minute to loose-fitting facepieces through the maximum length of hose for which certification is granted and at the minimum specified air-supply pressure. The maximum continuous 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) Negative-pressure and 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 51 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 24 times per minute by a breathing machine at a work rate of 100 watts.

(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, that 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 breathing machine operating at a work rate of 100 watts so that the negative- or positive-pressure regulator is actuated approximately 24 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 meter (25 feet) 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 tension of 445 N (100 pounds) for 5 minutes and when subjected, with blocked outlet, to an internal air pressure of two times the maximum respiratory-supply pressure that is specified by the applicant or at 17.2 kPa (25 psi) gauge, whichever is higher.

(f) Tightness. Leakage of air exceeding 50 cm^3 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 17.2 kPa 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.

§ 84.275 Harness test.

(a) Belts, rings, and attachments for life lines shall withstand a tension of 2668 N (600 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 tension of 445 N 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 tension 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 prevent tension 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.

§ 84.276 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 tension that will loosen the facepiece or restrict the wearer.

(b) Air-line respirators of the continuous-flow class shall employ one or two flexible breathing tubes of the non-kinking type that 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 that extends from the facepiece to the positive- or negative-pressure regulator, except where the regulator is attached directly to the facepiece.

§ 84.277 Airflow-resistance test; air-line respirator, continuous-flow class.

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

§ 84.278 Airflow-resistance test; air-line respirator, negative-pressure class.

(a) Inhalation resistance shall not exceed 51 millimeters (2 inches) of water-column height at an airflow of 115 liters per minute.

(b) The exhalation resistance to an airflow of 85 liters per minute shall not exceed 25 millimeters of water-column height.

§ 84.279 Airflow-resistance test; air-line respirator, positive-pressure class.

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

(b) The pressure in the facepiece shall not fall below atmospheric at an inhalation airflow of 115 liters per minute.

(c) The exhalation resistance to an airflow of 85 liters per minute shall not exceed the static pressure in the facepiece by more than 51 millimeters of water-column height.

Subpart U—Air-purifying Respirators; General Requirements

§ 84.280 Air-purifying respirators; description.

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

§ 84.281 Cartridges, canisters and filters in parallel; resistance requirements.

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

§ 84.282 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. If the manufacturer finds it necessary, an additional gas- or vapor-removing element may be placed at the inlet side of the filter or an additional filter element may be placed on the outlet side of the canister or cartridge.

§ 84.283 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 airflow for each is as follows:

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

(b) Loose-fitting, powered air-purifying respirators shall maintain an airflow 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 airflow is maintained.

Subpart V—Particulate Air-Purifying Respirators

§ 84.290 Particulate air-purifying respirators; description.

(a) Particulate air-purifying respirators have filters to remove solid, liquid, or both solid and liquid particulates from the ambient air. They are designed for use as respiratory protection against atmospheres with particulate contaminants

(e.g., dusts, fume, mists) that are non-IDLH and that contain adequate oxygen to support life.

(b) Particulate air-purifying respirators are classified as non-powered and powered, according to their design and are further classified for removal of solid, liquid, or combinations of solid and liquid particulates.

(c) Non-powered particulate air-purifying respirators are classified according to the efficiency of the filter element(s) as tested according to the requirements of this Part.

(1) Type I filters shall have a minimum efficiency of 90 percent.

(2) Type II filters shall have a minimum efficiency of 99 percent.

(3) Type III filters shall have a minimum efficiency of 99.97 percent.

(d) Powered particulate air-purifying respirators are classified according to the efficiency of the filter element(s) as tested according to the requirements of this Part.

(1) Type II filters shall have a minimum efficiency of 99 percent.

(2) Type III filters shall have a minimum efficiency of 99.97 percent.

§ 84.291 Particulate air-purifying respirators; performance requirements; general.

(a) Each particulate air-purifying respirator shall, as appropriate, meet the minimum construction requirements set forth in Subparts Q, R, and U, and § 84.293 of this Part.

(b) The manufacturer, as part of the application for certification, shall specify the single filter-efficiency particulate classification combination(s) (i.e., ≥ 90, ≥ 99, or ≥ 99.97 percent efficiency against solid, liquid, or both solid and liquid particulates) for which certification is being sought.

(c) Filters shall be marked or coded as follows:

(1) Type I shall be marked on all Type I filters.

(2) Type II shall be marked on all Type II filters.

(3) Type III shall be marked Type III and shall be color coded magenta.

(d) Filters shall be marked as to whether they are certified for solid, liquid, or both solid and liquid particulates.

§ 84.292 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 § 84.293 of this Part.

(b) The resistances for particulate respirators, in millimeters water-column height, shall not exceed 30 millimeters upon initial inhalation and 20 millimeters upon initial exhalation.

§ 84.293 Particulate instantaneous-penetration filter test.

(a) Filters of particulate respirators shall be tested for instantaneous penetration efficiency against:

(1) a solid particulate as per this section if solid particulate certification only is requested by the applicant.

(2) An oil liquid particulate as per this section if liquid particulate certification only is requested by the applicant.

(3) Both oil and a solid particulate as per this section if both solid and liquid particulate certification is requested by the applicant.

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

(c) 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 degrees Celsius for 24 hours. Following the humidity exposure, filters shall be sealed in a gas-tight container, and all tests shall be performed within 8 hours after conditioning.

(d) When 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.

(e) For air-purifying respirators with a single filter, filters shall be tested at a continuous airflow rate of 85 liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate shall be 42.5 liters per minute through each filter.

(f) Powered air-purifying particulate respirators (PAPRs) shall be tested while operating in their normal operational mode (with fully-charged batteries if they possess battery packs). The airflow of a powered air-purifying respirator will be measured after each of the penetration tests and it must meet the requirements of § 84.283(a) or § 84.283(b) of this Part. The airflow 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.

(g) Challenge aerosol.

(1) When testing for penetration of solid particulates, each respirator filter unit shall be challenged with a neutralized sodium chloride solid aerosol at 25 ± 5 degrees Celsius and at a relative humidity of less than 30 percent that contains no more than 200 mg/m^3 until at least 200 ± 5 mg of the aerosol has contacted the filter unit for non-powered respirators and at least 2000 ± 50 mg of the aerosol has contacted the filter unit for powered air-purifying respirators.

(2) When testing for penetration of oil liquid particulates, each respirator filter unit shall be challenged with a neutralized-oil liquid aerosol (oil mist must be liquid at room temperature and have a density between 0.91–0.99 gm/cm^3) at 25 ± 5 degrees Celsius that contains no more than 200 mg/m^3 until at least 200 ± 5 mg of the aerosol has contacted the filter unit for non-powered respirators and at least 2000 ± 50 mg of the aerosol has contacted the filter unit for powered air-purifying respirators.

(h) The particle size distribution of the test aerosol shall have a count median diameter of 0.10 to 0.25 micrometer and a standard geometric deviation not exceeding 1.8 at the specified flow rate.

(i) The instantaneous penetration of the filter shall be monitored and recorded throughout the test period by a suitable light-scattering photometer or equivalent instrumentation.

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

Subpart W—Gas and Vapor Air-Purifying Cartridge Respirators

§ 84.300 Gas and vapor air-purifying cartridge respirators; description.

(a) Gas and vapor air-purifying cartridge respirators (previously designated chemical-cartridge respirators) have a 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 that contain adequate oxygen to support life. They are described according to the following specific gases and vapors against which they are designed to provide respiratory protection: ammonia, chlorine, hydrogen chloride, hydrogen sulfide (approved for escape only unless equipped with an end-of-service-life indicator), methyl amine, mercury vapor (approved for escape only unless equipped with an end-of-service-life indicator), and sulfur dioxide.

(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 for respiratory protection against gases or vapor that are not specifically listed with their maximum use concentration may be certified according to the requirements set forth in Subpart Z.

§ 84.301 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.

§ 84.302 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 Subparts Q, R, and U, and §§ 84.303 and 84.304 of this Part.

§ 84.303 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 § 84.304 of this Part.

(b) The maximum allowable resistance requirements for gas and vapor air-purifying cartridge respirators are prescribed in Table 9 of this Part.

Table 9—Maximum initial resistance in millimeters water-column height

(42 CFR 84.303(b))

Respirator type	Inhalation	Exhalation
For gases, vapors, or gases and vapors	40	20
For gases, vapors, or gases and vapors, and particulates	50	20

(c) Combination gas and vapor and particulate air-purifying cartridge respirators shall meet the provisions of § 84.211 of this Part except that the maximum allowable resistance of such respirators shall not exceed the maximum allowable limits set forth in Table 9 of this Part.

§ 84.304 Gas and vapor cartridge service-life test.

(a) The service life of all gas and vapor cartridge(s) shall be determined by monitoring the downstream concentration for penetration while continually passing a test atmosphere through the cartridge(s) at the concentration and flow rate specified in Table 10 of this Part.

(b) Where two or more cartridges are used in parallel on a chemical cartridge respirator, the test will be performed with the cartridges arranged in parallel and the test requirements will apply to the combination rather than to the individual cartridges.

(c) Cartridges or sets of cartridges will be tested at 30 degrees Celsius and 25 percent relative humidity.

(d) Cartridges or sets of cartridges will be tested at 30 degrees Celsius and 50 percent relative humidity.

(e) Cartridges or sets of cartridges will be tested at 30 degrees Celsius and 80 percent relative humidity.

(f) 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 airflow rate of 64 liters per minute. Where cartridges are to be used in pairs, the flow rate shall be 64 liters per minute through each pair.

(2) Non-powered air-purifying respirators without exhalation valves shall be tested by the same regimen as in § 84.304(b) of this Part except that a breathing machine operating according to § 84.293(f)(1) of this Part 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.

(g) Cartridges shall be tested and shall meet or exceed the minimum service-life requirements set forth in Table 10 of this Part.

(h) The manufacturer shall establish and justify storage and shelf life for each cartridge type. Any adverse effects due to exposure to high relative humidity shall be considered in determining shelf life. The shelf life of a cartridge is defined as that period of time for which the cartridge will provide 90 percent of the service life specified when tested in accordance with this section.

Table 10—Cartridge service-life test conditions and performance requirements (42 CFR 84.304)

Cartridge type	Gas or Vapor	Concentration (ppm)	Flow rate (L/min) non-pwr	pwr tight	pwr loose	Penetration[a] (ppm)	Minimum life[b] (minutes)
Ammonia	NH_3	1,000	64	115	170	50	50
Chlorine	Cl_2	500	64	115	170	5	35
Chlorine dioxide	ClO_2	500	64	115	170	0.1	30
Hydrogen chloride	HCl	500	64	115	170	5	50
Hydrogen sulfide	H_2S	1,000	64	115	170	10	30
Mercury	Hg	21.5	64	115	170	0.05	480
Methylamine	CH_3NH_2	1,000	64	115	170	10	25
Sulfur dioxide	SO_2	500	64	115	170	5	30

[a]Service 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 protection against ammonia and chlorine or hydrogen chloride and organic vapors (§ 84.328(b) of this Part), 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 protection against chlorine and sulfur dioxide, the stated minimal life shall apply.

Subpart X—Gas and Vapor Air-Purifying Canister Respirators

§ 84.310 Description and classification.

(a) Gas and vapor air-purifying canister respirators (previously designated gas masks) have a 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 that contain a full facepiece are designed for use as respiratory protection in atmospheres that contain adequate oxygen to support life as follows: entry into and escape from non-IDLH atmospheres, and escape from IDLH atmospheres. However, such respirators that do not contain full facepieces but contain a half facepiece or mouthpiece/-noseclamps may only be used for escape from both non-IDLH and IDLH atmospheres.

(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 consisting of a full facepiece, canister(s) (previously designated front or back mounted), and associated harness and connections.

(2) Low-capacity. A gas and vapor air-purifying canister respirator consisting of a facepiece, canister(s) (previously designated 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, such as ammonia, carbon monoxide, chlorine, sulfur dioxide, or a combination of two or more of the above. Gas and vapor air-purifying canister respirators for respiratory protection against gases and vapors that are not specifically listed with their maximum use concentration may be certified according to the requirements of Subpart Z.

(d) Gas and vapor air-purifying canister respirators can be further classified as powered or non-powered according to their design.

§ 84.311 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.

§ 84.312 Performance requirements; general.

Gas and vapor, air-purifying, canister respirators shall meet the minimum construction requirements set forth in Subparts Q, R, U, and §§ 84.313 through 84.315 of this Part.

§ 84.313 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 before each test conducted in accordance with § 84.315 of this Part 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 prescribed in Table 11 of this Part.

Table 11—Maximum initial resistance in millimeters water-column height

(42 CFR 84.313(b))

Gas mask type	Inhalation	Exhalation
High-capacity		
without particulate filter	60	20
with certified particulate filter	70	20
Low-capacity		
without particulate filter	50	20
with certified particulate filter	65	20

§ 84.314 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 of this Part 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 § 84.313 of this Part.

§ 84.315 Canister service-life test.

(a) The service lives of all gas and vapor canisters except for carbon monoxide shall be determined by monitoring the downstream concentration for penetration while continually passing a test atmosphere through the canister at concentration and flow rate(s) specified in Tables 12 or 13 of this Part.

(b) Where two or more canister(s) are used in parallel on a canister respirator, the test will be performed with the canister arranged in parallel and the test requirements will apply to the combination rather than to the individual canisters.

(c) Canisters or sets of canisters will be tested at 30 degrees Celsius and 25 percent relative humidity.

(d) Canisters or sets of canisters will be tested at 30 degrees Celsius and 50 percent relative humidity.

(e) Canisters or sets of canisters will be tested at 30 degrees Celsius and 80 percent relative humidity.

(f) The flow rate through the canister(s) being tested are as follows:

(1) Non-powered, single-gas or vapor canister, air-purifying respirators with exhalation valves shall be tested, each at a continuous airflow rate of 64 liters per minute.

(2) Non-powered air-purifying respirators without exhalation valves shall be tested by the same regimen as in § 84.304(b) of this Part except that a breathing machine operating according to § 84.293(f)(1) of this Part 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.

(g) The manufacturer shall establish and justify storage and shelf life for each canister type. Any adverse effects due to exposure to high relative humidity must be considered in determining shelf life. The shelf life of a canister is defined as that period of time for which the canister will continue to provide 90 percent of the service life specified when tested in accordance with this section.

(h) High-capacity gas and vapor canisters shall be tested according to and shall meet or exceed the minimum requirements set forth in Table 12 of this Part.

(i) Low-capacity gas and vapor canisters will be tested according to and shall meet or exceed the minimum requirements set forth in Table 13 of this Part.

(j) 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 an indicator to warn the wearer at 90 percent or less of the total service life.

(k) Other canisters may also be equipped with an indicator to warn of imminent leakage of other gases or vapors. The window or other indicator canisters shall be tested as regular canisters, but shall show a satisfactory indicator change or other warning at 90 percent or less of the total service life.

Table 12—Canister service-life tests and requirements for high-capacity gas and vapor air-purifying canisters (42 CFR 84.315(h))

Canister type	Gas or Vapor	Concentration (ppm)	Flow rate (L/min) non-powered	Flow rate (L/min) powered tight	Flow rate (L/min) powered loose	Penetration[a] (ppm)	Minimum service life(min)
Ammonia	NH_3	30,000	64	115	170	50	12
Carbon monoxide	CO	20,000	64[b]	n/a	n/a	(c)	60
	CO	5,000	32[d]	n/a	n/a	(c)	60
	CO	3,000	32[b]	n/a	n/a	(c)	60
Chlorine	Cl_2	20,000	64	115	170	5	12
Hydrogen sulfide	H_2S	20,000	64	115	170	10	12
Sulfur dioxide	SO_2	20,000	64	115	170	5	12
Combination of 2 or 3 of above types[e]							
Combination of all of above types plus organic vapor (§ 84.328(a))[f]							

[a]Service 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 degrees Celsius.

[c]Maximum allowable CO penetration shall be 385 cm^3 during the minimum life. The penetration shall not exceed 500 ppm 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 and +2.5 degrees Celsius.

[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 minutes instead of 12 minutes.

Table 13—Canister service-life tests and requirements for low-capacity gas and vapor air-purifying canisters (42 CFR 84.315(i))

Canister type	Gas or Vapor	Concentration (ppm)	Flow rate (L/min) non-powered	Flow rate (L/min) powered tight	Flow rate (L/min) powered loose	Penetration[a] (ppm)	Minimum service life(min)
Ammonia	NH_3	5,000	64	115	170	50	12
Carbon monoxide	CO	20,000[h]	64[b]	n/a	n/a	(c)	60
	CO	10,000[i]	64[d]	n/a	n/a	(c)	60[g]
	CO	5,000	32[d]	n/a	n/a	(c)	60
	CO	3,000	32[b]	n/a	n/a	(c)	60
Chlorine	Cl_2	5,000	64	115	170	5	12
Hydrogen sulfide	H_2S	5,000	64	115	170	10	12
Sulfur dioxide	SO_2	5,000	64	115	170	5	12
Combination of 2 or 3 of above types[e]							
Combination of all of above types plus organic vapor (§ 84.328(a)[f])							

[a]Service 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 degrees Celsius.

[c]Maximum allowable CO penetration shall be 385 cm^3 during the minimum life. The penetration shall not exceed 500 ppm 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 and +2.5 degrees Celsius.

[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 minutes instead of 12 minutes.

[g]If effluent temperature exceeds 100 degrees Celsius 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.

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

§ 84.320 Description and limitations.

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

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

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

(a) Organic gas and vapor air-purifying cartridge respirators (previously designated chemical-cartridge respirators) are designed for use as respiratory protection during entry into and escape from non-IDLH atmospheres.

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

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

(a) Organic gas and vapor air-purifying canister respirators (previously called gas masks) that contain a full facepiece are designed for use as respiratory protection in atmospheres that 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 that do not contain full facepieces but contain a half facepiece or mouthpiece/noseclips may only be used for escape from non-IDLH and IDLH atmospheres.

(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 that 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 that consists of a facepiece, canister(s) (previously chin-style or escape), and associated harness and connections.

§ 84.323 Labeling requirements.

The manufacturer shall provide in the user instructions a list of organic vapor(s) and gas(es) for which they recommend their respirators can be used.

§ 84.324 Color and marking requirements.

The color and markings of all canisters and cartridges or labels shall conform to the requirements of the American National Standard for Identification of Air-Purifying Respirator Canisters and Cartridges, ANSI K13.1-1973.

§ 84.325 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 Subparts Q, R, and U, and §§ 84.326 through 84.328 of this Part.

§ 84.326 Breathing-resistance test.

(a) Organic gas and vapor air-purifying cartridge respirators shall meet the breathing resistances set forth in § 84.303 of this Part before each service-life test specified in § 84.328(b) of this Part.

(b) Organic gas and vapor air-purifying canister respirators shall meet the breathing resistances set forth in § 84.313 of this Part before each service-life test specified in § 84.328(a) of this Part.

§ 84.327 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 of this Part 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 § 84.326 of this Part.

§ 84.328 Service-life test.

(a) The service life of all organic gas and vapor canisters shall be determined by monitoring the downstream concentration for penetration while continually passing a carbon tetrachloride (CCl_4) test atmosphere through the canister at 30 ± 2.5 degrees Celsius at the concentration and flow rate specified in Table 14 of this Part. The canisters will be tested as described in § 84.315 of this Part except that the service-life test shall be as specified in Table 14 of this Part.

Table 14 —Organic gas and vapor canister service-life test conditions and performance requirements

(42 CFR 84.328(a))

Canister type	Test agent	Concentration (ppm)	Flow rate (L/min) non-powered	Flow rate (L/min) powered tight	Flow rate (L/min) powered loose	Penetration[a] (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

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

(b) The service life of all organic gas and vapor cartridges shall be determined by monitoring the downstream concentration for penetration while continually passing a carbon tetrachloride test atmosphere through the cartridge at 30 ± 2.5 degrees Celsius at the concentration and flow rate specified in Table 15 of this Part. The cartridge shall be tested as described in § 84.304 of this Part, except that the service-life test shall be as specified in Table 15 of this Part.

Table 15—Organic gas and vapor cartridge service-life test conditions and performance requirements

(42 CFR 84.328(b))

Cartridge type	Test agent	Concentration (ppm)	Penetration[a] (ppm)	Minimum life, minutes
OV cartridge	CCl_4	1000	5	50

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

(c) 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 in this section or in Table 10 of this Part.

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

§ 84.330 Description.

(a) Specific organic gas and vapor air-purifying cartridge respirators (previously designated chemical-cartridge respirators) are designed for use as respiratory protection during entry into and escape from non-IDLH atmospheres.

(b) Specific gas and vapor air-purifying canister respirators (previously designated gas masks) that contain a full facepiece are designed for use as respiratory protection in atmospheres that 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 that do not contain full facepieces, but contain a half facepiece or mouthpiece/noseclips may only be used for escape from non-IDLH atmospheres and IDLH atmospheres.

(c) Specific 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 that consists of a full facepiece, canister(s) (previously designated front or back mounted), and associated harness and connections.

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

§ 84.331 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.

§ 84.332 General test requirements.

(a) All applications for certification of such respirators designed as respiratory protection against substances not specifically set forth in this Part shall be in accordance with § 84.11 of this Part. In addition, the application shall also 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 that could impair the ability of the respirator to protect the wearer (e.g., decreased service life).

(7) 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.

§ 84.333 Performance requirements.

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

§ 84.334 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) that shows a satisfactory indicator change or

other obvious warning before the NIOSH-recommended exposure limit is reached. The indicator shall show such change or afford such warning less than of 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 that are reasonably representative of actual workplace conditions where it is anticipated that a given respirator will be used.

(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 that 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 that 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 that interferences could impair the effectiveness of the indicator and the degree of impairment and to show that 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 that predict 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 the cleaning specified by the manufacturer, if applicable, 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 without any adverse effects in performance.

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

(6) Effects of interferences for substances that are commonly found in workplaces where it is anticipated that a given respirator will be used must be determined and those substances that hinder ESLI performance shall be identified. Substances that 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.

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

§ 84.335 Combination air-line and air-purifying respirators.

(a) Combination air-line respirators and air-purifying respirators shall have the following criteria applied when evaluating them for certification.

(1) A combination air-line respirator and air-purifying respirator for which the air-purifying mode can be used for extensive periods of time shall meet all the air-line respirator requirements (Subpart T) and the applicable air-purifying respirator requirements (Subparts U through Z).

(2) A combination air-line respirator/air-purifying respirator for which the air-purifying element is certified for use during entry and egress or for escape only shall meet all the respirator air-line requirements (Subpart T) and the penetration or service-life requirements and the inhalation requirements plus 10 millimeters of water-column height for the specific air-purifying type (Subparts U through Z).

(b) A combination respirator air-line/air-purifying respirator for which the air-purifying element is certified for escape only shall meet the following requirements.

(1) The combination when used in the air-line mode must meet the resistance requirements of the air-line respirator.

(2) The combination when used in the air-purifying mode and tested mounted on a test fixture with a continuous-testing airflow rate of 85 liters per minute shall not exceed 85 millimeters of water-column height for inhalation resistance and 88 millimeters of water-column height for exhalation resistance. In addition, the total pressure drop across the apparatus (pressure swing) when also measured at 85 liters per minute shall not exceed 170 millimeters of water-column height.

(3) The combination, when used in the air-purifying escape mode, shall meet the penetration or service-life requirements of air-purifying respirators (Subparts T through U).

(c) The combination shall incorporate a check valve to help assure that when in the air-line mode, no air can be drawn through the air-purifying element and that high pressure air cannot be forced back through the air-purifying element;

(d) The combination shall incorporate a valve (i.e., a spring or other type pressure-activated valve) that will close when the air-line is disconnected so that contaminated air cannot be drawn through the hose when using the air-purifying element.

(e) The combination shall incorporate a cover or other means or protecting the air-purifying element from moisture contamination or physical damage.

(f) If the replacement frequency recommended exceeds one shift, then data demonstrating that the element remains efficient for the specified use period

under conditions representing its anticipated use shall be submitted to NIOSH as part of the certification application.

(g) The user instructions shall state that training on the combination unit include a brief familiarization period where the employee is allowed to wear the device in the air-purifying mode. This will allow the employee to recognize any higher breathing resistance associated with air-purifying mode and decrease the likelihood of the user panicking when airflow is shut off.

Appendix A—Assumed Conditions of Use

The use of respirators referred to in this Part is governed by the applicable regulatory agencies (e.g., Occupational Safety and Health Administration (OSHA), Mine Safety and Health Administration (MSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC)). However, for the purpose of certifying respirators under the provisions of this Part, this nonmandatory Appendix contains the generic assumptions concerning the conditions under which NIOSH-certified respirators will be used. These assumptions are consistent with NIOSH recommendations for the safe and effective use of respirators.[4] Most importantly, NIOSH assumes that all NIOSH-certified respirators

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[4]NIOSH Guide to Industrial Respiratory Protection, National Institute for Occupational Safety and Health publication DHHS (NIOSH) 87-116, Cincinnati, Ohio (1987).

will be used in accordance with a complete respirator program. Such a program should include, but is not limited to, the following elements:

- Adequate program administration
- Adequate written standard operating procedures
- Proper respirator selection for given hazard(s)
- Appropriate medical surveillance of wearers
- Adequate training programs for both supervisors and workers
- Adequate fitting and testing for inadequate fits on each wearer
- Respirator inspection, cleaning, maintenance, and storage
- Surveillance of workplace conditions and worker exposures
- Respirator program evaluation for safety and effectiveness

Additionally NIOSH assumes that:

(a) Cartridge respirators, canister respirators, particulate respirators, and air-line respirators will only be used in atmospheres that 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 that have adequate oxygen to support life.

(b) Positive-pressure, self-contained breathing apparatus can be used in all hazardous atmospheres including IDLH, provided appropriate use practices are followed.

(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 lacking adequate warning properties (i.e., the gas or vapor does not have physiological effects in humans (e.g., odor, taste, eye irritation, respiratory irritation) that have been demonstrated as being capable of providing respirator wearers with timely, consistent, persistent, and reliable warning of gas or vapor concentrations at or below the established exposure limit).

(e) Gas and vapor respirators without ESLI 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 that interfere with the odor or irritation threshold of the wearer.

(f) Gas and vapor cartridge respirators will not be used in concentrations in excess of the maximum use concentrations recommended by NIOSH. NIOSH recommends that maximum use concentration be set at the IDLH or 10 times the NIOSH-recommended exposure limit or other applicable exposure limit established by the applicable regulatory agency, whichever is lower.

(g) Gas and vapor respirators without ESLI will only be used by workers who are capable of recognizing the odor(s) of the contaminant(s) at a concentration at or below the applicable exposure limit. Odor-screening tests will be conducted on each worker for each gas or vapor contaminant for which the respirator is being used to protect the worker in the workplace.

(h) 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, l5th edition of the National Formulary (USP20NF15) dated July 1, 1980, and chemically-generated oxygen shall meet the requirements of Military Specification MIL-E-83252, dated 1972, or Military Specification MIL-O-15633, dated 1964, whichever is applicable.

(i) Respirators certified under the provisions of this Part will be used only as part of a complete respirator program that encompasses all aspects of proper respirator use including, but not limited to, hazard definition, selection, fitting, training, maintenance, storage, monitoring, use supervision, and administration.

(j) The breathing gas contained in self-contained breathing apparatus will 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 (USP2ONF15) dated July 1, 1980, and chemically generated oxygen shall meet the requirements of Military Specification MIL-E-83252, dated 1972, or Military Specification MIL-O-15633, dated 1964, whichever is applicable.

(2) Except as prescribed in paragraph (h) 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 or 25 percent for liquid breathing air.

(k) Positive-pressure self-contained breathing apparatus that have switching capability to a negative-pressure operation, are certified for negative-pressure use

only for donning and facepiece adjustment prior to entry into a contaminated atmosphere.

Appendix B—Major Respirator Components

The following are the major components of a respirator, referenced in §§ 84.41(b), 84.11(a)(6), and 84.11(a)(7) of this Part:

1. Self-contained breathing apparatus, open- and closed-circuit:

    Facepiece and breathing tube

    Regulator

    Harness and backpack

    Cylinder and valve

    Nose cup

    For closed-circuit operation add:

    Breathing bag

    Scrubber or chemical oxygen canister

2. Air-line respirators:

    Facepiece/hood or helmet and breathing tube

    Air-control valve or regulator

    Belt or harness

    Air-line hose and quick-disconnect

3. Non-powered particulate, chemical-cartridge or canister respirators:

Facepiece

Harness assembly, head, front or back mount

Filter holder assembly

Filter elements, cartridges or canisters, and prefilters

Breathing tube

4. Powered particulate, chemical-cartridge or canister respirators:

Facepiece/hood or helmet and breathing tube

Harness assembly, head, front or back mount

Filter holder assembly

Filter elements, cartridges or canisters, and prefilters

Motor/blower assembly

Battery/power supply

Belt/support harness assembly

Appendix C—Protection of Human Test Subjects and Laboratory Personnel

1. Protection of Human Test Subjects—The purpose of this Appendix is to provide guidance for protecting human subjects participating in tests under this regulation who might be exposed to greater than minimal risk (i.e., §§ 84.255, 84.257, 84.259, 84.260, 84.261, and 84.262 in Subpart S of this Part). Minimal risk means that the anticipated risks of harm to human subjects participating in respirator certification tests are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance

Facepiece

Harness assembly, head, front or back mount

Filter holder assembly

Filter elements, cartridges or canisters, and prefilters

Breathing tube

4. Powered particulate, chemical-cartridge or canister respirators:

Facepiece/hood or helmet and breathing tube

Harness assembly, head, front or back mount

Filter holder assembly

Filter elements, cartridges or canisters, and prefilters

Motor/blower assembly

Battery/power supply

Belt/support harness assembly

Appendix C—Protection of Human Test Subjects and Laboratory Personnel

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of routine physical examinations or tests. The requirements of this Appendix will be applicable to human-subjects testing under Subpart S of this Part. It is not intended to apply to human-subjects testing under Subpart R of this Part, because only nontoxic aerosols or oil mists are used and human subjects are not subjected to other risks.

The provisions of this Appendix are consistent with the procedures of 45 CFR Part 46 and the Proposed Model Federal Policy for the Protection of Human Subjects published June 3, 1986 (51 Federal Register 20204) by the Office of Science and Technology Policy.

For certification under Subpart S of this Part and any other certification procedures that pose greater than minimal risk to human subjects (as defined above), the applicant must submit with the application, documentation of compliance with the following provisions:

(a) The certification applicant will prepare a written statement of principles governing the test laboratory in the discharge of its responsibilities to protect the rights and welfare of human subjects during certification performance tests conducted by or sponsored by the applicant.

(b) The certification applicant will designate a Human Subjects Review Board (HSRB), meeting the requirements contained in 45 CFR Part 46, to review test equipment and procedures before testing is begun.

(c) Before testing is initiated and at least annually thereafter, the HSRB will issue a written description of the testing, describing any apparent or potential hazards to test subjects and prescribing procedures for minimizing those hazards.

Any modification of the test procedure(s) must be reviewed and approved by the HSRB before it is instituted.

(d) The HSRB will require documentation of informed consent by all human subjects. Such informed consent will include a description of the research procedure, risk, and benefits to the subject. Both the consent and documentation must meet the requirements contained in 45 CFR Part 46.

(e) The HSRB will assure that personal information provided by or obtained on human subjects will be safeguarded.

(f) The HSRB will have the authority to approve, require modification of, or disapprove all testing involving human subjects.

2. Protection of Laboratory Personnel—NIOSH requires, at a minimum, that all laboratory personnel performing certification performance tests be protected in accordance with all applicable Federal, state, and municipal regulations.

Appendix D—Performance Requirements from 30 CFR Part 11

The following performance requirements of 30 CFR Part 11 shall be used to evaluate and certify major modifications to NIOSH/MSHA certifications, in accordance with § 84.60 of this Part.

Subpart G—General Construction and Performance Requirements

§ 11.60 Construction and performance requirements; general.

(a) MSHA and the Institute shall issue approvals for the types of respirators described in Subparts H through M of this part which have met the minimum requirements set forth for such respirators in this Part 11.

(b) In addition to the types of respirators specified in Subparts H through M, MSHA and the Institute shall issue approvals for other respiratory protective devices not specifically described in this Part 11 subject to such additional requirements as may be imposed in accordance with § 11.63(c).

§ 11.61 General construction requirements.

(a) Respirators will not be accepted by the Institute for examination, inspection and testing unless they are designed on sound engineering and scientific principles, constructed of suitable materials and evidence good workmanship.

(b) Respirator components which come into contact with the wearer's skin shall be made of nonirritating materials.

(c) Components replaced during or after use shall be constructed of mate-

(a) The component parts of each respirator shall be:

(1) Designed, constructed, and fitted to insure against creation of any hazard to the wearer;

(2) Assembled to permit easy access for inspection and repair of functional parts; and

(3) Assembled to permit easy access to parts which require periodic cleaning and disinfecting.

(b) Replacement parts shall be designed and constructed to permit easy installation and to maintain the effectiveness of the respirator.

§ 11.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in Subparts H through M of this part.

(b) Where a combination respirator is assembled from two or more types of respirators, as described in this part, each of the individual respirator types which have been combined shall, as applicable, meet the minimum requirements for such respirators set forth in Subparts H through M of this part, and such combination respirators, except as specified in § 11.70(b)(2), will be classified by the type of respirator in the combination which provides the least protection to the user.

(c) In addition to the minimum requirements set forth in Subparts H through M of this part, MSHA and the Institute reserve the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.64 Pretesting by applicant; approval of test methods.

(a) Prior to making or filing any application for approval or modification of approval, the applicant shall conduct, or cause to be conducted, examinations, inspections, and tests of respirator performance which are equal to or exceed the severity of those prescribed in this part.

(b) With the application, the applicant shall provide a statement to the Institute showing the types and results of the examinations, inspections, and tests required under paragraph (a) of this section and state that the respirator meets the minimum requirements of Subparts H through M of this part, as applicable. Complete examination, inspection, and test data shall be retained on file by the applicant and be submitted, upon request, to the Institute.

(c) The Institute may, upon written request by the applicant, provide drawings and descriptions of its test equipment and otherwise assist the applicant in establishing a test laboratory or securing the services of a testing agency.

(d) No approval will be issued until the Institute has validated the applicant's test results.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.65 Conduct of examinations, inspections, and tests by MSHA and the Institute; assistance by applicant; observers; recorded data; public demonstrations.

(a) All examinations, inspections, and tests conducted pursuant to Subparts H through M of this part will be under the sole direction and control of MSHA and the Institute.

(b) MSHA and the Institute may, as a condition of approval, require the assistance of the applicant or agents of the applicant during the assembly, disassembly, or preparation of any respirator or respirator component prior to testing or in the operation of such equipment during testing.

(c) Only MSHA and Institute personnel, persons assisting MSHA pursuant to paragraph (b) of this section, and such other persons as are requested by MSHA, the Institute, or the applicant to be observers, shall be present during any examination, inspection, or test conducted prior to the issuance of an approval by MSHA and the Institute for the equipment under consideration.

(d) MSHA and the Institute shall hold as confidential any analyses, drawings, specifications, or materials submitted by the applicant and shall not disclose any principles or patentable features of such equipment, except as required by statute or regulation.

(e) As a condition of each approval issued for any respirator, MSHA and the Institute reserve the right, following the issuance of such approval, to conduct such public tests and demonstrations of the approved respiratory equipment as is deemed appropriate.

§ 11.66 Withdrawal of applications; refund of fees.

(a) Any applicant may, upon a written request submitted to MSHA or the Institute, withdraw any application for approval of any respirator.

(b) Upon receipt of a written request for the withdrawal of an application, the Institute shall determine the total man-days expended and the amount due for services already performed during the course of any examinations, inspections, or tests conducted pursuant to such application. The

total amount due shall be determined in accordance with the provisions of § 11.22 and assessed against the fees submitted by the applicant. If the total amount assessed is less than the fees submitted, the Institute shall refund the balance together with a statement of the charges made for services rendered.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

Subpart H—Self-Contained Breathing Apparatus

§ 11.70 Self-contained breathing apparatus; description.

(a) Self-contained breathing apparatus, including all completely assembled, portable, self-contained devices designed for use as respiratory protection during entry into and escape from or escape only from hazardous atmospheres, are described as follows:

(1) *Closed-circuit apparatus.* An apparatus of the type in which the exhalation is rebreathed by the wearer after the carbon dioxide has been effectively removed and a suitable oxygen concentration restored from sources composed of:

(i) Compressed oxygen; or

(ii) Chemical oxygen; or

(iii) Liquid-oxygen.

(2) *Open-circuit apparatus.* An apparatus of the following types from which exhalation is vented to the atmosphere and not rebreathed:

(i) *Demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during exhalation and negative during inhalation.

(ii) *Pressure-demand-type apparatus.* An apparatus in which the pressure inside the facepiece in relation to the immediate environment is positive during both inhalation and exhalation.

(b) The following respirators may be classified as designed and approved for use during emergency entry into a hazardous atmosphere: A combination respirator which includes a self-contained breathing apparatus and a Type "C" or Type "CE" supplied air respirator, where (1) the self-contained breathing apparatus is classified for 3-, 5-, or 10-minute service time and the air line supply is used during entry, or (2) the self-contained breathing apparatus is classified for 15 minutes or longer service time and not more than 20 percent of the rated capacity of the air supply is used during entry.

(c) Self-contained breathing apparatus classified for less than 1 hour service time will not be approved for use during underground mine rescue and recovery operations except as auxiliary equipment.

(d) Self-contained breathing apparatus classified for less than 30 minutes' service time will not be approved for use as auxiliary equipment during underground mine rescue and recovery operations.

§ 11.71 Self-contained breathing apparatus; required components.

(a) Each self-contained breathing apparatus described in § 11.70 shall, where its design requires, contain the following component parts:

(1) Facepiece or mouthpiece, and noseclip;

(2) Respirable breathing gas container;

(3) Supply of respirable breathing gas;

(4) Gas pressure or liquid level gages;

(5) Timer;

(6) Remaining service life indicator or warning device;

(7) Hand-operated valves;

(8) Breathing bag;

(9) Safety relief valve or safety relief system; and

(10) Harness.

(b) The components of each self-contained breathing apparatus shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.72 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with breathing apparatus shall be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces and mouthpieces;

(3) Interference with the wearer's activities; and,

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

§ 11.73 Harnesses; installation and construction; minimum requirements.

(a) Each apparatus shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the apparatus in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of apparatus parts, and, where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 11.74 Apparatus containers; minimum requirements.

(a) Apparatus may be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains, and all appropriate approval labels.

(b) 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 approval is sought.

(c) Containers for self-contained breathing apparatus shall be designed and constructed to permit easy removal of the apparatus.

§ 11.75 Half-mask facepieces, full facepieces, mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes, either (1) by providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for the optional use of corrective spectacles or lenses which shall not reduce the respiratory protective qualities of the apparatus.

(c) Apparatus with mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or apparatus and provide an airtight seal.

(d) Facepieces shall be designed to prevent eyepiece, spectacle, and lens fogging.

§ 11.76 Facepieces; eyepieces; minimum requirements.

(a) Facepieces shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.

(b) All eyepieces shall be designed and constructed to meet the impact and penetration requirements specified in Federal Specification, Mask, Air Line, and Respirator, Air Filtering, Industrial, GGG-M-125d, October 11, 1965. This Federal Specification is available from the Government Printing Office or the General Services Administration.

§ 11.77 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against damage and distortion.

(b) Exhalation valves shall be:

(1) Protected against external influence, and

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

§ 11.78 Head harnesses; minimum requirements.

(a) Facepieces shall be equipped with adjustable and replaceable head harnesses designed and constructed to provide adequate tension during suspension and an even distribution of pressure over the entire area in contact with the face.

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

§ 11.79 Breathing gas; minimum requirements.

(a) Breathing gas used to supply apparatus shall be respirable and contain no less than 19.5 (dry atmosphere) volume percent of oxygen.

(b) Oxygen, including liquid oxygen, shall meet the minimum requirements for medical or breathing oxygen set forth in the U.S. Pharmacopeia.

(c) Compressed, gaseous breathing air shall meet the applicable minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association Commodity Specification for Air, G-7.1 (Grade D or higher quality).

(d) Compressed, liquefied breathing air shall meet the applicable minimum grade requirements for Type II liquid air set forth in the Compressed Gas Association Commodity Specification for Air, G-7.1 (Grade B or higher quality).

§ 11.79-1 Interchangeability of oxygen and air prohibited.

Approvals shall not be issued by MSHA and the Institute for any apparatus, combination of respirator assemblies, or any apparatus or respirator component which is designed or constructed to permit the interchangeable use of oxygen and air.

§ 11.80 Compressed breathing gas and liquefied breathing gas containers; minimum requirements.

(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.

(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 a dial indicating gage which shows the pressure in the container.

(d) Compressed breathing gas contained 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, B57.1 (1965), obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

§ 11.81 Gas pressure gages; minimum requirements.

(a) Gas pressure gages employed on compressed breathing gas containers shall be calibrated in pounds per square inch.

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

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

(1) Pounds per square inch, or

(2) In fractions of total container capacity, or

(3) Both in pounds per square inch and fractions of total container capacity.

(d) (1) Dial-indicating gages 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 gages shall not exceed 150 percent of the maximum rated cylinder pressures specified for the container in applicable Department of Transportation specifications or permits.

(e) (1) Stem-type gages 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 gage and these graduations shall include readings for empty, one-quarter, one-half, three-quarters, and full.

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

(f) The loss of gas through a broken gage or severed gage connection shall not exceed 70 liters per minute when the cylinder pressure is 6,900 kN/m.^{2} (1,000 pounds per square inch gage) or when the liquid level is at one-half.

(g) Where gages are connected to the apparatus through a gage line, the gage and line shall be capable of being isolated from the apparatus except where the failure of the gage or line

would not impair the performance or service life of the apparatus.

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

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

(2) Apparatus using liquefied breathing gas, except apparatus classified for escape only, shall be equipped with gages 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 gage.

§ 11.82 Timers; elapsed time indicators; remaining service life indicators; minimum requirements.

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

(1) Apparatus used for escape only; or,

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

(b) The timer or other indicator shall be accurately calibrated in minutes of 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 gage 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 when the remaining service life of the apparatus is reduced within a range of 20 to 25 percent of its rated service time.

§ 11.83 Hand-operated valves; minimum requirements.

(a) Hand-operated valves shall be designed and constructed to prevent removal of the stem from the valve body during normal usage to insure 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 bypass system valve control shall be colored red.

(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 breathing circuit on the inhalation side of the breathing bag reaches 13 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.

(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 manual overriding for test purposes and in the event of a failure in the valve or system.

§ 11.84 Breathing bags; minimum requirements.

(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.

§ 11.85 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 §§ 11.85-1 through 11.85-19.

§ 11.85-1 Component parts exposed to oxygen pressures; minimum requirements.

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.

§ 11.85-2 Compressed gas filters; minimum requirements.

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.

§ 11.85-3 Breathing bag test.

(a) Breathing bags will be tested in an air atmosphere saturated with gasoline vapor at room temperature (24-30° C./75-85° F.) 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 will 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 622 kg.-m./min. will be used.[1]

(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.

§ 11.85-4 Weight requirement.

(a) The completely assembled and fully charged apparatus shall not weigh more than 16 kg. (35 pounds); however, where the weight decreases by more than 25 percent of its initial charge weight during its rated service life, the maximum allowable weight of a completely assembled and fully charged apparatus shall be 18 kg. (40 pounds).

(b) Where an apparatus employs equipment which contributes materially to the wearer's comfort, e.g., a cooling system, the completely assembled and fully charged apparatus shall not weigh more than 18 kg. (40 pounds) regardless of the decrease in weight during use.

§ 11.85-5 Breathing resistance test; inhalation.

(a) Resistance to inhalation airflow will be measured in the facepiece or mouthpiece while the apparatus is operated by a breathing machine as described in § 11.85-3.

(b) The inhalation resistance of open-circuit apparatus shall not exceed 32 mm. (1.25 inch) water-column height (at a flow rate of 120 liters per minute).

(c) The inhalation resistance of closed-circuit apparatus shall not exceed the difference between exhalation resistance (§ 11.85-6(e)) and 10 cm. (4 inches) water-column height.

[1] Silverman, L., C. Lee, T. Piotkin, 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.

§ 11.85-6 Breathing resistance test; exhalation.

(a) Resistance to exhalation airflow will be measured in the facepiece or mouthpiece of open-circuit apparatus with air flowing at a continuous rate of 85 liters per minute.

(b) The exhalation resistance of demand apparatus shall not exceed 25 mm. (1 inch) water-column height.

(c) The exhalation resistance of pressure-demand apparatus shall not exceed the static pressure in the facepiece by more than 51 mm. (2 inches) water-column height.

(d) The static pressure (at zero flow) in the facepiece shall not exceed 38 mm. (1.5 inches) water-column height.

(e) Resistance to exhalation airflow will be measured in the facepiece or mouthpiece of closed-circuit apparatus with a breathing machine as described in § 11.85-3, and the exhalation resistance shall not exceed 51 mm. (2 inches) water-column height.

§ 11.85-7 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm. (1 inch) water-column height while in a normal operating position.

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

§ 11.85-8 Gas flow test; open-circuit apparatus.

(a) A static-flow test will be performed on all open-circuit apparatus.

(b) The flow from the apparatus shall be greater than 200 liters per minute when the pressure in the facepiece of demand-apparatus is lowered by 51 mm. (2 inches) water-column height when full container pressure is applied.

(c) Where pressure demand apparatus are tested, the flow will be measured at zero gage pressure in the facepiece.

(d) Where apparatus with compressed-breathing-gas containers are tested, the flow test shall also be made with 3,450 kN/m.[2] (500 p.s.i.g.) container pressure applied.

§ 11.85-9 Gas flow test; closed-circuit apparatus.

(a) Where oxygen is supplied by a constant-flow device only, the rate of flow shall be at least 3 liters per minute for the entire rated service time of the apparatus.

(b) Where constant flow is used in conjunction with demand flow, the constant flow shall be greater than 1.5 liters per minute for the entire rated service time.

(c) All demand-flow devices shall provide at least 30 liters of oxygen per minute when in the fully open position.

§ 11.85-10 Service time test; open-circuit apparatus.

(a) Service time will be measured with a breathing machine as described in § 11.85-3.

(b) The open-circuit apparatus will 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 will be used to classify the open-circuit apparatus in accordance with § 11.53.

§ 11.85-11 Service time test; closed-circuit apparatus.

(a) The closed-circuit apparatus will be classified according to the length of time it supplies adequate breathing gas to the wearer during man test No. 4 described in Table 4.

(b) The service time obtained on man test No. 4 will be used to classify the closed-circuit apparatus in accordance with § 11.53.

§ 11.85-12 Test for carbon dioxide in inspired gas; open- and closed-circuit apparatus; maximum allowable limits.

(a) Open-circuit apparatus:

(1) The concentration of carbon dioxide in inspired gas in open-circuit apparatus will be measured at the mouth while the apparatus mounted on a dummy head is operated by a breathing machine.[1]

[1] 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.

Continued

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

(3) A sedentary breathing machine cam will be used.

(4) The apparatus will be tested at a temperature of 27°±2° C. (80°±5° F.).

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

(b) Closed-circuit apparatus: (1) The concentration of carbon dioxide in inspired gas in closed-circuit apparatus will 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 in paragraphs (a)(1) through (5) 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 will be continuously recorded, and the maximum average concentration during the inhalation portion of the breathing cycle shall not exceed the following limits:

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 will be taken during the course of the man tests described in Tables 1, 2, 3, and 4. These gas samples will 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.

§ 11.85-13 Tests during low temperature operation.

(a) The applicant shall specify the minimum temperature for safe operation and two persons will 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 will be precooled at the specified minimum temperature for 4 hours.

(c) The apparatus will 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 will be required with the exercise periods consisting of stepping onto and off a box 21.5 cm. (8-½ inches) high at a rate of 30 cycles per minute.

(e) (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.

(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.

[37 FR 6244, Mar. 25, 1972, as amended at 41 FR 10892, Mar. 15, 1976]

§ 11.85-14 Man tests; testing conditions; general requirements.

(a) The man tests described in Tables 1, 2, 3, and 4 represent the workload performed in the mining, mineral, or allied industries by a person wearing the apparatus tested.

(b) The apparatus tested will be worn by Institute personnel trained in the use of self-contained breathing apparatus using a mouthpiece only, the sample shall not contain more than 1.5 percent carbon dioxide at any time.

paratus, and the wearer will, before participating in these tests, pass a physical examination conducted by a qualified physician.

(c) All man tests will be conducted by the Institute.

(d) The apparatus will be examined before each man test to ensure that it is in proper working order.

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

(f) Man tests 1, 2, 3, 4, 5, and 6 will be conducted in duplicate.

(g) If man tests are not completed through no fault of the apparatus, the test will be repeated.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.85-15 Man tests 1, 2, 3, and 4; requirements.

(a) Man 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 will 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.

§ 11.85-16 Man test 5; requirements.

(a) Test 5 will be conducted to determine the maximum length of time the apparatus will supply the respiratory needs of the wearer while he is sitting at rest.

(b) The wearer will manipulate the devices controlling the supply of breathing gas to the advantage of the apparatus.

(c) Samples of inspiration from within the apparatus facepiece or mouthpiece shall be taken once every 15 minutes, and shall meet the minimum requirement for oxygen specified in § 11.79(a), and the maximum allowable average concentration of carbon dioxide specified in § 11.85-12(c).

(d) One sample of inspiration will be taken in the case of 3-, 5-, and 10-minute apparatus.

§ 11.85-17 Man test 6; requirements.

(a) Man test 6 will be conducted with respect to liquefied breathing gas apparatus only.

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

(c) The wearer will 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.

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

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

§ 11.85-18 Man tests; performance 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. (75°±10° F.), the maximum temperature of inspired air recorded during man tests shall not exceed the following, after correction for deviation from 24° C. (75° F.):

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.
½ hour or less	0-100	135	57
½ hour to ¾ hour	0-50	125	52
	50-100	[1]110	[1]43
1 to 2 hours	0-50	115	46
	50-100	[1]105	[1]41
3 hours	0-50	110	43
	50-100	[1]100	[1]38
4 hours	0-50	105	41
	50-100	[1]95	[1]35

[1] Where percent relative humidity is 50-100 and apparatus is designed for escape only, these maximum permissible temperatures will be increased by 5° C. (10° F.).

§ 11.85-19 Gas tightness test; minimum requirements.

(a) Each apparatus will be tested for tightness by persons wearing it in an atmosphere of 1,000 p.p.m. isoamyl acetate.

(b) Six persons will each wear the apparatus in the test concentrations specified in paragraph (a) of this section for 2 minutes and none shall detect the odor or taste of the test vapor.

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

[30 CFR Part 11, Subpart H, § 11.85, 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	Perform 1 hour test 2, 3, or 4 times respectively.
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	

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

[30 CFR Part 11, Subpart H, § 11.85, et seq.]

Activity	Service time—							
	3 minutes	75 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3 and 4 hours [1]
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) weight over overcast.			1 time in 2 minutes.	1 time in 2 minutes.	2 times in 4 minutes.	3 times in 8 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 [2] (or equivalent)	1	1	1	1	1	1	1	1.
Walks at 4.8 km. (3 miles) 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) weight 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 km. (3 miles) per hour			2			2	3	
Climbs vertical treadmill (or equivalent)						1	1	
Carries 20 kg. (45 pound) weight and walks at 4.8 km. (3 miles) per hour.	1						2	
Walks at 4.8 km. (3 miles) per hour	1	2				1	4	
Sampling and readings				2	2	2	2	

[1] Total test time for Test 2 for 2-hour, 3-hour, and 4-hour apparatus is 2 hours.
[2] 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

[30 CFR Part 11, Subpart H, § 11.85, et seq.]

Activity	Service time—							
	3 minutes	75 minutes	10 minutes	15 minutes	30 minutes	45 minutes	1 hour	2, 3 and 4 hours [1]
Sampling and readings				2	2	2	2	(1)
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 pound) weight 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	½	1	1	2	3	4	5	
Lies on back	½	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 pound) weight 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	

[1] Total test time for Test 3 for 2-hour, 3-hour, and 4-hour apparatus is 2 hours.
[2] Perform test No. 3 for 1 hr. apparatus; then perform test No. 1 for 1 hour apparatus.

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

[30 CFR Part 11, Subpart H, § 11.85, 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	(2)	(2)	(2)
Walks at 4.8 km. (3 miles) per hour.				1	2	2	2			

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

[30 CFR Part 11, Subpart H, § 11.85, 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
Climbs vertical treadmill [1] (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) weight 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) weight over overcast.				1 time in 1 minute.	1 time in 1 minute.	2 times in 3 minutes.	4 times in 6 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) weight 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 (45 pound) weight to 5 feet.	15 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) weight to 5 feet.						60 times in 5 minutes.	60 times in 5 minutes.			
Carries 20 kg. (45 pound) weight and walks at 4.8 km. (3 miles) per hour.						3	3			
Sampling and readings.						2	2			

[1] Treadmill shall be inclined 15° from vertical and operated at a speed of 30 cm. (1 foot) per second.

[redacted]

[2] Perform test No. 1 for 30-minute apparatus; then perform test No. 1 for 1-hour apparatus; then perform test No. 1 for 30-minute apparatus.
[3] 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.
[4] 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).

Subpart I—Gas Masks

§ 11.90 Gas masks; description.

(a) Gas masks including all completely assembled air purifying masks designed for use as respiratory protection during entry into atmospheres not immediately dangerous to life or health or escape only from hazardous atmospheres containing adequate oxygen to support life are described as follows:

(1) *Front-mounted or back-mounted gas mask.* A gas mask which consists of a full facepiece, a breathing tube, a canister at the front or back, a canister harness, and associated connections.

(2) *Chin-style gas mask.* A gas mask which consists of a full facepiece, a canister which is usually attached to the facepiece, and associated connections.

(3) *Escape gas mask.* A gas mask designed for use during escape only from hazardous atmospheres which consists of a facepiece or mouthpiece, a canister, and associated connections.

(b) Gas masks shall be further described according to the types of gases or vapors against which they are designed to provide respiratory protection, as follows:

Type of front-mounted or back-mounted gas mask

Acid gas[1 4 5]
Ammonia
Carbon monoxide
Organic Vapor [2 4 5]
Other gas(es) and vapor(s) [2 4 5]
Combination of two or more of the above gases and vapors.[2 4 5]
Combination of acid gas, ammonia, carbon monoxide, and organic vapors.[2 4 5]

Type of chin-style gas mask

Acid gas [2 4 5]
Ammonia
Carbon monoxide
Organic vapor [2 4 5]
Other gas(es) and vapor(s) [2*4 5]
Combination of two or more of the above gases and vapors.[2 4 5]

Type of escape gas mask

Acid gas [3 4 5 6]
Ammonia [3]
Carbon monoxide
Organic vapor [3 4 5 6]
Other gas(s) and vapor(s) [3 4 5 6]
Combination of two or more of the above gases and vapors.[3 4 5 6]

(c) Gas masks for respiratory protection against gases and vapors other than those specified in paragraph (b) of this section, may be approved upon submittal of an application in writing for approval to the Testing and Certification Laboratory listing the gas or vapor and suggested maximum use concentration for the specific type of gas mask. The Institute and MSHA will consider the application and accept or reject it on the basis of effect on the wearer's health and safety and any field experience in use of gas masks for such exposures. If the application is accepted, the Institute will test such masks in accordance with the requirements of this subpart.

NOTE: For information on safe use concentrations and for information governing the selection, use, and maintenance of gas masks, the gas mask user should refer to regulations issued by the Mine Safety and Health Administration or by the Occupational Safety and Health Administration, and to other applicable regulations concerning gas masks. Recommendations based on such regulations may also be obtained from the National Institute for Occupational Safety and Health, 944 Chestnut Ridge Road, Morgantown, W. Va. 26505, Attention: Director, TCL; or from the NIOSH Regional Consultants for Occupational Safety and Health in the DHHS Regional Offices throughout the country.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6994, Mar. 15, 1973; 41 FR 10893, Mar. 15, 1976; 42 FR 65167, Dec. 30, 1977; 47 FR 28095, June 29, 1982]

[1] Approval may be for acid gases or organic vapors as a class or for specific acid gases or organic vapors.

[2] Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent materials in the canister.

[3] Use of the gas mask may be limited by factors such as lower explosive limit, toxicological effects, and facepiece fit. Limitations on gas mask service life and sorbent capacity limitations, shall be specified by the applicant in instructions for selection, use and maintenance of the gas mask.

[4] Eye protection may be required in certain concentrations of gases and vapors.

§ 11.91 Gas masks; required components.

(a) Each gas mask described in § 11.90 shall, where its design requires, contain the following component parts:

(1) Facepiece or mouthpiece and noseclip;
(2) Canister or cartridge;
(3) Canister harness;
(4) External check valve; and
(5) Breathing tube.

(b) The components of each gas mask shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.92 Canisters and cartridges in parallel; resistance requirements.

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

§ 11.93 Canisters and cartridges; color and markings; 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, K 13.1-1973, obtainable from the American National Standards Institute, Inc.; 1430 Broadway; New York, N.Y. 10018.

[41 FR 10894, Mar. 15, 1976]

§ 11.94 Filters used with canisters and cartridges; location; replacement.

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

(b) Filters shall be incorporated in 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 in the canister or cartridge.

§ 11.95 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with gas masks shall be designed and constructed to prevent:

(1) Restriction of free head movement;
(2) Disturbance of the fit of facepieces or mouthpieces;
(3) Interference with the wearer's activities; and,
(4) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 11.96 Harnesses; installation and construction; minimum requirements.

(a) Each gas mask shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the gas mask in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of gas mask parts, and where applicable, provide for holding a full facepiece in the ready position when not in use.

§ 11.97 Gas mask containers; minimum requirements.

(a) Gas masks shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of mask it contains and all appropriate approval labels.

(b) Containers for gas masks shall be designed and constructed to permit easy removal of the mask.

§ 11.98 Half-mask facepieces, full facepieces and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the gas mask.

(c) Half-mask facepieces shall not interfere with the fit of common industrial safety spectacles, as determined by the Institute's facepiece tests in § 11.102-3.

(d) Gas masks with mouthpieces shall be equipped with noseclips which

are securely attached to the mouthpiece or gas mask and provide an airtight seal.

(e) Facepieces shall be designed to prevent eyepiece fogging.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.99 Facepieces; eyepieces; minimum requirements.

(a) Full facepieces shall be designed and constructed to provide adequate vision which is not distorted by the eye.

(b) All eyepieces shall be designed and constructed to meet the impact and penetration requirements specified in Federal Specification, Mask, Air Line: and Respirator, Air Filtering, Industrial, GGG-M-125d, October 11, 1965.

§ 11.100 Inhalation and exhalation valves; minimum requirements.

(a) Inhalation and exhalation valves shall be provided where necessary and protected against damage and distortion.

(b) Inhalation valves shall be designed and constructed to prevent excessive exhaled air from adversely affecting cartridges, canisters, and filters.

(c) Exhalation valves shall be protected against external influence, and designed and constructed to prevent inward leakage of contaminated air.

§ 11.101 Head harnesses; minimum requirements.

(a) Facepieces shall be equipped with adjustable and replaceable 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) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place.

§ 11.102 Gas masks; performance requirements; general.

Gas masks and the individual components of each such device shall, as appropriate, meet the requirements for performance and protection specified in the tests described in §§ 11.102-1 through 11.102-5.

§ 11.102-1 Breathing resistance test; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece or mouthpiece of a gas mask mounted on a breathing machine both before and after each test conducted in accordance with §§ 11.102-3, 11.102-4, and 11.102-5, with air flowing at a continuous rate of 85 liters per minute.

(b) The maximum allowable resistance requirements for gas masks are as follows:

MAXIMUM RESISTANCE

[mm. water-column height]

Type of gas mask	Inhalation		Exhalation
	Initial	Final [1]	
Front-mounted or back-mounted (without particulate filter)	60	75	20
Front-mounted or back-mounted (with approved particulate filter)	70	85	20
Chin-style (without particulate filter)	40	55	20
Chin-style (with approved particulate filter)	65	80	20
Escape (without particulate filter)	60	75	20
Escape (with approved particulate filter)	70	85	20

[1] Measured at end of the service life specified in Tables 5, 6, and 7.

§ 11.102-2 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will 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 milliliters per minute.

§ 11.102-3 Facepiece tests; minimum requirements.

(a) The complete gas mask will be fitted to the faces of persons having varying facial shapes and sizes.

(b) Where the applicant specifies a facepiece size or sizes for the gas mask, together with the approximate measurements of faces they are designed to fit, the Institute will insure that test subjects suit such facial measurements.

(c) Any gas mask parts which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing the facepiece or mouthpiece fit.

(d) The facepiece or mouthpiece fit test, using positive or negative pressure recommended by the applicant and described in his instructions will be used before each test specified in paragraph (e) of this section, and in § 11.102-4.

(e) (1) Each wearer will enter a chamber containing 100 p.p.m. isoamyl acetate vapor for a half-mask facepiece and 1,000 p.p.m. isoamyl acetate vapor for a full facepiece or mouthpiece.

(2) The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the tests.

(3) Each wearer will remain in the chamber for 8 minutes while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place, and

(iv) Two minutes, pumping with a tire pump into a 28 liter (1 cubic foot) container.

(4) Each wearer shall not detect the odor of isoamyl acetate during the test.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.102-4 Dust, fume, mist, and smoke tests; canisters containing filters; minimum requirements.

(a) Gas mask canisters containing filters for protection against dusts, fumes, mists, and smokes in combination with gases, vapors, or gases and vapors, will be tested as prescribed in § 11.140.

(b) Gas mask canisters designed for protection against smokes will be tested in an atmospheric concentration of 100 micrograms of dioctyl phthalate per liter of air at continuous flow rates of (1) 32 liters per minute, and (2) 85 liters per minute for a period of 5 to 10 seconds, and the DOP leakage through the canister shall not exceed 0.03 percent of the test concentration.

§ 11.102-5 Canister bench tests; minimum requirements.

(a) (1) Bench tests, except for carbon monoxide tests, will be made on an apparatus that allows the test atmosphere at 50±5 percent relative humidity and room temperature (25°±2.5° C.) to enter the canister continuously at concentrations and rates of flow specified in Tables 5, 6, and 7.

(2) Three canisters will be removed from containers and tested as received from the applicant.

(3) Two canisters, other than those described in paragraph (a)(2) of this section, will be equilibrated at room temperature by passing 25 percent relative humidity air through them at 64 liters per minute for 6 hours.

(4) Two canisters, other than those described in paragraphs (a)(2) and (3) of this section, will be equilibrated at room temperature by passing 85 percent relative humidity air through them at 64 liters per minute for 6 hours.

(5) The equilibrated canisters will be resealed, kept in an upright position at room temperature, and tested within 18 hours.

(b) Front-mounted and back-mounted gas mask canisters will be tested and shall meet the minimum requirements set forth in Table 5.

(c) (1) Front-mounted, and back-mounted, and chin-style canisters designated as providing respiratory protection against gases, ammonia, organic vapors, carbon monoxide and particulate contaminants shall have a window or other indicator to warn the gas mask wearer when the canister will no longer satisfactorily remove carbon monoxide from the inhaled air.

(2) Other types of front- and back-mounted 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 will be tested as regular canisters, but shall show a satisfactory indicator change or other warning before the al-

lowable canister penetration has occurred.

(d) Chin-style gas mask canisters shall meet the minimum requirements set forth in Table 6.

(e) Escape gas mask canisters shall meet the minimum requirements set forth in Table 7.

TABLE 5—CANISTER BENCH TESTS AND REQUIREMENTS FOR FRONT-MOUNTED AND BACK-MOUNTED GAS MASK CANISTERS

[30 CFR Part 11, Subpart I, § 11.102-5]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes)[1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute			
Acid gas	As received	SO_2	20,000	64	3	5	12
		Cl_2	20,000	64	3	5	12
	Equilibrated	SO_2	20,000	32	4	5	12
		Cl_2	20,000	32	4	5	12
Organic vapor	As received	CCl_4	20,000	64	3	5	12
	Equilibrated	CCl_4	20,000	32	4	5	12
Ammonia	As received	NH_3	30,000	64	3	50	12
	Equilibrated	NH_3	30,000	32	4	50	12
Carbon monoxide	As received	CO	20,000	[2]64	2	(3)	[4]60
		CO	5,000	[4]32	3	(3)	60
		CO	3,000	[4]32	3	(3)	60
Combination of 2 or 3 of above types[5]							
Combination of all of above types[6]							

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere will be 25±2.5° C.
[3] Maximum allowable CO penetration will be 385 cm³ during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere entering the test fixture will be 0 +2.5° C −0°.
[5] Test conditions and requirements will be applicable as shown above.
[6] Test conditions and requirements will be applicable as shown above, except the minimum service lives for acid as, organic vapor, and ammonia will be 6 min instead of 12 min.

TABLE 6—CANISTER BENCH TESTS AND REQUIREMENTS FOR CHIN-STYLE GAS MASK CANISTERS

[30 CFR Part 11, Subpart I, § 11.102-5]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes)[1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute			
Acid gas	As received	SO_2	5,000	64	3	5	12
		Cl_2	5,000	64	3	5	12
	Equilibrated	SO_2	5,000	32	4	5	12
		Cl_2	5,000	32	4	5	12
Organic vapor	As received	CCl_4	5,000	64	3	5	12
	Equilibrated	CCl_4	5,000	32	4	5	12
Ammonia	As received	NH_3	5,000	64	3	50	12
	Equilibrated	NH_3	5,000	32	4	50	12
Carbon monoxide	As received	CO	20,000	[2]64	2	(3)	60
		CO	5,000	[4]32	3	(3)	60
		CO	3,000	[4]32	3	(3)	60
Combination of 2 or 3 of above types[5]							
Combination of all of above types[6]							

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere will be 25±2.5° C.
[3] Maximum allowable CO penetration will be 385 cm³ during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere entering the test fixture will be 0 ±2.5° C −0°.

[5] Test conditions and requirements will be applicable as shown above.
[6] Test conditions and requirements will be applicable as shown above, except the minimum service lives for acid gas organic vapor, and ammonia will be 6 min instead of 12 min.

TABLE 7—CANISTER BENCH TESTS AND REQUIREMENTS FOR ESCAPE GAS MASK CANISTERS

[30 CFR Part 11, Subpart I, § 11.102-5]

Canister type	Test condition	Test atmosphere			Number of tests	Maximum allowable penetration (parts per million)	Minimum service life (minutes)[1]
		Gas or vapor	Concentration (parts per million)	Flow rate (liters per minute			
Acid gas	As received	SO_2	5,000	64	3	5	12
		Cl_2	5,000	64	3	5	12
	Equilibrated	SO_2	5,000	32	4	5	12
		Cl_2	5,000	32	4	5	12
Organic vapor	As received	CCl_4	5,000	64	3	5	12
	Equilibrated	CCl_4	5,000	32	4	5	12
Ammonia	As received	NH_3	5,000	64	3	50	12
	Equilibrated	NH_3	5,000	32	4	50	12
Carbon monoxide	As received	CO	10,000	[2]32	2	(3)	[4]60
		CO	5,000	[4]32	3	(3)	60
		CO	3,000	[4]32	3	(3)	60

[1] Minimum life will be determined at the indicated penetration.
[2] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere will be 25±2.5° C.
[3] Maximum allowable CO penetration will be 385 cm³ during the minimum life. The penetration shall not exceed 500 p/m during this time.
[4] If effluent temperature exceeds 100° C during this test, the escape gas mask shall be equipped with an effective heat exchanger.
[5] Relative humidity of test atmosphere will be 95±3pct; temperature of test atmosphere entering the test fixture will be 0 +2.5° C −0° C.

[37 FR 6244, Mar. 25, 1972, as amended at 41 FR 10893, Mar. 15, 1976; 41 FR 12302, Mar. 25, 1976]

Subpart J—Supplied-Air Respirators

§ 11.110 Supplied-air respirators; description.

(a) Supplied-air respirators, including all completely assembled respirators designed for use as respiratory protection during entry into and escape from atmospheres not immediately dangerous to life or health are described as follows:

(1) *Type "A" supplied-air respirators.* A hose mask respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a motor-driven or hand-operated blower that permits the free entrance of air when the blower is not operating, a strong large-diameter hose having a low resistance to airflow, a harness to which the hose and the life-line are attached and a tight-fitting facepiece.

(2) *Type "AE" supplied-air respirators.* A Type "A" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods, and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

(3) *Type "B" supplied-air respirators.* A hose mask respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a strong large-diameter hose with low resistance to airflow through which the user draws inspired air by means of his lungs alone, a harness to which the hose is attached, and a tight-fitting facepiece.

(4) *Type "BE" supplied-air respirators.* A type "B" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods,

and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

(5) *Type "C" supplied-air respirators.* An airline respirator, for entry into and escape from atmospheres not immediately dangerous to life or health, which consists of a source of respirable breathing air, a hose, a detachable coupling, a control valve, orifice, a demand valve or pressure demand valve, an arrangement for attaching the hose to the wearer, and a facepiece, hood, or helmet.

(6) *Type "CE" supplied-air respirators.* A type "C" supplied-air respirator equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material, and with shielding material such as plastic, glass, woven wire, sheet metal, or other suitable material to protect the window(s) of facepieces, hoods, and helmets which do not unduly interfere with the wearer's vision and permit easy access to the external surface of such window(s) for cleaning.

[37 FR 6244, Mar. 25, 1972, as amended at 42 FR 65167, Dec. 30, 1977]

§ 11.111 Supplied-air respirators; required components.

(a) Each supplied-air respirator described in § 11.110 shall, where its design requires, contain the following component parts:

(1) Facepiece, hood, or helmet;

(2) Air supply valve, orifice, or demand or pressure-demand regulator;

(3) Hand operated or motor driven air blower;

(4) Air supply hose;

(5) Detachable couplings;

(6) Flexible breathing tube; and

(7) Respirator harness.

(b) The component parts of each supplied-air respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.112 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with supplied-air respirators shall be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

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

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

§ 11.113 Harnesses; installation and construction; minimum requirements.

(a) Each supplied-air respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

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

§ 11.114 Respirator containers; minimum requirements.

Supplied-air respirators shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains, and all appropriate approval labels.

§ 11.115 Half-mask facepieces, full facepieces, hoods, and helmets; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either (1) by providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(d) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

§ 11.116 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

(a) Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.

(b) All eyepieces except those on Types B, BE, C, and CE supplied-air respirators shall be designed and constructed to meet the impact and penetration requirements specified in Federal Specification, Mask, Air Line, and Respirator, Air Filtering, Industrial GGG-M-125d, October 11, 1965.

(c) (1) The eyepieces of AE, BE, and CE type supplied-air respirators shall be shielded by plastic, glass, woven wire, sheet metal, or other suitable material which does not interfere with the vision of the wearer.

(2) Shields shall be mounted and attached to the facepiece to provide easy access to the external surface of the eyepiece for cleaning.

§ 11.117 Inhalation and exhalation valves; check valves; minimum requirements.

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

(b) Exhalation valves shall be:

(1) Protected against damage and external influence; and

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

(c) Check valves designed and constructed to allow airflow toward the facepiece only shall be provided in the connections to the facepiece or in the hose fitting near the facepiece of all Type A, AE, B, and BE supplied-air respirators.

§ 11.118 Head harnesses; minimum requirements.

Facepieces shall be equipped with adjustable and replaceable head harnesses which are designed and constructed to provide adequate tension during use, and an even distribution of pressure over the entire area in contact with the face.

§ 11.119 Head and neck protection; supplied-air respirators; minimum requirements.

Type AE, BE, and CE supplied-air respirators shall be designed and constructed to provide protection against impact and abrasion from rebounding abrasive materials to the wearer's head and neck.

§ 11.120 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable within pressure and hose length requirements and shall not exceed 80 dBA.

§ 11.121 Breathing gas; minimum requirements.

(a) Breathing gas used to supply supplied-air respirators shall be respirable breathing air and contain no less than 19.5 volume-percent of oxygen.

(b) Compressed, gaseous breathing air shall meet the applicable minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association Commodity Specification for Air, G-7.1 (Grade D or higher quality).

(c) Compressed, liquefied breathing air shall meet the applicable minimum grade requirements for Type II liquid air set forth in the Compressed Gas Association Commodity Specification for Air, G-7.1 (Grade B or higher quality).

§ 11.122 Air supply source; hand-operated or motor driven air blowers; Type A supplied-air respirators; minimum requirements.

(a) Blowers shall be designed and constructed to deliver an adequate amount of air to the wearer with either direction of rotation, unless constructed to permit rotation in one direction only, and to permit the free entrance of air to the hose when the blower is not operated.

(b) No multiple systems, whereby more than one user is supplied by one blower, will be approved, unless each hose line is connected directly to a manifold at the blower.

§ 11.123 Terminal fittings or chambers; Type B supplied-air respirators; minimum requirements.

(a) Blowers or connections to air supplies providing positive pressures shall not be approved for use on Type B supplied-air respirators.

(b) Terminal fittings or chambers employed in Type B supplied-air respirators, shall be:

(1) Installed in the inlet of the hose.

(2) Designed and constructed to provide for the drawing of air through corrosion resistant material arranged so as to be capable of removing material larger than 0.149 mm. in diameter (149 micrometers, 100-mesh, U.S. Standard sieve).

(3) Installed to provide a means for fastening or anchoring the fitting or chamber in a fixed position in a zone of respirable air.

§ 11.124 Supplied-air respirators; performance requirements; general.

Supplied-air 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 §§ 11.124-1 through 11.124-24.

§ 11.124-1 Hand-operated blower test; minimum requirements.

(a) Hand-operated blowers shall be tested by attaching them to a mechanical drive and operating them 6 to 8 hours daily for a period of 100 hours at a speed necessary to deliver 50 liters of air per minute through each completely assembled respirator. Each respirator shall be equipped with the maximum length of hose with which the device is to be approved and the hose shall be connected to each blower or manifold outlet designed for hose connections.

(b) The crank speed of the hand-operated blower shall not exceed 50 revolutions per minute in order to deliver the required 50 liters of air per minute to each facepiece.

(c) The power required to deliver 50 liters of air per minute to each wearer through the maximum length of hose shall not exceed one-fiftieth horsepower, and the torque shall not exceed a force of 2.3 kg. (5 pounds) on a 20 cm. (8-inch) crank, as defined in § 11.124-3.

(d) The blower shall operate throughout the period without failure or indication of excessive wear of bearings or other working parts.

§ 11.124-2 Motor-operated blower test; minimum requirements.

(a) Motor-operated blowers shall be tested by operating them at their specified running speed 6 to 8 hours daily for a period of 100 hours when assembled with the kind and maximum length of hose for which the device is to be approved and when connected to each blower or manifold outlet designed for hose connections.

(b) The connection between the motor and the blower shall be so constructed that the motor may be disengaged from the blower when the blower is operated by hand.

(c) The blower shall operate throughout the period without failure or indication of excessive wear of bearings or other working parts.

(d) Where a blower, which is ordinarily motor driven, is operated by hand, the power required to deliver 50 liters of air per minute to each wearer through the maximum length of hose shall not exceed one-fiftieth horsepower, and the torque shall not exceed a force of 2.3 kg. (5 pounds) on a 20 cm. (8-inch) crank, as defined in § 11.124-3.

(e) Where the respirator is assembled with the facepiece and 15 m. (50 feet) of the hose for which it is to be approved, and when connected to one outlet with all other outlets closed and operated at a speed not exceeding 50 revolutions of the crank per minute, the amount of air delivered into the respiratory-inlet covering shall not exceed 150 liters per minute.

§ 11.124-3 Method of measuring the power and torque required to operate blowers.

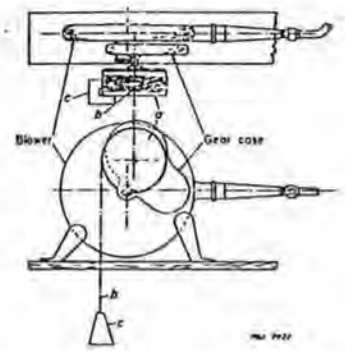

FIGURE 1—Apparatus for measuring power required to operate blower. (30 CFR Part 11, Subpart J, § 11.124-3)

As shown in Figure 1, the blower crank is replaced by a wooden drum, *a* (13 cm. (5 inches) in diameter is convenient). This drum is wound with about 12 m. (40 feet) of No. 2 picture cord, *b*. A weight, *c*, of sufficient mass to rotate the blower at the desired speed is suspended from this wire cord. A mark is made on the cord about 3 to 4.5 m. (10 to 15 feet) from the weight, *c*. Another mark is placed at a measured distance (6-9 m./20-30 feet is convenient) from the first. These are used to facilitate timing. To determine the torque or horsepower required to operate the blower, the drum is started in rotation manually at or slightly above the speed at which the power measurement is to be made. The blower is then permitted to assume constant speed, and then as the first mark on the wire leaves the drum, a stopwatch is started. The watch is stopped when the second mark leaves the drum. From these data the foot-pounds per minute and the torque may be calculated.

§ 11.124-4 Type B supplied-air respirator; minimum requirements.

No Type B supplied-air respirator shall be approved for use with a blower or with connection to an air supply device at positive pressures.

§ 11.124-5 Type C supplied-air respirator, continuous flow class; minimum requirements.

(a) Respirators tested under this section shall be approved only when they supply respirable air at the pressures and quantities required.

(b) The pressure at the inlet of the hose connection shall not exceed 863 kN/m.^{2} (125 pounds per square inch gage).

(c) Where the pressure at any point in the supply system exceeds 863 kN/m.^{2} (125 pounds per square inch gage), the respirator shall be equipped with a pressure-release mechanism that will prevent the pressure at the hose connection from exceeding 863 kN/m.^{2} (125 pounds per square inch gage) under any conditions.

§ 11.124-6 Type C supplied-air respirator, demand and pressure demand class; minimum requirements.

(a) Respirators tested under this section shall be approved only when used to supply respirable air at the pressures and quantities required.

(b) The manufacturer shall specify the range of air pressure at the point of attachment of the air-supply hose to the air-supply system, and the range of hose length for the respirator. For example, he might specify that the respirator be used with compressed air at pressures ranging from 280-550 kN/m.^{2} (40 to 80 pounds per square inch) with from 6 to 76 m. (15 to 250 feet) of air-supply hose.

(c) The specified air pressure at the point of attachment of the hose to the air-supply system shall not exceed 863 kN/m.^{2} (125 pounds per square inch gage).

(d) (1) Where the pressure in the air-supply system exceeds 863 kN/m.^{2} (125 pounds per square inch gage), the respirator shall be equipped with a pressure-release mechanism that will prevent the pressure at the point of attachment of the hose to the air-supply system from exceeding 863 kN/m.^{2} (125 pounds per square inch gage).

(2) The pressure-release mechanism shall be set to operate at a pressure not more than 20 percent above the manufacturer's highest specified pressure. For example, if the highest speci-

fied pressure is 863 kN/m.² (125 pounds per square inch), the pressure-release mechanism would be set to operate at a maximum of 1,035 kN/m.² (150 pounds per square inch).

§ 11.124-7 Air-supply line tests; minimum requirements.

Air supply lines employed on Type A, Type B, and Type C supplied-air respirators shall meet the minimum test requirements set forth in Table 8.

TABLE 8—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS

[30 CFR Part 11, Subpart J, § 11.124-7]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
Length of hose	Maximum of 91 m. (300 feet), in multiples of 7.6 m. (25 feet).	Maximum of 23 m. (75 feet) in multiples of 7.6 m. (25 feet).	Maximum of 91 m. (300 feet) in multiples of 7.6 m. (25 feet). It will be permissible for the applicant to supply hose of the approved type of shorter length than 7.6 m. (25 feet) provided it meets the requirements of the part.
Air flow	None	None	The air-supply hose with air regulating valve or orifice shall permit a flow of not less than 115 liters (4 cubic feet) per minute to tight-fitting and 170 liters (6 cubic feet) per minute to loose-fitting respiratory-inlet coverings 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 for which approval is granted.
Air flow	do	do	The air-supply hose, detachable coupling, and demand valve of the demand class or pressure-demand valve of the pressure-demand class for Type C supplied-air respirators, demand and pressure-demand classes, shall be capable of delivering respirable air at a rate of not less than 115 liters (4 cubic feet) per minute to the respiratory-inlet covering at an inhalation resistance not exceeding 50 millimeters (2 inches) of water-column height measured in the respiratory-inlet covering with any combination of air-supply pressure and length of hose within the applicant's specified range of pressure and hose length. The airflow rate and resistance to inhalation shall be measured while the demand or pressure-demand valve is actuated 20 times per minute by a source of intermittent suction. The maximum rate of flow to the respiratory-inlet covering shall not exceed 425 liters (15 cubic feet) per minute under the specified operating conditions.
Air-regulating valve	do	do	If an air-regulating valve is provided, 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.

TABLE 8—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS—Continued

[30 CFR Part 11, Subpart J, § 11.124-7]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
			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 (4 cubic feet) of air per minute to tight-fitting and 170 liters (6 cubic feet) of air per minute of loose-fitting respiratory inlet coverings for any adjustment of the valve. If a demand or pressure-demand valve replaces the air-regulating valve, it shall be connected to the air-supply at the maximum air pressure for which approval is sought by means of the minimum length of air-supply hose for which approval is sought. The outlet of the demand or pressure-demand valve shall be connected to a source of intermittent suction so that the demand or pressure-demand valve 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 MSHA. During this test the valve shall function without failure and without excessive wear of the moving parts.
			The demand or pressure-demand valve shall not be damaged in any way when subjected at the outlet to a pressure or suction of 25 cm. (10 inches) of water gage for 2 minutes.
Noncollapsibility	The hose shall not collapse or exhibit permanent deformation when a force of 90 kg. (200 pounds) is applied for 5 minutes between 2 planes 7.6 cm. (3 inches) wide on opposite sides of the hose.	Same as Type A	None.
Nonkinkability	None	None	A 7.6 m. (25 foot) section of the hose will 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 will 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.
Strength of hose and couplings	Hose and couplings shall not separate or fail when tested with a pull of 113 kg. (250 pounds) for 5 minutes.	Same as Type A	Hose and couplings shall not exhibit any separation or failure when tested with a pull of 45 kg. (100 pounds) for 5 minutes and when tested by subjecting them to an internal air pressure of 2 times the maximum respirator-supply pressure that is specified by the applicant or at 173 kN/m.² (25 pounds per square inch) gage, whichever is higher.

TABLE 6—AIR-SUPPLY-LINE REQUIREMENTS AND TESTS—Continued

[30 CFR Part 11, Subpart J, § 11.124-7]

Specific requirements	Requirements for the air-supply lines of the indicated type of supplied-air respirators		
	Type A	Type B	Type C
Tightness	No air leakage shall occur when the hose and couplings are joined and the joint(s) are immersed in water and subjected to an internal air pressure of 35 kN/m.² (5 pounds per square inch) gage.	None	Leakage of air exceeding 50 cc. per minute at each coupling shall not be permitted when the hose and couplings are joined and are immersed in water, with air flowing through the respirator under a pressure of 173 kN/m.² (25 pounds per square inch) gage applied to the inlet end of the air-supply hose, or at twice the maximum respirator-supply pressure that is specified by the applicant, whichever is higher.
Permeation of hose by gasoline	The permeation of the hose by gasoline will be tested by immersing 7.6 m (25 feet) of hose and one coupling in gasoline, with air flowing through the hose at the rate of 8 liters per minute for 6 hours. The air from the hose shall not contain more than 0.01 percent by volume of gasoline vapor at the end of the test.	Same as for Type A	Same as for Type A, except the test period shall be 1 hour.
Detachable coupling	None	None	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.

§ 11.124-8 Harness test; minimum requirements.

(a) (1) Shoulder straps employed on Type A supplied-air respirators shall be tested for strength of material, joints, and seams and must separately withstand a pull of 113 kg. (250 pounds) for 30 minutes without failure.

(2) Belts, rings, and attachments for life lines must withstand a pull of 136 kg. (300 pounds) for 30 minutes without failure.

(3) The hose shall be firmly attached to the harness so as to withstand a pull of 113 kg. (250 pounds) for 30 minutes without separating, and the hose attachments shall be arranged so that the pull or drag of the hose behind an advancing wearer does not disarrange the harness or exert pull upon the facepiece.

(4) The arrangement and suitability of all harness accessories and fittings will be considered.

(b) (1) The harness employed on Type B supplied-air respirators shall not be uncomfortable, disturbing, or interfere with the movements of the wearer.

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

(3) The hose shall be attached to the harness in a manner that will withstand a pull of 45 kg. (100 pounds) for 30 minutes without separating or showing signs of failure.

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

(5) The arrangement and suitability of all harness accessories and fittings will be considered.

(c) The harness employed on Type C respirators shall be similar to that required on the Type B respirator, or, it may 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 equivalent to dragging the maximum length of the hose over a concrete floor from exerting pull upon the respiratory-inlet covering.

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

§ 11.124-9 Breathing tube test; minimum requirements.

(a) (1) Type A and Type B supplied-air respirators shall employ one or two flexible breathing tubes of the nonkinking type which extend from the facepiece to a connecting hose coupling attached to the belt or harness.

(2) The breathing tubes employed shall permit free head movement, insure against closing off by kinking or by chin or arm pressure, and they shall not create a pull that will loosen the facepiece or disturb the wearer.

(b) Breathing tubes employed on Type C supplied-air respirators of the continuous flow class shall meet the minimum requirements set forth in paragraph (a) of this section, however, an extension of the connecting hose may be employed in lieu of the breathing tubes required.

(c) (1) A flexible, nonkinking type breathing tube shall: (i) Be employed on Type C supplied-air respirators of the demand and pressure-demand class; and (ii) extend from the facepiece to the demand or pressure-demand valve, except where the valve is attached directly to the facepiece.

(2) The breathing tube shall permit free head movement, insure 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.

§ 11.124-10 Airflow resistance test, Type A and Type AE supplied-air respirators; minimum requirements.

(a) Airflow resistance will be determined when the respirator is completely assembled with the respiratory-inlet covering, the air-supply device, and the maximum length of air-supply hose coiled for one-half its length in loops 1.5 to 2.1 m. (5 to 7 feet) in diameter.

(b) The inhalation resistance, drawn at the rate of 85 liters (3 cubic feet) per minute when the blower is not operating or under any practical condition of blower operation shall not exceed the following amounts:

Maximum length of hose for which respirator is approved		Maximum resistance, water column height	
Feet	Meters	Inches	Millimeters
75	23	1.5	38
150	46	2.5	64
250	76	3.5	89
300	91	4.0	102

(c) The exhalation resistance shall not exceed 25 mm. (1 inch) of water-column height at a flow rate of 85 liters (3 cubic feet) per minute when the blower is not operating or under any practical condition of blower operation.

§ 11.124-11 Airflow resistance test; Type B and Type BE supplied-air respirators; minimum requirements.

(a) Airflow resistance shall be determined when the respirator is completely assembled with the respiratory-inlet covering and the hose in the maximum length to be considered for approval, coiled in loops 1.5 to 2.1 m. (5 to 7 feet) in diameter.

(b) Airflow resistance shall not exceed 38 mm. (1.5 inches) of water-column height to air drawn at the flow rate of 85 liters (3 cubic feet) per minute.

(c) The exhalation resistance shall not exceed 25 mm. (1 inch) of water-column height at this flow rate.

§ 11.124-12 Airflow resistance test; Type C supplied-air respirator, continuous flow class and Type CE supplied-air respirator; minimum requirements.

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 respiratory-inlet covering is 115 liters (4 cubic feet) per minute.

§ 11.124-13 Airflow resistance test; Type C supplied-air respirator, demand class; minimum requirements.

(a) Inhalation resistance shall not exceed 50 millimeters (2 inches) of water at an air flow of 115 liters (4 cubic feet) per minute.

(b) The exhalation resistance to a flow of air at a rate of 85 liters (3 cubic feet) per minute shall not exceed 25 millimeters (1 inch) of water.

§ 11.124-14 Airflow resistance test; Type C supplied-air respirator, pressure-demand class; minimum requirements.

(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 (4 cubic feet) per minute.

(c) The exhalation resistance to a flow of air at a rate of 85 liters (3 cubic feet) per minute shall not exceed the static pressure in the facepiece by more than 51 mm. (2 inches) of water-column height.

§ 11.124-15 Exhalation valve leakage test.

(a) Dry exhalation valves and valve seats will 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 milliliters per minute.

§ 11.124-16 Man tests for gases and vapors; supplied-air respirators; general performance requirements.

(a) Wearers will enter a chamber containing a gas or vapor as prescribed in §§ 11.124-17, 11.124-18, 11.124-19, and 11.124-20.

(b) Each wearer will spend 10 minutes in work to provide observations on freedom of the device from leakage. The freedom and comfort allowed the wearer will also be considered.

(c) Time during the test period will be divided as follows:

(1) *Five minutes.* Walking, turning head, dipping chin; and

(2) *Five minutes.* Pumping air with a tire pump into a 28-liter (1 cubic foot) container, or equivalent work.

(d) No odor of the test gas or vapor shall be detected by the wearer in the air breathed during any such test, and the wearer shall not be subjected to any undue discomfort or encumbrance because of the fit, air delivery, or other features of the respirator during the testing period.

§ 11.124-17 Man test for gases and vapors; Type A and Type AE respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, and the blower, the intake of the hose, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The man in the isoamyl acetate atmosphere will draw his inspired air through the hose, connections, and all parts of the air device by means of his lungs alone (blower not operating).

(c) The 10-minute work test will be repeated with the blower in operation at any practical speed up to 50 revolutions of the crank per minute.

§ 11.124-18 Man test for gases and vapors; Type B and Type BE respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, and the intake of the hose, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The man in the isoamyl acetate atmosphere will draw his inspired air through the hose and connections by means of his lungs alone.

§ 11.124-19 Man test for gases and vapors; Type C respirators, continuous-flow class and Type CE supplied-air respirators; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, the intake of the hose will be connected to a suitable source of respirable air, and not more than 25 percent of the hose length will be located in isoamyl acetate-free air.

(b) The minimum flow of air required to maintain a positive pressure in the respiratory-inlet covering throughout the entire breathing cycle will be supplied to the wearer, provided however, that airflow shall not be less than 115 liters per minute for tight-fitting and not less than 170 liters per minute for loose-fitting respiratory inlet-coverings.

(c) The test will be repeated with the maximum rate of flow attainable within specified operating pressures.

§ 11.124-20 Man test for gases and vapors; Type C supplied-air respirators, demand and pressure-demand classes; test requirements.

(a) The completely assembled respirator will be worn in a chamber containing 0.1±0.025 percent isoamyl acetate vapor, the intake of the hose will be connected to a suitable source of respirable air, and not more than 25 percent of the hose length will be located in isoamyl acetate free air.

(b) The test will be conducted at the minimum pressure with the maximum hose length and will be repeated at the maximum pressure with the minimum hose length.

§ 11.124-21 Tests for protection during abrasive blasting; Type AE, Type BE, and Type CE supplied-air respirators; general performance requirements.

(a) Tests will be made under conditions of typical abrasive blasting operation.

(b) The tests prescribed in §§ 11.124-22, 11.124-23, and 11.124-24 will be conducted under the following conditions:

(1) A suction-feed abrasive blasting outfit will be used by the wearer;

(2) The diameter of the air jet shall be 5 mm. (3/16 inch);

(3) Air pressure will be 276-483 kN/m.^{2} (40-70 pounds per square inch);

(4) The abrasive used will contain a composition of 99+ percent free silica (SiO_2);

(5) The size properties of the abrasive used will be a mixture of 90 percent by weight of essentially No. 1 sandblast sand and 10 percent air-floated fines; and

(6) The No. 1 sand used will meet a size specification of not more than 10 percent on a 20-mesh sieve and not more than 10 percent through a 35-mesh sieve; 99+ percent of the fines will be able to pass through a 270-mesh sieve. All size determinations will be made by standard-mesh sieves.

(c) Tests will be conducted for 30 minutes continuously.

(d) (1) The person wearing the respirator will sandblast the inside surface of a common iron kettle of approximate hemispherical shape (about 76 cm. (30 inches) in diameter, and 113.6 liters (30 gallons) capacity).

(2) The kettle will be placed with the plane of the opening inclined 45° from a vertical position and with the lowest point of the rim at about the height of the person's hips.

(3) The wearer will stand at one position in front of the kettle and lean over until the upper part of the body is inclined to parallel the face of the kettle.

(4) The wearer will blast the entire inner surface of the kettle with the blast at all times directed approximately at right angles to the surface with the nozzle of the gun approximately 15 cm. (6 inches) from the surface, and with his head approximately 46 cm. (18 inches) from the nozzle.

(5) The wearer will move his head forward, backward, and sideways during each blasting operation.

(e)(1) Air will be withdrawn continuously during the test at the rate of 32 liters (1.13 cubic feet) per minute from the respiratory-inlet covering at a point as near as convenient to the wearer's nostrils.

(2) Simultaneously air will be drawn at the same rate from the source of intake air to the respirator.

(f) Respirators tested in accordance with §§ 11.124-22, 11.124-23, and

11.124-24 shall meet the following minimum requirements:

(1) The amount of particulate matter in the air withdrawn from the respiratory-inlet covering shall not exceed the amount of particulate matter supplied to the respirator by more than 0.5 mg. for the 30-minute test period;

(2) The wearer of the respirator in this test shall not experience undue encumbrance and discomfort because of the fit, air delivery, or other features of the respirator; and,

(3) The head and shoulder covering shall adequately protect the wearer from discomfort or injury due to impact or abrasion from the rebounding material during the test.

§ 11.124-22 Test for protection during abrasive blasting; Type AE supplied-air respirator; test requirements.

(a) The respirator will be arranged as prescribed in § 11.124-17(a), and the tests prescribed in § 11.124-21 will be performed.

(b) The wearer will draw his inspired air through the hose, connections, and all parts of the air device by means of his lungs alone (blower not operating).

(c) The test will be repeated with the blower in operation at any practical speed up to 50 revolutions per minute of the crank.

§ 11.124-23 Test for protection during abrasive blasting; Type BE supplied-air respirator; test requirements.

(a) The respirator will be arranged as prescribed in § 11.124-18(a), and the tests prescribed in § 11.124-21 will be performed.

(b) The wearer will draw his inspired air through the hose, connections, and all parts of the air device by means of his lungs alone.

§ 11.124-24 Test for protection during abrasive blasting; Type CE supplied-air respirator; test requirements.

(a) The respirator will be arranged as prescribed in § 11.124-19(a), and the tests prescribed in § 11.124-21 will be performed.

Subpart K—Dust, Fume, and Mist Respirators

§ 11.130 Dust, fume, and mist respirators; description.

Dust, fume, and mist respirators, including all completely assembled respirators designed for use as respiratory protection during entry into and escape from hazardous particulate atmospheres which contain adequate oxygen to support life, are described as follows:

(a) Respirators, either with replaceable or reusable filters, designed as respiratory protection against dusts (1) having an air contamination level not less than 0.05 milligram per cubic meter of air, including but not limited to coal, arsenic, cadmium, chromium, lead, and manganese; or (2) dusts having an air contamination level not less than 2 million particles per cubic foot of air, including but not limited to aluminum, flour, iron ore, and free silica, resulting principally from the disintegration of a solid, e.g., dust clouds produced in mining, quarrying, and tunneling, and in dusts produced during industrial operations, such as grinding, crushing, and the general processing of minerals and other materials.

(b) Respirators, with replaceable filters, designed as respiratory protection against fumes of various metals having an air contamination level not less than 0.05 milligram per cubic meter, including but not limited to aluminum, antimony, arsenic, cadmium, chromium, copper, iron, lead, magnesium, manganese, mercury (except mercury vapor), and zinc, which result from the sublimation or condensation of their respective vapors, or from the chemical reaction between their respective vapors and gases.

(c) Respirators, with replaceable filters, designed as respiratory protection against mists of materials having an air contamination level not less than 0.05 milligram per cubic meter or 2 million particles per cubic foot, e.g., mists produced by spray coating with vitreous enamels, chromic acid mist produced during chromium plating, and other mists of materials whose liquid vehicle does not produce harmful gases or vapors.

(d) Respirators, with replaceable filters, designed as respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter, including but not limited to lithium hydride and beryllium, and against radionuclides.

(e) Respirators, with replaceable filters, designed as respiratory protection against radon daughters, and radon daughters attached to dusts, fumes, and mists.

(f) Respirators, with replaceable filters, designed as respiratory protection against asbestos-containing dusts and mists.

(g) Respirators, with replaceable filters, designed as protection against various combinations of particulate matter.

(h) Single-use dust respirators designed as respiratory protection against pneumoconiosis- and fibrosis-producing dusts, or dusts and mists, including but not limited to aluminum, asbestos, coal, flour, iron ore, and free silica.

(i) The types of dust, fume, and mist respirators in paragraphs (a) through (g) of this section may also be classified according to their design as follows:

(1) Air-purifying respirators; and

(2) Powered air-purifying respirators.

§ 11.131 Dust, fume and mist respirators; required components.

(a) Each dust, fume, and mist respirator described in § 11.130 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece with noseclip, hood, or helmet;

(2) Filter unit;

(3) Harness;

(4) Attached blower; and

(5) Breathing tube.

(b) The components of each dust, fume, and mist respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.132 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

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

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

§ 11.133 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

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

§ 11.134 Respirator containers; minimum requirements.

(a) Except as provided in paragraph (b) of this section each respirator shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type of respirator it contains, and all appropriate approval labels.

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

§ 11.135 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(d) Mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

(f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles, as determined by the Institute's facepiece tests in §§ 11.140-1 and 11.140-2.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.136 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

§ 11.137 Inhalation and exhalation valves; minimum requirements.

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

(b) Inhalation valves shall be designed and constructed and provided where necessary to prevent excessive exhaled air from adversely affecting filters, except where filters are specifically designed to resist moisture as prescribed in § 11.140-5.

(c) Exhalation valves shall be: (1) Provided where necessary; (2) protected against damage and external influence; and (3) designed and constructed to prevent inward leakage of contaminated air.

§ 11.138 Head harnesses; minimum requirements.

(a) All 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) Facepiece head harnesses, except those employed on single-use respirators, shall be adjustable and replaceable.

(c) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses, designed and constructed to hold the mouthpiece in place.

§ 11.139 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable and shall not exceed 80 dBA.

§ 11.140 Dust, fume, and mist respirators; performance requirements; general.

Dust, fume, and mist 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 §§ 11.140-1 through 11.140-12 and prescribed in Tables 9 and 10.

§ 11.140-1 Isoamyl acetate tightness test; dust, fume, and mist respirators designed for respiratory protection against fumes of various metals having an air contamination level not less than 0.05 milligram per cubic meter; minimum requirements.

(a) The respirator will be modified in such a manner that all of the air that normally would be inhaled through the inhalation port(s) is drawn through an efficient activated charcoal-filled canister, or cartridge(s), without interference with the face-contacting portion of the facepiece.

(b) The modified respirator will be worn by persons for at least 2 minutes each in a test chamber containing 100 parts (by volume) of isoamyl-acetate vapor per million parts of air.

(c) The odor of isoamyl-acetate shall not be detected by the wearers of the modified respirator while in the test atmosphere.

§ 11.140-2 Isoamyl acetate tightness test; respirators designed for respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter, or against radionuclides; minimum requirements.

(a) The applicant shall provide a charcoal-filled canister or cartridge of a size and resistance similar to the filter unit with connectors which can be attached to the facepiece in the same manner as the filter unit.

(b)(1) The canister or cartridge will be used in place of the filter unit, and persons will each wear a modified half-mask facepiece for 5 minutes in a test chamber containing 100 parts (by volume) of isoamyl-acetate vapor per million parts of air.

(2) The following work schedule will be performed by each wearer in the test chamber:

(i) Two minutes walking, nodding, and shaking head in normal movements; and

(ii) Three minutes exercising and running in place.

(3) The facepiece shall be capable of adjustment, according to the applicant's instructions, to each wearer's face, and the odor of isoamyl-acetate shall not be detectable by any wearer during the test.

(c) Where the respirator is equipped with a full facepiece, hood, helmet, or mouthpiece, the canister or cartridge will be used in place of the filter unit, and persons will each wear the modified respiratory-inlet covering for 5 minutes in a test chamber containing 1,000 parts (by volume) of isoamyl-acetate vapor per million parts of air, performing the work schedule specified in paragraph (b)(2) of this section.

§ 11.140-3 Air-purifying filter tests; performance requirements; general.

Dust, fume, and mist respirators will be tested in accordance with the schedule set forth in Table 10 to determine their effectiveness as protection against the particulate hazards specified therein.

§ 11.140-4 Silica dust test; single-use or reusable filters; minimum requirements.

(a) Three respirators with single-use filters will be tested for periods of 90 minutes each at a continuous airflow rate of 32 liters per minute for air-purifying respirators, and for periods of 4 hours each at a flowrate not less than 115 liters per minute to tight-fitting facepieces, and not less than 170 liters per minute to loose-fitting hoods and helmets for powered air-purifying respirators.

(b) The relative humidity in the test chamber will be 20-80 percent, and the room temperature approximately 25° C.

(c) The test suspension in the chamber will not be less than 50 nor more than 60 milligrams of flint (99+ percent free silica) per cubic meter of air.

(d) The flint in suspension will be ground to pass 99+ percent through a 270-mesh sieve.

(e) The particle-size distribution of the test suspension will have a geometric mean of 0.4 to 0.6 micrometer, and the standard geometric deviation will not exceed 2.

(f) The total amount of unretained test suspension in samples taken during testing shall not exceed 1.5 milligrams for an air-purifying respirator, 14.4 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 21.3 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

(g) Three respirators with reusable filters will be tested and shall meet the requirements specified in paragraphs (a) through (f) of this section; each filter shall be tested three times: Once as received; once after cleaning; and once after recleaning. The applicant's instructions shall be followed for each cleaning.

§ 11.140-5 Silica-dust test; single-use dust respirators; minimum requirements.

(a) Three respirators will be tested.

(b) As described in § 11.140-4, airflow will 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 622 kg.-m.²/minute shall be used.

(c) Air exhaled through the respirator will be 35° ±2° C. (95° ±3°F.) with 94 ±3 percent relative humidity.

(d) Air inhaled through the respirator will be sampled and analyzed for respirator leakage.

(e) The total amount of unretained test suspension, after drying, in samples taken during testing, shall not exceed 1.8 milligrams for any single test.

§ 11.140-6 Lead fume test; minimum requirements.

(a) Three respirators will be tested for a period of 312 minutes each at a continuous airflow rate of 32 liters per minute for air-purifying respirators, and for periods of 4 hours each at a flow rate not less than 115 liters per minute to tight-fitting facepieces, and not less than 170 liters per minute to loose-fitting hoods and helmets for powered air-purifying respirators.

(b) The relative humidity in the test chamber will be 20-80 percent, and the room temperature approximately 25° C.

(c) The test suspension in the test chamber will not be less than 15 nor more than 20 milligrams of freshly generated lead-oxide fume, calculated as lead (Pb), per cubic meter of air.

(d) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(e) Samples of the test suspension will be taken during each test period for analysis.

(f) The total amount of unretained test suspension in the samples taken during testing, which is analyzed and calculated as lead (Pb), shall not exceed 1.5 milligrams of lead for an air-purifying respirator, 4.2 milligrams of lead for a powered air-purifying respirator with tight-fitting facepiece, and 6.2 milligrams of lead for a powered air-purifying respirator with loose-fitting hood or helmet.

§ 11.140-7 Silica mist test; minimum requirements.

(a) Three respirators will be tested for a period of 312 minutes each at a continuous airflow rate of 32 liters per minute for air-purifying respirators, and for periods of 4 hours each at a flow rate not less than 115 liters per minute to tight-fitting facepieces, and not less than 170 liters per minute to loose-fitting hoods and helmets for powered air-purifying respirators.

(b) The room temperature in the test chamber will be approximately 25° C.

(c) The test suspension in the test chamber will not be less than 20 nor more than 25 milligrams of silica mist, weighed as silica dust, per cubic meter of air.

(d) Mist will be produced by spraying an aqueous suspension of flint (99+ percent free silica), and the flint shall be ground to pass 99+ percent through a 270-mesh sieve.

(e) Samples of the test suspension will be taken during each test period for analysis.

(f) The total amount of silica mist unretained in the samples taken during testing, weighed as silica dust, shall not exceed 2.5 milligrams for an air-purifying respirator, 6.9 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 10.2 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

§ 11.140-8 Tests for respirators designed for respiratory protection against more than one type of dispersoid; minimum requirements.

Respirators designed as respiratory protection against more than one particulate hazard (dust, fume, or mist) shall comply with all the requirements of this part, with respect to each of the specific hazards involved.

§ 11.140-9 Airflow resistance tests; all dust, fume, and mist respirators; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a dust, fume, or mist 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 §§ 11.140-4 through 11.140-7.

(b) The maximum allowable resistance requirements for dust, fume, and mist respirators are as follows:

MAXIMUM RESISTANCE

[mm. water-column height]

Type of respirator	Initial inhalation	Final inhalation	Exhalation
Single-use	12	15	15
Dust, fume, and mist, with single-use filter	30	50	20
Dust, fume, and mist, with reusable filter	20	40	20
Radon daughter	18	[1]25	15
Asbestos dust and mist	18	25	15

[1] Measured after silica dust test described in § 11.140-4.

§ 11.140-10 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will 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 milliliters per minute.

§ 11.140-11 DOP filter test; respirators designed as respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

(a) All single air-purifying respirator filter units will be tested in an atmosphere concentration of 100 micrograms of DOP per liter of air at continuous flow rates of 32 and 85 liters per minute for a period of 5 to 10 seconds.

(b) Where filters are to be used in pairs, the flow rates will be 16 and 42.5 liters per minute, respectively, through each filter.

(c) The filter will be mounted on a connector in the same manner as used on the respirator, and the total leakage for the connector and filter shall not exceed 0.03 percent of the ambient DOP concentration at either flow rate.

§ 11.140-12 Silica dust loading test; respirators designed as protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

Three respirators will be tested in accordance with the provisions of § 11.140-4 and shall meet the minimum requirements of §§ 11.140-4 and 11.140-9.

TABLE 9—FACEPIECE TEST REQUIREMENTS

[30 CFR Part 11, Subpart K, § 11.140-1, et seq.]

Respirator types	Pressure tightness test[1]	Isoamyl acetate test	
		11.140-1	11.140-2
Dusts: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf	X		
Fumes: Air Contamination Level not less than 0.05 mg/M³	X	X	
Mists: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf	X		
Dusts, Fumes, and Mists: Air Contamination Level less than 0.05 mg/M³ or 2 mppcf, and radionuclides	X		X
Radon daughters	X	X	
Asbestos-containing dusts and mists	X		

[1] Test is required only where applicable.

TABLE 10—AIR-PURIFYING AND POWERED AIR-PURIFYING RESPIRATOR FILTER TESTS REQUIRED FOR APPROVAL

[30 CFR Part 11, Subpart K, § 11.140-4, et seq.]

Respirator types	Silica dust tests			Lead fume test 11.140-6	Silica mist test 11.140-7	DOP test 11.140-11
	11.140-4	11.140-5	11.140-12			
Dusts: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf	X					
Fumes: Air Contamination Level not less than 0.05 mg/M³				X		

TABLE 10—AIR-PURIFYING AND POWERED AIR-PURIFYING RESPIRATOR FILTER TESTS REQUIRED FOR APPROVAL—Continued

[30 CFR Part 11, Subpart K, § 11.140-4, et seq.]

Respirator types	Silica dust tests			Lead fume test 11.140-6	Silica mist test 11.140-7	DOP test 11.140-11
	11.140-4	11.140-5	11.140-12			
Mists: Air Contamination Level not less than 0.05 mg/M³ or 2 mppcf					X	
Dusts, Fumes, and Mists: Air Contamination Level less than 0.05 mg/M³ or 2 mppcf, and radionuclides			X			X
Radon daughters	[1] X				[3] X	
Asbestos-containing dusts and mists	[2] X				[3] X	
Single use dust and mist respirators		[3] X			[3] X	

[1] For resistance only.
[2] For penetration only.
[3] Test required only where applicable.

Subpart L—Chemical Cartridge Respirators

§ 11.150 Chemical cartridge respirators: description.

Chemical cartridge respirators including all completely assembled respirators which are designed for use as respiratory protection during entry into or escape from atmospheres not immediately dangerous to life and health, are described according to the specific gases or vapors against which they are designed to provide respiratory protection, as follows:

Type of chemical cartridge respirator [1]	Maximum use concentration, parts per million
Ammonia	300
Chlorine	10
Hydrogen chloride	50
Methyl amine	100
Organic vapor	[2] 1,000
Sulfur dioxide	50
Vinyl chloride	10

[1] Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the cartridge.
[2] Maximum use concentrations are lower for organic vapors which produce atmospheres immediately hazardous to life or health at concentrations equal to or lower than this concentration.

NOTE: Chemical cartridge respirators for respiratory protection against gases or vapors, which are not specifically listed with their maximum use concentration except pesticides, may be approved if the applicant submits a request for such approval, in writing, to the Institute. MSHA and the Institute shall consider each such application and accept or reject the application after a review of the effects on the wearer's health and safety and in the light of any field experience in use of chemical cartridge respirators as protection against such hazards.

[37 FR 6242, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973; 42 FR 65167, Dec. 30, 1977]

§ 11.151 Chemical cartridge respirators; required components.

(a) Each chemical cartridge respirator described in § 11.150 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece, and noseclip, hood, or helmet;
(2) Cartridge;
(3) Cartridge with filter;
(4) Harness;
(5) Breathing tube; and
(6) Attached blower.

(b) The components of each chemical cartridge respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.152 Cartridges in parallel; resistance requirements.

Where two or more cartridges are used in parallel, their resistance to airflow shall be essentially equal.

§ 11.153 Cartridges; color and markings; requirements.

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

§ 11.154 Filters used with chemical cartridges; location; replacement.

(a) Particulate matter filters used in conjunction with a chemical cartridge shall be located on the inlet side of the cartridge.

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

§ 11.155 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(1) Restriction of free head movement;
(2) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;
(3) Interference with the wearer's activities; and
(4) Shutoff of airflow due to kinking, or from chin or arm pressure.

§ 11.156 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

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

§ 11.157 Respirator containers; minimum requirements.

Respirators shall be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains and all appropriate approval labels.

§ 11.158 Half-mask facepieces, full facepieces, mouthpieces, hoods, and helmets; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, provide for the optional use of corrective spectacles or lenses, and insure against any restriction of movement by the wearer.

(c) Mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight fit.

(d) Full facepieces shall provide for optional use of corrective spectacles or lenses which shall not reduce the respiratory protective qualities of the respirator.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

§ 11.158-1 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.

§ 11.159 Inhalation and exhalation valves; minimum requirements.

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

(b) Inhalation valves shall be designed and constructed to prevent excessive exhaled air from entering cartridges or adversely affecting canisters.

(c) Exhalation valves shall be: (1) Protected against damage and external influence, and (2) designed and constructed to prevent inward leakage of contaminated air.

§ 11.160 Head harnesses; minimum requirements.

(a) Facepieces for chemical cartridge respirators other than single-use vinyl chloride shall be equipped with adjustable and replaceable 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.

(a-1) Facepieces for single-use vinyl chloride respirators shall be equipped with adjustable 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) Mouthpieces shall be equipped where applicable, with an adjustable and replaceable harness designed and constructed to hold the mouthpiece in place.

[37 FR 6244, Mar. 25, 1972, as amended at 42 FR 65167, Dec. 30, 1977]

§ 11.161 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum airflow obtainable and shall not exceed 80 dBA.

§ 11.162 Chemical cartridge respirators; performance requirements; general.

Chemical cartridge respirators and the individual components of each such device shall, as appropriate, meet the minimum requirements for performance and protection specified in the tests described in §§ 11.162-1 through 11.162-8.

§ 11.162-1 Breathing resistance test; minimum requirements.

(a) Resistance to airflow will be measured in the facepiece, mouthpiece, hood, or helmet of a chemical 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 §§ 11.162-5 through 11.162-8.

(b) The maximum allowable resistance requirements for chemical cartridge respirators are as follows:

MAXIMUM RESISTANCE

[Millimeter water column height]

Type of chemical-cartridge respirator	Inhalation		Exhalation
	Initial	Final [1]	
Other than single-use vinyl chloride respirators:			
For gases, vapors, or gases and vapors	40	45	20
For gases, vapors, or gases and vapors, and dusts, fumes, and mists	50	70	20
For gases, vapors, or gases and vapors, and mists of paints, lacquers, and enamels	50	70	20
Single-use respirator with valves:			
For vinyl chloride	20	25	20
For vinyl chloride and pneumoconiosis and fibrosis producing dusts	30	45	20
Single-use respirator without valves:			
For vinyl chloride	15	20	[2]
For vinyl chloride and pneumoconiosis and fibrosis producing dusts	25	40	[2]

[1] Measured at end of service life specified in Tables 11 and 11a.
[2] Same as inhalation.

[37 FR 6244, Mar. 25, 1972, as amended at 42 FR 65167, Dec. 30, 1977]

§ 11.162-2 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will 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 milliliters per minute.

§ 11.162-3 Facepiece test; minimum requirements.

(a) The complete chemical cartridge respirator will be fitted to the faces of persons having varying facial shapes and sizes.

(b) Where the applicant specifies a facepiece size or sizes for the respirator together with the approximate measurement of faces they are designed to fit, the Institute will provide test subjects to suit such facial measurements.

(c) Any chemical cartridge respirator part which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing facepiece or mouthpiece fit.

(d) The facepiece or mouthpiece fit test using the positive or negative pressure recommended by the applicant and described in his instructions will be used before each test.

(e) (1) Each wearer will enter a chamber containing 100 p.p.m. isoamyl acetate vapor for half-mask facepieces, and 1,000 p.p.m. for full facepieces, mouthpieces, hoods, and helmets.

(2) The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the test.

(3) Each wearer will remain in the chamber for 8 minutes while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place; and

(iv) Two minutes, pumping with a fire pump into a 28-liter (1 cubic-foot) container.

(4) Each wearer shall not detect the odor of isoamyl-acetate vapor during the test.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.162-4 Lacquer and enamel mist tests; respirators with filters; minimum requirements; general.

(a) Three respirators with cartridges containing or having attached to them, filters for protection against mists of paints, lacquers, and enamels shall be tested in accordance with the provisions of § 11.162-8.

(b) In addition to the test requirements set forth in paragraph (a) of this section, three such respirators will be tested against each aerosol in accordance with the provisions of §§ 11.162-5 and 11.162-6.

§ 11.162-5 Lacquer mist test; minimum requirements.

(a) Temperature in the test chamber will be approximately 25° C.

(b) Continuous airflow through the respirator will be 32 liters per minute for air-purifying respirators, and not less than 115 liters per minute to tight fitting facepieces and 170 liters per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(c) Airflow through the chamber will be 20-25 air changes per minute.

(d) The atomizer employed will be a No. 64-5 nozzle with setup 3, or equivalent, operating at 69 kN/m.^{2} (10 pounds per square inch gage).

(e) The test aerosol will be prepared by atomizing a mixture of one volume of clear cellulose nitrate lacquer and one volume of lacquer thinner.

(f) The lacquer used will conform essentially to Federal Specification TT-L-31, October 7, 1953.

(g) The concentration of cellulose nitrate in the test aerosol will be 95-125 milligrams per cubic meter.

(h) The test aerosol will be drawn to each respirator for a total of 156 minutes for air-purifying respirators and 240 minutes for powered air-purifying respirators.

(i) The total amount of unretained mist in the samples taken during testing, weighed as cellulose nitrate, shall not exceed 5 milligrams for an air-purifying respirator, 28 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 41 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

§ 11.162-6 Enamel mist test; minimum requirements.

(a) Temperature in the test chamber will be approximately 25° C.

(b) Continuous airflow through the respirator will be 32 liters per minute for air-purifying respirators, and not less than 115 liters per minute to tight-fitting facepieces and 170 liters per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(c) Airflow through the chamber will be 20-25 air changes per minute.

(d) The atomizer employed will be a No. 64 nozzle with setup 1A, or equivalent, operating at 69 kN/m.² (10 pounds per square inch gage).

(e) The test aerosol will be prepared by atomizing a mixture of 1 volume of white enamel and 1 volume of turpentine.

(f) The enamel used will conform essentially to Federal Specification TT-E-489b, May 12, 1953 (an enamel having a phthalic alkyd resin vehicle and a titanium dioxide pigment).

(g) The concentration of pigment in the test aerosol, weighed as ash, will be 95-125 milligrams per cubic meter.

(h) The test aerosol will be drawn to each respirator for a total of 156 minutes for air-purifying respirators and 240 minutes for power air-purifying respirators.

(i) The total amount of unretained mist in the samples taken during testing, weighed as ash, shall not exceed 1.5 milligrams for any air-purifying respirator, 8.3 milligrams for a powered air-purifying respirator with tight-fitting facepiece, and 12.3 milligrams for a powered air-purifying respirator with loose-fitting hood or helmet.

§ 11.162-7 Dust, fume, and mist tests; respirators with filters; minimum requirements; general.

(a) Three respirators with cartridges containing, or having attached to them, filters for protection against dusts, fumes, and mists, except the mists of paints, lacquers, and enamels, will be tested in accordance with the provisions of § 11.162-8.

(b) In addition to the test requirements set forth in paragraph (a) of this section, three such respirators will be tested, as appropriate, in accordance with the provisions of §§ 11.140-1 through 11.140-14; however, the maximum allowable resistance of complete dust, fume, and mist, and gas, vapor, or gas and vapor chemical cartridge respirators shall not exceed the maximum allowable limits set forth in § 11.162-1.

§ 11.162-8 Bench tests; gas and vapor tests; minimum requirements; general.

(a) Bench tests will be made on an apparatus that allows the test atmosphere at 50 ±5 percent relative humidity and room temperature, approximately 25° C., to enter the cartridges continuously at predetermined concentrations and rates of flow, and that has means for determining the test life of the cartridges.

(b) Where two cartridges are used in parallel on a chemical cartridge respirator, the bench test will be performed with the cartridges arranged in parallel, and the test requirements will apply to the combination rather than to the individual cartridges.

(c) Three cartridges or pairs of cartridges will be removed from containers and tested as received from the applicant.

(d) Two cartridges or pairs of cartridges will be equilibrated at room temperature by passing 25 percent relative humidity air through them at the following flow rates (expressed in liters per minute (l.p.m.)) for 6 hours:

Type of cartridge	Airflow rate, l.p.m.
Air purifying	25
Powered air purifying with tight-fitting facepiece	115
Powered air purifying with loose-fitting hood or helmet	170

(e) Two cartridges or pairs of cartridges will be equilibrated by passing 85 percent relative humidity air through them at the flow rates stated in paragraph (d) of this section.

(f) All cartridges will be resealed, kept in an upright position, at room temperatures, and tested within 18 hours.

(g) Cartridges will be tested and shall meet the minimum requirements set forth in Table 11.

TABLE 11—CARTRIDGE BENCH TESTS AND REQUIREMENTS

[30 CFR Part 11, Subpart L, § 11.162-8]

Cartridge	Test condition	Test atmosphere		Flowrate (l.p.m.)	Number of tests	Penetration[1] (p.p.m.)	Minimum life[2] (min.)
		Gas or vapor	Concentration (p.p.m.)				
Ammonia	As received	NH_3	1000	64	3	50	50
Ammonia	Equilibrated	NH_3	1000	32	4	50	50
Chlorine	As received	Cl_2	500	64	3	5	35
Chlorine	Equilibrated	Cl_2	500	32	4	5	35
Hydrogen chloride	As received	HCl	500	64	3	5	50
Hydrogen chloride	Equilibrated	HCl	500	32	4	5	50
Methylamine	As received	CH_3NH_2	1000	64	3	10	25
Methylamine	Equilibrated	CH_3NH_2	1000	32	4	10	25
Organic vapors	As received	CCl_4	1000	64	3	5	50
Organic vapors	Equilibrated	CCl_4	1000	32	4	5	50
Sulfur dioxide	As received	SO_2	500	64	3	5	30
Sulfur dioxide	Equilibrated	SO_2	500	32	4	5	30

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

[2] 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, 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 M—Pesticide Respirators

§ 11.170 Pesticide respirators; description.

Pesticide respirators, including all completely assembled respirators which are designed for use as respiratory protection during entry into and escape from atmospheres which contain pesticide hazards, are described according to their construction as follows:

(a) Front-mounted or back-mounted gas masks;

(b) Chin-style gas mask;

(c) Chemical cartridge;

(d) Air-purifying respirator with attached blower; and,

(e) Other devices, including combination respirators.

§ 11.171 Pesticide respirators; required components.

(a) Each pesticide respirator described in § 11.170 shall, where its design requires, contain the following component parts:

(1) Facepiece, mouthpiece, and nose-clip, helmet, or hood;

(2) Canister with filter;

(3) Cartridge with filter;

(4) Harness;

(5) Attached blower; and,

(6) Breathing tube.

(b) The components of each pesticide respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.172 Canisters and cartridges in parallel; resistance requirements.

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

§ 11.173 Canisters and cartridges; color and markings; 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 Gas Mask Canisters, ge 7r102.002K13.1.

§ 11.174 Filters used with canisters and cartridges; location; replacement.

(a) Particulate matter filters used in conjunction with a 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.

§ 11.175 Breathing tubes; minimum requirements.

(a) Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:

(1) Restriction of free head movement;

(2) Disturbance of the fit of facepieces, mouthpieces, hoods, or helmets;

(3) Interference with the wearer's activities; and,

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

§ 11.176 Harnesses; installation and construction; minimum requirements.

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

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

§ 11.177 Respirator containers; minimum requirements.

(a) Respirators shall be equipped with a substantial, durable, container bearing markings which show the applicant's name, type, and commercial designation of the respirator it contains, and all appropriate approval labels.

(b) Containers for gas masks shall be designed and constructed to permit easy removal of the mask.

§ 11.178 Half-mask facepieces, full facepieces, hoods and helmets, and mouthpieces; fit; minimum requirements.

(a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size, or (2) by providing one facepiece size which will fit varying facial shapes and sizes.

(b) Full facepieces shall provide for optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective quality of the respirator.

(c) Hoods and helmets shall be designed and constructed to fit persons with various head sizes, permit optional use of corrective spectacles without reducing the respiratory protective qualities of the respirator, and insure against any restriction of movement by the wearer.

(d) Pesticide respirators with mouthpieces shall be equipped with noseclips which are securely attached to the mouthpiece or respirator and provide an airtight seal.

(e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging.

(f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles as determined by the facepiece tests in § 11.183-3.

§ 11.179 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

(a) Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.

(b) All eyepieces of gas masks shall be designed and constructed to meet the impact and penetration requirements specified in Federal Specification, Mask, Air line: and Respirator, Air Filtering, Industrial, GGG-M-125d, October 11, 1965.

§ 11.180 Inhalation and exhalation valves; minimum requirements.

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

(b) Inhalation valves shall be designed and constructed and provided where necessary to prevent excessive exhaled air from adversely affecting cartridges, canisters, and filters.

(c) Exhalation valves shall be:

(1) Provided where necessary;

(2) Protected against damage and external influence; and,

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

§ 11.181 Head harnesses; minimum requirements.

(a) Facepieces shall be equipped with adjustable and replaceable 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) Mouthpieces shall be equipped, where applicable, with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place.

§ 11.182 Air velocity and noise levels; hoods and helmets; minimum requirements.

Noise levels generated by the respirator will be measured inside the hood or helmet at maximum obtainable airflow and shall not exceed 80 dBA.

§ 11.183 Pesticide respirators; performance requirements; general.

Pesticide 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 §§ 11.183-1 through 11.183-7.

§ 11.183-1 Breathing resistance test; minimum requirements.

(a) Airflow resistance will be measured in the facepiece, mouthpiece, hood, or helmet of a pesticide 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 §§ 11.183-4 and 11.183-7.

(b) The maximum allowable resistance requirements for pesticide respirators are as follows:

MAXIMUM RESISTANCE

(mm water-column height)

Type of pesticide respirator	Inhalation		Exhalation
	Initial	Final [1]	
Front- or back-mounted gas mask	70	85	20
Chin-style gas mask	65	80	20
Powered air-purifying	[2] 50	[2] 70	[2] 20
Chemical cartridge	50	70	20

[1] Measured at end of the service life specified in Table 12.
[2] Resistance of filter(s), cartridge(s), and breathing tube(s) only with blower not operating.

§ 11.183-2 Exhalation valve leakage test; minimum requirements.

(a) Dry exhalation valves and valve seats will 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 milliliters per minute.

§ 11.183-3 Facepiece test; minimum requirements.

(a) The complete pesticide respirator will be fitted to the faces of persons having varying facial shapes and sizes.

(b) Where the applicant specifies a facepiece size or sizes for his respirator together with the approximate measurements of faces they are designed to fit, the Institute will provide test subjects to suit such facial measurements.

(c) Any pesticide respirator part which must be removed to perform the facepiece fit test shall be replaceable without special tools and without disturbing facepiece fit.

(d) The facepiece or mouthpiece fit test using positive or negative pressure recommended by the applicant and described in his instructions will be used during each test.

(e)(1) Each wearer will enter a chamber containing 1,000 p.p.m. isoamyl-acetate vapor for a respirator equipped with a full facepiece, mouthpiece, hood, or helmet and 100 p.p.m. isoamyl-acetate vapor for a respirator equipped with a half-mask facepiece.

(2) The facepiece, mouthpiece, hood, or helmet may be adjusted, if necessary, in the test chamber before starting the test.

(3) Each wearer will remain in the chamber while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

(iii) Two minutes, running in place; and,

(iv) Two minutes, pumping with a tire pump into a 28-liter (1 cubic foot) container.

(4) Each wearer shall not detect the odor of isoamyl-acetate during the test.

[37 FR 6244, Mar. 25, 1972, as amended at 38 FR 6993, Mar. 15, 1973]

§ 11.183-4 Silica dust test; minimum requirements.

Three completely assembled pesticide respirators will be tested with a mechanical-testing apparatus as follows:

(a) Temperature in the test chamber will be approximately 25° C.

(b) Continuous airflow through the respirator will be 32 liters per minute for front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators, and not less than 115 (4 cubic feet) liters per minute to tight-fitting facepieces and 170 liters (6 cubic feet) per minute to loose-fitting hoods and helmets of powered air-purifying respirators.

(c) The test aerosol will contain 50–60 milligrams of 99+ percent free silica per cubic meter of air.

(d) The particle size distribution of the test suspension will have a geometric mean diameter of 0.4 to 0.6 micrometer, with a standard geometric deviation less than 2.

(e) Front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators will be tested for 90 minutes and powered air-purifying respirators will be tested for 4 hours.

§ 11.183-5 Lead fume test; minimum requirements.

Three completely assembled pesticide respirators will be tested with a mechanical-testing apparatus as follows:

(a) Continuous airflow through the respirator will be 32 liters per minute for front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators and not less than 115 liters (4 cubic feet) per minute, for powered air-purifying respirators with tight-fitting facepieces, and not less than 170 liters (6 cubic feet) per minute for powered air-purifying respirators with loose-fitting hoods and helmets.

(b) The test aerosol will contain 15–20 milligrams of freshly generated lead-oxide fume, calculated as lead, per cubic meter of air.

(c) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(d) Front-mounted, back-mounted, and chin-style gas mask pesticide respirators and chemical cartridge pesticide respirators will be tested for 90 minutes and powered air-purifying pesticide respirators will be tested for 4 hours.

(e) The total amount of unretained test suspension, which is analyzed and calculated as lead, shall not exceed: (1) 0.43 milligram for any 90-minute test; (2) 4.8 milligrams for any 4-hour test made at 115 liters (4 cubic feet) per minute; or (3) 6.2 milligrams for any 4-hour test made at 170 liters (6 cubic feet) per minute.

§ 11.183-6 Dioctyl-phthalate test; minimum requirements.

(a) All canisters submitted for use with front-mounted and back-mounted gas mask pesticide respirators will be tested in an atmospheric concentration of 100 micrograms of dioctylphthalate per liter of air at continuous flow rates of 32 and 85 liters per minute for a test period of 5 to 10 seconds.

(b) The DOP leakage through the canister shall not exceed 0.03 percent of the ambient DOP concentration.

§ 11.183-7 Bench tests; minimum requirements.

(a) (1) Bench tests will be made on an apparatus that allows the test atmosphere at 50±5 percent relative humidity and at room temperature (25°±2.5° C.) to enter the canister or cartridge at predetermined concentrations and rates of flow, and that has a means for determining the test life of the canister or cartridge against carbon tetrachloride.

(2) Canisters and cartridges will be tested as they are used on each pesticide respirator, either singly or in pairs.

(3) Three canisters or cartridges or pairs of cartridges will be removed from containers and tested as received from the applicant.

(4) Two canisters, cartridges, or pairs of cartridges will be equilibrated at room temperature by passing 25 percent relative humidity air through them at the following flow rates (expressed as liters per minute (l.p.m.)) for 6 hours:

Type of canister or cartridge	Airflow rate, l.p.m.
Air-purifying canister	64
Air-purifying cartridge	25
Powered air-purifying with tight-fitting facepiece	115
Powered air-purifying with loose-fitting hood or helmet	170

(5) Two canisters, cartridges, or pairs of cartridges will be equilibrated at room temperature by passing 85 percent relative humidity air through them at the flow rates stated in paragraph (a)(4) of this section for 6 hours.

(6) The equilibrated canisters or cartridges will be resealed, kept in an upright position at room temperature, and tested within 18 hours.

(b) Canisters and cartridges tested in accordance with the provisions of this section shall meet the requirements specified in Table 12.

TABLE 12—CARBON TETRACHLORIDE BENCH TESTS AND REQUIREMENTS FOR CANISTERS AND CARTRIDGES

(30 CFR Part 11, Subpart M, § 11.183-7)

Type of pesticide respirator	Test concentrations, p.p.m. CCl₄	Flow rate l.p.m.	Number of tests	Minimum life minutes[1]
Chest-mounted or back-mounted gas mask (as received)	20,000	64	3	
Chest-mounted or back-mounted gas mask (equilibrated)	20,000	32	4	
Chin-style gas mask (as received)	5,000	64	3	
Chin-style gas mask (equilibrated)	5,000	32	4	
Chemical-cartridge respirator (as received)	1,000	64	3	
Chemical-cartridge respirator (equilibrated)	1,000	32	4	
Powered air-purifying respirator (tight-fitting facepiece, as received)	1,000	[2] 115	3	
Powered air-purifying respirator (tight-fitting facepiece, equilibrated)	1,000	[2] 115	4	
Powered air-purifying respirator (loose-fitting hood or helmet as received)	1,000	[3] 170	3	
Powered air-purifying respirator (loose-fitting hood or helmet, equilibrated)	1,000	[3] 170	4	

[1] Minimum life will be determined at 5 p.p.m. leakage.
[2] The flow rate shall be the effective flow rate of the device, but shall be not less than 115 l.p.m.
[3] The flow rate shall be the effective flow rate of the device, but shall be not less than 170 l.p.m.

Subpart N—Special Use Respirators

SOURCE: 39 FR 45013, Dec. 30, 1974, unless otherwise noted.

§ 11.200 Vinyl chloride respirators; description.

Vinyl chloride respirators, including all completely assembled respirators which are designed for use as respiratory protection during entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life, are described according to their construction as follows:

(a) Front-mounted or back-mounted gas masks;

(b) Chin-style gas masks;

(c) Chemical-cartridge respirators;

(d) Powered air-purifying respirators; and,

(e) Other devices, including combination respirators.

§ 11.201 Required components.

(a) Each vinyl chloride respirator described in § 11.200 shall, where its design requires, contain the following component parts:

(1) Facepiece;

(2) Canister with end-of-service-life indicator;

(3) Cartridge with end-of-service-life indicator;

(4) Harness;

(5) Attached blower; and,

(6) Breathing tube.

(b) The components of each vinyl chloride respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

§ 11.202 Gas masks; requirements and tests.

(a) Except for the tests prescribed in 11.102-5, the minimum requirements and performance tests for gas masks, prescribed in Subpart I of this part, are applicable to vinyl chloride gas masks.

(b) The following bench tests are applicable to canisters designed for use with gas masks for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life:

(1) Four canisters will be equilibrated at 25±5° C by passing 85±5 percent relative humidity air through them at 64 liters per minute for six hours.

(2) The equilibrated canisters will be resealed, kept in an upright position at room temperature, and tested according to paragraph (b) (3) of this section within 18 hours.

(3) The canisters equilibrated and stored as described in subparagraphs (1) and (2) of this paragraph will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5° C to enter the canister continuously at a concentration of 25 ppm vinyl chloride monomer at a total flow rate of 64 liters per minute.

(4) The maximum allowable penetration after six hours of testing according to paragraph (b) (3) of this section shall not exceed 1 ppm vinyl chloride.

(c) Where canisters are submitted for testing and approval with a service life of more than four hours, the period of time for testing for vinyl chloride penetration will be performed at 150% of the service life specified in the manufacturer's application. Example: If a manufacturer requests approval of a respirator for six hours use against exposure to vinyl chloride, the maximum allowable penetration after nine hours of testing shall not exceed 1 ppm vinyl chloride.

§ 11.203 Chemical-cartridge respirators; requirements and tests.

(a) Except for the tests prescribed in §§ 11.162-4 through 11.162-8, the minimum requirements and performance tests for chemical-cartridge respirators prescribed in Subpart L of this part are applicable to replaceable-cartridge and single-use vinyl chloride chemical-cartridge respirators.

(b) The following bench tests are applicable to cartridges designed for use with chemical-cartridge respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life:

(1) Where two cartridges are used in parallel on a chemical-cartridge respirator, the bench test requirements will apply to the combination rather than the individual cartridges.

(2) Four cartridges or pairs of cartridges will be equilibrated at 25±5° C by passing 85±5 percent relative humidity air through them at 25 liters per minute for six hours.

(3) The equilibrated cartridges will be resealed, kept in an upright position, at room temperature, and tested according to paragraphs (b) (4) and (b) (5) for other than single-use respirators or according to paragraphs (b) (6) and (b) (7) for single-use respirators within 18 hours.

(4) The cartridges or pairs of cartridges for other than single-use respirators, equilibrated and stored as described in paragraphs (b) (1), (b) (2), and (b) (3) of this section, will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5° C, to enter the cartridges or pairs of cartridges continuously at a concentration of 10 ppm vinyl chloride monomer at a total flowrate of 64 liters per minute.

(5) The maximum allowable penetration after 90 minutes testing of cartridges or pairs of cartridges for other than single-use respirators, according to paragraph (b) (4) of this section shall not exceed 1 ppm vinyl chloride.

(6) The single-use respirators, equilibrated and stored as described in paragraphs (b) (2) and (b) (3) of this section, will be tested on an apparatus that allows a test atmosphere at 85±5 percent relative humidity and 25°±5° C to be cycled through the respirator by a breathing machine at a concentration of 10 ppm vinyl chloride monomer at the rate of 24 respirations per minute at a minute volume of 40±0.6 liters. Air exhaled through the respirator will be 35±2° C with 94±3 percent relative humidity.

(7) The maximum allowable penetration after 144 minutes testing of respirators, according to paragraph (b) (6) of this section, shall not exceed 1 ppm vinyl chloride.

[39 FR 45013, Dec. 30, 1974, as amended at 42 FR 65168, Dec. 30, 1977]

§ 11.204 Powered air-purifying respirators; requirements and tests.

(a) Except for the tests prescribed in § 11.162-8, the minimum requirements and performance tests for powered air-purifying respirators prescribed in Subpart L of this part are applicable to vinyl chloride powered air-purifying respirators.

(b) The following bench tests are applicable to cartridges designed for use with powered air-purifying respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life.

(1) Four cartridges will be equilibrated at 25±5° C by passing 85±5 percent relative humidity air through them at 115 liters per minute for tight-fitting facepieces and 170 liters per minute for loose-fitting hoods and helmets, for six hours.

(2) The equilibrated cartridges will be resealed, kept in an upright position at room temperature and tested according to paragraph (b) (3) of this section within 18 hours.

(3) The cartridges equilibrated and stored as described in paragraphs (b) (1) and (2) of this section will be tested on an apparatus that allows the test atmosphere at 85±5 percent relative humidity and 25±5° C to enter the cartridge continuously at a concentration of 25 ppm vinyl chloride monomer at a total flow rate of 115 liters per minute for tight-fitting facepieces and 170 liters per minute for loose-fitting hoods and helmets.

(4) The maximum allowable penetration after six hours of testing according to paragraph (b) (3) of this section shall not exceed 1 ppm vinyl chloride.

§ 11.205 Requirements for end-of-service-life indicator.

(a) After June 30, 1975, each canister or cartridge submitted for testing and approval in accordance with §§ 11.202, and 11.203, and 11.204 shall be equipped with a canister or cartridge end-of-service-life indicator which shows a satisfactory indicator change or other obvious warning before 1 ppm vinyl chloride penetration occurs. The indicator shall show such change or afford such warning at 80±10 percent of the total service life to 1 ppm leakage, as determined by continuing each test described in paragraphs (b) of each of §§ 11.202, 11.203, and 11.204 until a 1 ppm leakage of vinyl chloride occurs. After September 30, 1976, a cartridge or canister without an end-of-service-life indicator will not be considered approved for use by employees exposed to vinyl chloride.

(b) The applicant shall provide sufficient pretest data to verify the performance of the end-of-service-life indicator required in paragraph (a) of this section.

[37 FR 6244, Mar. 25, 1972, as amended at 41 FR 13919, Apr. 1, 1976]

§ 11.206 Quality control requirements.

(a) In addition to the construction and performance requirements specified in §§ 11.201, 11.202, 11.203, 11.204, and 11.205, the quality control requirements in paragraphs (b), (c), and (d) of this section apply to approval of gas masks, chemical cartridge respirators, and powered air-purifying respirators for entry into and escape from vinyl chloride atmospheres containing adequate oxygen to support life.

(b) The respirators submitted for approval as described in paragraph (a) of this section shall be accompanied by a complete quality control plan meeting the requirements of Subpart E of this part.

(c) The applicant shall specify in the plan that a sufficient number of samples will be drawn from each bulk container of sorbent material and that where activated carbon is used, the following specific tests will be performed:

(1) Apparent density,

(2) Iodine number,

(3) Moisture content,

(4) Carbon tetrachloride number, and,

(5) Mesh size.

Such tests shall be performed in a quantity necessary to assure continued satisfactory conformance of the canis-

ters and cartridges to the requirements of this subpart.

(d) Final performance quality control tests on the complete canisters and cartridges shall be accomplished using the bench tests and procedures prescribed in §§ 11.202, 11.203, 11.204, and 11.205.

§ 11.207 Labeling requirements.

(a) A warning shall be placed on the label of each gas mask, chemical-cartridge respirator, and powered air-purifying respirator, and on the label of each canister and cartridge, alerting the wearer to the need for a fitting test in accordance with the manufacturer's facepiece fitting instructions, providing service life information, providing specific instructions for disposal, and advising that the wearer may communicate to NIOSH any difficulties that may be experienced in the design and performance of any gas mask, chemical-cartridge respirator, or powered air-purifying respirator approved under the requirements of this subpart. The service lives of respirators meeting the test requirements of this subpart shall be specified as follows:

Chemical-cartridge respirator	1 hour.
Gas mask	4 hours.
Powered air-purifying respirator	4 hours.

(b) Where the service life of a respirator is approved for more than four hours, the service life for which the respirator has been approved will be specified.

§ 11.208 Fees.

The following fees shall be charged for the examination, inspection, and testing of complete assemblies and components of respirators described in §§ 11.200 and 11.201.

Complete gas mask	$1,100
Complete chemical-cartridge respirator	1,150
Complete powered air-purifying respirator	1,500
Canister or cartridge only	750