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9M-000

A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists

WORKING DRAFT

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Mention of the name of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health.

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Acknowledgments

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1—Background

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 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.

During the last 20 years, NIOSH and MSHA have made only minor amendments to the certification test criteria promulgated in 1972.[1] Then on August 27, 1987, the National Institute for Occupational Safety and Health (NIOSH) published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) for certification of respiratory protective devices.[2] The Notice proposed a regulation for 42 CFR Part 84. Upon promulgation, 42 CFR Part 84 will replace 30 CFR Part 11. In the first NPRM, NIOSH proposed extensive changes in the current performance test requirements for certifying respirators.

A substantial portion of the respirators certified by NIOSH are air-purifying respirators equipped with DM or DFM filters. These filter respirators play a critical role in American workplaces in providing worker protection against airborne chemical

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[1]U. S. Department of the Interior, Bureau of Mines: Final Rule—Respiratory Protective Devices; Tests for Permissibility; Fees (30 CFR Part 11), Federal Register 37(#59):6244–6271 (March 25, 1972), pp. 6244–6271.

[2]52 FR 32401.

hazards. NIOSH-certified DM and DFM filters are produced, sold, and widely used for protection against over 200 toxic dusts and mists regulated by OSHA. NIOSH estimates that several million workers depend on DM- and DFM-filter halfmasks for protection against toxic contaminants in their workplaces. Safe and effective filter respirators are essential for assuring safe and healthful working conditions and preventing work-related diseases and injuries in millions of American workers.

In support of its ongoing rulemaking activities to promulgate 42 CFR Part 84, NIOSH conducted a performance evaluation of dust and mist (DM) and dust, fume, and mist (DFM) filter respirators certified by NIOSH for protection against toxic dusts, fumes, and mists with exposure limits equal to or exceeding 50 micrograms per cubic meter. Based on this evaluation, NIOSH is recommending that the *assigned protection factors* (APFs) for these devices be substantially lowered from the values currently in general use.

2—Nonregulatory APF values used during the 1970s and 1980s.

Assigned protection factors are a necessity for correct respirator selection and proper use. In 1976, OSHA gave the following guidance on the use of respirator-class APFs to its compliance officers during an evaluation of an employer's respiratory protection program for acceptability:

> (4) Compare air contaminant exposure measurements collected during the inspection to the [assigned] protection factor for the respirator device. [Assigned] Protection factors ([A]PFs) should be considered as an element in determining compliance with 29 CFR 1910.134(c).
> (a) A protection factor is the ratio of the ambient airborne concentration of the contaminant to the concentration of that contaminant inside the facepiece. It is a measure of the facepiece fit of a respirator based on quantitative respirator fit tests. The product of the [A]PF and the permissible exposure limit (PEL) is the maximum use concentration (MUC).[3]

Prior to the revised APFs for filter respirators recommended in this evaluation, there have been numerous APF tables recommended by NIOSH, OSHA, and the American National Standards Institute (ANSI). These are given as follows:

Tables in this evaluation	Recommending Organization
A, B	OSHA (1976)
C	ANSI (1980), OSHA (1984)
D	ANSI (1991)
E, F	NIOSH (1976)
J, K	NIOSH (1987)

OSHA has previously used APFs to derive respirator-selection tables in numerous contaminant-specific regulations.[4] OSHA has also published APFs in their 1976

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[3]OSHA: *Industrial Hygiene Manual*, Chapter III—OSHA Standard Method for Determination of Respiratory Protection Program Acceptability (June 28, 1976), p. 82.

[4]To determine the "required apparatus" or "required respirator" for differing "atmospheric concentrations" of a specified contaminant. For example, but not limited to: 29 CFR 1910.1017(g)(4), 29 CFR 1910.1018(h)(2)(i), 29 CFR 1910.1025(f)(2), 29 CFR 1910.1043(f)(2), 29 CFR 1910.1044(h)(2)(i).

Industrial Hygiene Manual (IHM)[5] and 1984 *Industrial Hygiene Technical Manual (IHTM)*[6]. The latter publication was replaced in 1990 by the *OSHA Technical Manual (OTM)*. OSHA's 1976 APFs from their *IHM* are given in Tables A and B of this evaluation. OSHA cited a Los Alamos Scientific Laboratory publication written by Hyatt as the source for their APFs.[7] OSHA's 1984 APFs in their *IHTM* were reproduced from those given in the nonregulatory 1980 ANSI Z88.2–1980 *American National Standard*[8] and were preceded by the following explanatory material:

8. *[Assigned] Protection Factors.* The protection afforded by respirators is dependent upon the seal of the facepiece to the face, leakage around valves, and leakage through or around cartridges or canisters. Depending on these criteria, the degree of protection may be ascertained and a relative safety factor assigned. [Assigned] Protection factors are only applicable if all elements of an effective respirator program are in place and being enforced.

a. The [assigned] protection factor is a ratio of the air contaminant concentration outside the respirator to the air contaminant concentration inside the respirator facepiece. The higher the [assigned] protection factor, the greater the degree of protection offered by the respirator.

b. [Assigned] Protection factors are used in conjunction with permissible exposure limits of contaminants to estimate the upper concentration limits to which respirators can be utilized safely. Table V–3, which is reproduced from ANSI Z88.2–1980, provides [assigned] protection factors and explanations for various types of respirators.

c. [Assigned] Protection factors are invalid when employees remove their respiratory protection for unspecified periods while in the contaminated atmosphere.

NOTE: Field studies of respirator performance have not correlated well with the laboratory test data. Hence, the reported values should only be taken as estimates. For example, recent studies have found that Powered Air-Purifying Respirators (PAPR's) have not achieved the [assigned] protection factors suggested by laboratory data.[9]

The 1980 APFs from the ANSI Z88.2–1980 nonregulatory consensus standard and OSHA's 1984 APFs are given in Table C of this evaluation.

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[5]OSHA: *Industrial Hygiene Manual*, Chapter III—OSHA Standard Method for Determination of Respiratory Protection Program Acceptability (June 28, 1976), Figures III–5 and III–6, pp. 89–90.

[6]OSHA: *Industrial Hygiene Technical Manual*, Chapter V—Respiratory Protection, Issued by OSHA Instruction CPL 2–2.20 A, (March 30, 1984) and amended by OSHA Instruction CPL 2–2.20 A CH–1, October 29, 1984), pp. 75–77.

[7]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), Table I, p. 4.

[8]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1980, New York, New York, (1980), Table 5, pp. 21–23.

[9]OSHA: *Industrial Hygiene Technical Manual*, Chapter V—Respiratory Protection, Issued by OSHA Instruction CPL 2–2.20 A, (March 30, 1984) and amended by OSHA Instruction CPL 2–2.20 A CH–1, October 29, 1984), pp. 63–64.

In late 1990 the ANSI Subcommittee Z88.2 (Practices for Respiratory Protection) completed a revision of their 1980 standard, which was accepted by the Z88 Committee for Respiratory Protection.[10] Their 1991 revision has been forwarded by the ANSI Z88 Committee's Secretariat to the ANSI Board of Standards Review for their approval.[11] However, as of September 1992, a formal appeal to the ANSI Secretariat regarding the submitted revision was in the process of adjudication.[12] A successful appeal could result in changes to the APFs given in Table D of this evaluation.[13] Refer to the material titled *Evaluation of the ANSI 1991 APF-Determination Strategy* given later in this evaluation for an extended discussion of the 1991 ANSI Z88 APFs.

[10]Da Roza, R. A. and P. R. Steinmeyer: The New ANSI Z88.2, *Respiratory Protection Newsletter* 6(5):1–7 (September–October 1990).

[11]Da Roza, R. A.: Letter to ANSI Board of Standards Review: Submittal of Revised Standard Z88.2, from the Lawrence Livermore National Laboratory, Livermore, California (March 6, 1991).

[12]Bevis, D.: Letter to Ms. Nancy Kippenhan, Chairperson, ANSI Board of Standards Review, from Darell Bevis Associates, Inc., Chantilly, Virginia (August 24, 1992).

[13]ANSI Z88 Committee on Respiratory Protection: *American National Standard Practices for Respiratory Protection, ANSI Z88.2–1991*, submitted by Z88 Secretariat for ANSI approval, Livermore, California (March 6, 1991), Table 1, pp. 19–22.

Table A—OSHA's 1976 Assigned Protection Factors for Particulate-Filter Respirators.

Concentrations in multiples of permissible exposure limits	Facepiece Pressure	Permissible Respirators
5X	-	Single use dust
	-	Quarter-mask dust
10X	-	Half mask dust
	-	Half- or quarter mask, fume
	-	Half- or quarter mask, high-efficiency
50X	-	Full facepiece, high efficiency
1,000X	+	Powered, high-efficiency, all enclosures

Note: Half-mask and quarter-mask respirators should not be used if the particulate matter causes eye irritation at the use concentration.

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Table B—OSHA's 1976 Assigned Protection Factors for Gas Or Vapor Respirators.

Concentrations in multiples of permissible exposure limits	Facepiece Pressure	Permissible Respirators
10X	-	Quarter or half-mask chemical cartridge respirator with "Name" cartridges or canister half mask, supplied-air
50X	-	Full facepiece gas mask or chemical cartridge with "Name" cartridges or canister
	-	Full facepiece SCBA
		Full facepiece supplied-air
1,000X	+	Half-mask, supplied-air
2,000X	+	Supplied-air with full facepiece, hood, helmet or suit
10,000X	+	Full facepiece, SCBA
	+	Full facepiece supplied-air with auxiliary self-contained air supply
Emergency entry into unknown concentrations or firefighting	+	Full facepiece SCBA
Escape only[1]	+	Any full facepiece SCBA
	-	Gas mask with a "Name" canister
	-	Any self rescuer

[1]In an atmosphere which is immediately dangerous to life or health.

Notes:
1. The "Name" means approved chemical canisters or cartridges against a specific contaminant or a combination of contaminants such as organic vapor, acid gases, organic vapor plus particulates or acid gases plus organic vapor.
2. Quarter or half-mask respirators should not be used if eye irritation occurs at the use concentration.
3. Full facepiece supplied-air respirators should not be used in any atmosphere which is immediately dangerous to life or health unless it is equipped with an auxiliary air supply which can be operated in the positive pressure mode.

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Table C—ANSI Z88.2–1980 and OSHA 1984 Assigned Protection Factors.

Type of Respirator	Permitted for Use in Oxygen-Deficient Atmosphere	Permitted for Use in Immediately-Dangerous-to-Life-or-Health Atmosphere[f]	Respirator Protection Factor	
			Qualitative Test	Quantitative Test
Particulate-filter, quarter-mask or half-mask facepiece[b,c]	No	No	10	As measured on each person with maximum of 100.
Vapor- or gas-removing, quarter-mask or half-mask facepiece[c]	No	No	10, or maximum use limit of cartridge or canister for vapor or gas, whichever is less.	As measured on each person with maximum of 100, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.
Combination particulate-filter and vapor- or gas-removing, quarter-mask or half-mask facepiece[b,c]	No	No	10, or maximum use limit of cartridge or canister for vapor or gas, whichever is less.	As measured on each person with maximum of 100, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.
Particulate-filter, full facepiece[b]	No	No	100	As measured on each person with maximum of 100 if dust, fume, or mist filter is used, or maximum of 1000 if high-efficiency filter is used.
Vapor- or gas-removing, full facepiece	No	No	100, or maximum use limit of cartridge or canister for vapor or gas, whichever is less.	As measured on each person with maximum of 1000, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.
Combination particulate-filter and vapor- or gas-removing, full facepiece[b]	No	No	100, or maximum use limit of cartridge or canister for vapor or gas, whichever is less.	As measured on each person with maximum of 100 if dust, fume, or mist filter is used and maximum of 1000 if high-efficiency filter is used, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.
Powered particulate-filter, any respiratory-inlet covering[b,c,d]	No	No (yes, if escape provisions are provided[d])	N/A	N/A
			No tests are required due to positive-pressure operation of respirator. The maximum protection factor is 100 if dust, fume, or mist filter is used and 3000 if high-efficiency filter is used.	
Powered vapor- or gas-removing, any respiratory-inlet covering[c,d]	No	No (yes, if escape provisions are provided[d])	N/A	N/A
			No tests are required due to positive pressure operation of respirator. The maximum protection factor is 3000, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.	
Powered combination particulate-filter and vapor- or gas-removing, any respiratory-inlet covering[b,c,d]	No	No (yes, if escape provisions are provided[d])	N/A	N/A
			No tests are required due to positive-pressure operation of respirator. The maximum protection factor is 100 if dust, fume, or mist filter is used and 3000 if high-efficiency filter is used, or maximum use limit of cartridge or canister for vapor or gas[i,j], whichever is less.	

Table C (Continued)—ANSI Z88.2–1980 and OSHA 1984 Assigned Protection Factors.

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Type of Respirator	Permitted for Use in Oxygen-Deficient Atmosphere	Permitted for Use in Immediately-Dangerous-to-Life-or-Health Atmosphere[f]	Respirator Protection Factor	
			Qualitative Test	Quantitative Test
Air-line, demand, quarter-mask or half-mask facepiece, with or without escape provisions[c,g]	Yes[f]	No	10	As measured on each person, but limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.
Air-line, demand, full facepiece, with or without escape provisions[g]	Yes[f]	No	100	As measured on each person, but limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.
Air-line, continuous-flow or pressure-demand type, any facepiece, without escape provisions[g]	Yes[f]	No	N/A No tests are required due to positive-pressure operation of respirator. The protection factor provided by the respirator is limited to use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.	
Air-line, continuous-flow or pressure-demand type, any facepiece, with escape provisions[c,g]	Yes[f]	Yes	N/A No tests are required due to positive-pressure operation of respirator. The maximum protection factor is 10 000 plus.[h]	
Air-line, continuous flow, helmet, hood, or suit, without escape provisions	Yes[f]	No	N/A No tests are required due to positive-pressure operation of respirator. The protection factor provided by the respirator is limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.	
Air-line, continuous-flow, helmet, hood, or suit, with escape provisions[g]	Yes[f]	Yes	N/A No tests are required due to positive-pressure operation of respirator. The maximum protection factor is 10 000 plus.[h]	
Hose mask, with or without blower, full facepiece	Yes[f]	No	10	As measured on each person, but limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.
Self-contained breathing apparatus, demand-type open-circuit or negative-pressure-type closed-circuit, quarter-mask or half-mask facepiece[c]	Yes[f]	No	10	As measured on each person, but limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values.
Self-contained breathing apparatus, demand-type open-circuit or negative-pressure-type closed-circuit, full facepiece or mouthpiece/nose clamp[c]	Yes[f] (Yes[f], if respirator is used for mine rescue and mine recovery operations.)	No (yes, if respirator is used for mine rescue and mine recovery operations.)	100	As measured on each person, but limited to the use of the respirator in concentrations of contaminants below the immediately-dangerous-to-life-or-health (IDLH) values, except when the respirator is used for mine rescue and mine recovery operations.

Table C (Continued)—ANSI Z88.2–1980 and OSHA 1984 Assigned Protection Factors.

Self-contained breathing apparatus, pressure-demand-type open-circuit or positive-pressure-type closed circuit, quarter-mask or half-mask facepiece, full facepiece, or mouthpiece/nose clamp[c]	Yes[d]	N/A No tests are required due to positive-pressure operation of respirator. The maximum protection factor is 10 000 plus.[h]	N/A
Combination respirators not listed.	The type and mode of operation having the lowest respirator protection factor shall be applied to the combination respirator.		

N/A means not applicable since a respirator-fitting test is not carried out.

[a]A respirator protection factor is a measure of the degree of protection provided by a respirator to a respirator wearer. Multiplying the permissible time-weighted average concentration or the permissible ceiling concentration, whichever is applicable, for a toxic substance, or the maximum permissible airborne concentration for a radionuclide, by a protection factor assigned to a respirator gives the maximum concentration of the hazardous substance for which the respirator can be used. Limitations of filters, cartridges, and canisters used in air-purifying respirators shall be considered in determining protection factors.

[b]Where the respirator is used for protection against airborne particulate matter having a permissible time-weighted average concentration less than 0.05 milligram particulate matter per cubic meter of air or less than 2 million particles per cubic foot of air, or for protection against airborne radionuclide particulate matter, the respirator shall be equipped with a high-efficiency filter(s).

[c]If the air contaminant causes eye irritation, the wearer of a respirator equipped with a quarter-mask or half-mask facepiece or mouthpiece and nose clamp shall be permitted to use a protective goggle or to use a respirator equipped with a full facepiece.

[d]If the powered air-purifying respirator is equipped with a facepiece, the escape provision means that the wearer is able to breathe through the filter, cartridge, or canister and through the pump. If the powered air-purifying respirator is equipped with a helmet, hood, or suit, the escape provision shall be an auxiliary self-contained supply of respirable air.

[e]The escape provision shall be an auxiliary self-contained supply of respirable air.

[f]For definition of "oxygen deficiency – not immediately dangerous to life or health" see Section 2.

[g]For definition of "oxygen deficiency – immediately dangerous to life or health" see Section 2 and A10.

[h]The protection factor measurement exceeds the limit of sensitivity of the test apparatus. Therefore, the respirator has been classified for use in atmospheres having unknown concentrations of contaminants.

[i]The service life of a vapor- or gas-removing cartridge or canister depends on the specific vapor or gas in air, the concentration of the vapor or gas in air, the temperature and humidity of the air, the type and quantity of the sorbent in the cartridge or canister, and the activity of the respirator wearer. Cartridges and canisters may provide only very short service lives for certain vapors and gases. Vapor/gas service life testing is recommended to ensure that cartridges and canisters provide adequate service lives. Reference should be made to published reports which give vapor/gas life data for cartridges and canisters.

[j]Vapor- and gas-removing respirators are not approved for contaminants that lack adequate warning properties of odor, irritation, or taste at concentrations in air at or above the permissible exposure limits.

NOTE: Respirator protection factors for air-purifying-type respirators equipped with a mouthpiece/nose clamp form of respiratory-inlet covering are not given, since such respirators are approved only for escape purposes.

Table D—ANSI Z88 Committee's 1991 Assigned Protection Factors for Particulate-Filter Respirators in ANSI Z88.2–1991 Submitted to ANSI for Approval on March 6, 1991.

Type of Respirator	Respiratory Inlet Covering	
	Half Mask[A]	Full Facepiece
Air Purifying	10[D]	100[D]

Type of Respirator	Respirator Inlet Covering			
	Half Mask	Full Face	Helmet/Hood	Loose Fitting Facepiece
Powered Air Purifying	50[D]	1,000[B,D]	1,000[B,D]	25[D]

[A] Includes 1/4 mask, disposable half masks, and half masks with elastomeric facepieces.

[B] Protection factors listed are for high efficiency filters and sorbents (cartridges and canisters). With dust filters an assigned protection factor of 100 is to be used due to the limitations of the filter.

[C] Although positive pressure respirators are currently regarded as providing the highest level of respiratory protection, a limited number of recent simulated workplace studies concluded that all users may not achieve protection factors of 10,000. Based on this limited data, a definitive assigned protection factor could not be listed for positive pressure SCBA's. For emergency planning purposes where hazardous concentrations can be estimated, an assigned protection factor of no higher than 10,000 should be used.

[D] Where the particle size is unknown or less than 2 μm (MMAD), a high efficiency filter shall be used. If the contaminant is a fume, use a filter approved for fumes or a high efficiency filter. If the contaminant size is known to be greater than 2 μm (MMAD), any filter type (dust, fumes, mist or high efficiency) may be used.

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3—History of NIOSH's Recommended APFs.

Prior to this evaluation, NIOSH has published *recommended APFs* (RAPFs) in the Institute's *Respirator Decision Logic* (RDL). The Institute's 1976 RAPFs for air-purifying devices are given in Tables E and F of this evaluation.[14] The Institute's 1987 RAPFs for air-purifying devices are given in Tables J and K of this evaluation.[15] The NIOSH *RDL* with its necessary RAPF tables, has always been nonregulatory in nature. It contains scientific evaluations, information, and recommendations for employers, respirator purchasers, and users for their consideration when selecting and using respirators.

The Institute's *Respirator Decision Logic* and RAPF recommendations are similar in nature to respirator recommendations in the 1986 EPA/NIOSH respiratory protection guide for asbestos.[16] In 1988, this guide was ruled to be advisory only.[17] The NIOSH RDL and its RAPFs are without binding effect, have not changed law or regulatory policy, have not affected the agencies' own certifications under 30 CFR Part 11, nor have they altered anyone's obligations or duties.

Respirator purchasers and users and employers of users should note that the RAPFs published in this evaluation constitute NIOSH's most current *recommended APFs*. As such they supersede certain previous NIOSH RAPFs published in the Institute's 1987 RDL.[18]

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[14]NIOSH: *A Guide to Industrial Respiratory Protection*, DHEW (NIOSH) Publication No. 76–189, Cincinnati, Ohio (June 1976), Appendix F, pp. 137–148.

[15]*NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87–108, Cincinnati, OH (May, 1987), Tables 1–3, pp. 2–4, 13–18, and 27–29.

[16]Environmental Protection Agency and the National Institute for Occupational Safety and Health: *A Guide to Respiratory Protection for the Asbestos Abatement Industry*, EPA–560–OPTS–86–001, Washington, D.C. (April 1986).

[17]*Industrial Safety Equipment Association (ISEA) v. E.P.A.*, 837 F.2d 1115 (D.C. Cir. 1988).

[18]*NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87–108, Cincinnati, OH (May, 1987), Tables 1–3, pp. 2–4, 13–18, and 27–29.

Table E—NIOSH's 1976 Recommended Assigned Protection Factors for Particulate-Filter Respirators.

Protection Factor (Minimal)	Permissible Respiratory Protection
5X	Any dust and mist respirator (30 CFR 11.130)
5X	Any dust and mist respirator, except single use (30 CFR 11.130)
10X	Any dust and mist respirator, except single-use or quarter-mask respirator (30 CFR 11.130
10X	Any fume respirator or high efficiency particulate filter respirator (30 CFR 11.130)
10X	Any high efficiency particulate filter respirator (30 CFR 11.130)
50X	A high efficiency particulate filter respirator with a full facepiece (30 CFR 11.130)
1,000X	A powered air-purifying respirator with a high efficiency particulate filter (30 CFR 11.130)

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Table F—NIOSH's 1987 Recommended Assigned Protection Factors for Particulate-Filter Respirators.

Assigned Protection Factor	Type of respirator[1]
5	Single-use (see definition in Glossary) or quarter mask[2] respirator
10	—Any air-purifying half-mask respirator including disposable[3] (see definition in Glossary) equipped with any type of particulate filter except single use[2,4] —Any air-purifying full facepiece respirator equipped with any type of particulate filter[5]
25	—Any powered air-purifying respirator equipped with a hood or helmet and any type of particulate filter[4]
50	—Any air-purifying full facepiece respirator equipped with a high efficiency filter[2] —Any powered air-purifying respirator equipped with a tight-fitting facepiece and a high efficiency filter[4]

[1]Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m^3.
[2]The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers.
[3]An APF of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test. Otherwise a 5 shall be assigned.
[4]The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data.
[5]The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

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Table J—NIOSH's 1987 Recommended Assigned Protection Factors for Protection Against Particulate Exposures.

Assigned Protection Factor	Type of respirator[1]
5	Single-use (see definition in Glossary) or quarter mask[2] respirator
10	—Any air-purifying half-mask respirator including disposable[3] (see definition in Glossary) equipped with any type of particulate filter except single use[2,4] —Any air-purifying full facepiece respirator equipped with any type of particulate filter[5] —Any supplied-air respirator equipped with a half-mask and operated in a demand (negative pressure) mode[2]
25	—Any powered air-purifying respirator equipped with a hood or helmet and any type of particulate filter[4] —Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode[4]
50	—Any air-purifying full facepiece respirator equipped with a high efficiency filter[2] —Any powered air-purifying respirator equipped with a tight-fitting facepiece and a high efficiency filter[4] —Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode[2] —Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode[4] —Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode[2]
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode[2]
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode[2]
10,000	—Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode[2] —Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode[2]

[1]Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m^3.
[2]The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers.
[3]An APF of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test. Otherwise a 5 shall be assigned.
[4]The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data.
[5]The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

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Table K—NIOSH's 1987 Recommended Assigned Protection Factors for Protection Against Gas/Vapor Exposures.

Assigned Protection Factor[1]	Type of respirator
10	—Any air-purifying half-mask respirator (including disposable) equipped with appropriate gas/vapor cartridges[2] —Any supplied-air respirator equipped with a half-mask and operated in a demand (negative pressure) mode[2]
25	—Any powered air-purifying respirator with a loose-fitting hood or helmet[3] —Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode[3]
50	—Any air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or gas mask (canister respirator)[2] —Any powered air-purifying respirator equipped with a tight-fitting facepiece and appropriate gas/vapor cartridges or canisters[3] —Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode[2] —Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode[3] —Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode[2]
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode[2]
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode[2]
10,000	—Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode[2] —Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode[2]

[1]The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
[2]The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers.
[3]The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data.

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4—Strategy used by NIOSH for RAPF determinations.

It is not feasible for NIOSH to test or evaluate respirator performance over an entire range of typical use conditions that may adversely affect their protection levels. As will be discussed at length in this evaluation,[19] the strategy for equipment testing is totally consistent with the professional practice used for at least 20 years by respirator experts to determine respirator-class APFs through evaluation of face-seal leakage measurements. That is, it has not been the accepted standard of professional practice to use the makes and models with average or typical face-seal leakage in a class to determine APFs. Instead, it has been the practice to use the makes and model with *greater or higher face-seal leakage in the class* to determine APFs. This practice has been founded on the rationale that virtually no purchasers nor users know whether their particular respirator model and use conditions may result in hazardous, poor, average, or superior face-seal fit.

Because the nature and technology of industrial respirators prevents purchasers and users from adequately assessing respirator safety and protection under widely-varying use conditions, NIOSH has determined that demanding-use considerations are necessary when determining APFs in order to protect the health and safety of *all* respirator users.

Absent some means of continually assuring a respirator's proper fit every time it is worn, the RAPFs given in this evaluation reflect *only* the Institute's assessment of the *protection potential* that can be afforded by the listed masks. The RAPFs *do not consider* whether certain types of respirators certified by NIOSH can be reliably fit tested periodically *and* reliably fit checked by a wearer each time they don their mask. The NIOSH RAPFs *do not necessarily indicate* and *do not guarantee* the personal protection that will actually be provided every day to every wearer as respirators are used on the job.

Reliable and effective facepiece-seal tests (*both* periodic fit tests *and* fit checks every time a mask is donned) are essential for the likelihood of each wearer achieving the RAPFs given in this report. Thus, when users and purchasers utilize NIOSH RAPFs, they must take into account any questionable efficacy and reliability of those fit tests and fit checks they rely upon. For example, the U. S. Court of Appeals for the District of Columbia Circuit ruled, in 1987, that OSHA had correctly assigned an APF of 5 to those "disposable respirators" that could not be fit checked by wearers

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[19]Refer to discussion presented in this evaluation under *Review and Evaluation of Professional Practices Used During the 1970s and 1980s for Respirator Evaluations and APF Determinations.*

for adequate inhalation protection against cotton dust.[20] That is, certain "maintenance-free" halfmasks with filtering facepieces for which it is "difficult, if not impossible, for the wearer to cover the entire [filtering] surface area, but not the seal between the respirator and the wearer's face"[21] during the user fit check recommended by the manufacturer. The federal court stated that:

> OSHA recognized that, in the case of [certain filtering-facepiece] disposable respirators, the worker's hands cannot effectively block intended air intake, and that intake only, while leaving unobstructed air taken in because of the respirator's improper fit.[22]

The federal court also noted that:

> Absent assurance of a respirator's proper fit, the NIOSH and ANSI ratings can reliably indicate only the efficiency of the filter, not the effectiveness of the entire respirator as it is used on the job.[23]

Therefore, filter mask purchasers and users must recognize that indispensable as they are, reliable and effective fit testing and fit checks *cannot detect* excessive filter leakage.

The 1987 NIOSH-recommended APFs for dust, fume, and mist (DFM) filter respirators certified under 30 CFR Part 11 were determined by a process that did not fully embody the fundamental strategy underlying the performance tests and APFs recommended in this evaluation and did not fully recognize the potential protection defects for certain filter types. Therefore, NIOSH decided to reexamine the basic assumptions underlying the Institute's 1987 APF recommendations for both air-purifying and atmosphere-supplying respirators.

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[20] *National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration*, 825 F.2d 482 (D.C. Cir. 1987)

[21] Ibid., p. 489, footnote 6.

[22] Ibid., p. 492.

[23] Ibid., p. 493.

5—Introduction to respirator-performance evaluations, APF determinations, and use of APFs.

The accepted standards of professional practice for respirator-performance evaluations have evolved slowly since the early research efforts of the U.S. Public Health Service and U.S. Bureau of Mines in the 1920s.[24] Part of this evolution over the last three decades first involved efforts to quantitatively evaluate respirator performance.[25,26,27,28,29,30,31,32,33]

These early research efforts were then followed by the determination and use of APFs for respirator selection. In order to understand the complex technical and policy issues associated with this performance-evaluation evolution, it is useful to examine the process elements involved in evaluating respirator performance and

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[24]Katz, S. H., E. G. Meiter, and F. H. Gibson: *Efficiencies of Painters' Respirators Filtering Lead Paint, Benzol and Vitreous Enamel Sprays*, Public Health Bulletin No. 177, Treasury Department, U.S. Public Health Service (June 1928).

[25]Burgess, W. A., L. Silverman, and F. Stein: A New Technique for Evaluating Respirator Performance, *Amer. Ind. Hyg. Assoc. J.* 22:422 (1961).

[26]Letts, H. J. R.: The Limitations of Gas Masks as Means of Protection Against Occupational Hazards, in *Design and Use of Respirators*, D. N. Davies, Ed., Pergamon Press, Oxford, England (1961), p. 119.

[27]Adley, F. E. and D. E. Wisehart: Methods for Performance Testing of Respiratory Protective Equipment, *Am. Ind. Hyg. Assoc. J.* 23:251–256 (1962).

[28]Hounam, R. F.: *A Method for Evaluating the Protection Afforded When Wearing a Respirator*, Report No. AERE–R–4125, United Kingdom Atomic Energy Authority, Harwell, Berkshire (1962).

[29]Hounam, R. F., D. J. Morgan, D. T. O'Conner, and R. J. Sherwood: The Evaluation of Protection Afforded by Respirators, *Ann. Occup. Hyg.* 7:353– 363 (1964).

[30]Morgan, D. J.: *A Method of Testing the Efficiency of a Respirator Using a Halogenated Hydrocarbon Test Gas*, Report No. AERE–R–4485, United Kingdom Atomic Energy Authority, Harwell, Berkshire (1964).

[31]White, J. M. and R. J. Beal: The Measurement of Leakage of Respirators, *Am. Ind. Hyg. Assoc. J.* 27:239–242 (1966).

[32]Burgess, W. A., W. C. Hinds, and S. Shook: *Performance and Acceptance of Respirator Facial Seals*, presented at the Annual Conference of the Ergonomics Research Society, University of Sussex, England (March 20–26, 1968).

[33]Griffin, D. G. and D. J. Longson: The Hazard Due to Inward Leakage of Gas Into a Full Face Mask, *Ann. Occup. Hyg.* 13:147–151 (1970).

subsequent determination of APFs. These are presented in Table L of this evaluation.

It is also important to understand how APFs are used in respirator selection in order to appreciate both their significance and limitations. A simplified version of this information is given in Table M of this evaluation. Respirator selection and use activities are regulated by OSHA (under 29 CFR 1910.134) and other Federal agencies.[34]

Table P presents recommended APFs for various respirator types (classes), facepieces, and certification performance tests (i.e., 30 CFR Part 11). APFs can be considered to be potential "effectiveness" or "protection" ratings. They reflect the fact that different types of respirators are capable of providing different degrees of protection to wearers. Differences between potential protection values (APFs) afforded by different respirator types can be quite substantial.

Step 4 of Table M in this evaluation summarizes how APFs are used in respirator selection. Possible low levels of user protection exhibited by devices with lower APFs must be recognized and considered by purchasers and users when selecting and using NIOSH-certified respirators. Hence valid APFs are essential for correct respirator selection.

Most respirator evaluation studies that will be discussed later in this evaluation[35] have measured respirator performance after the test subjects have gone through Steps 1 through 7 shown in Table M of this evaluation. However there are numerous factors that can affect the protection levels exhibited by respirators. With regard to the determinant factors affecting protection levels provided by respirators, Galvin et al. have stated:

> The protection afforded by an air-purifying respirator is determined by two major factors. One is the fit of the respirator around the face seal [face-seal leakage] and the second is the efficiency of the cartridge in removing the contaminant from the airstream [filter leakage]. Fit is influenced by the ability of the respirator to conform to individual facial structure and to maintain the facial seal during work activities.[36]

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[34]Refer to discussion presented in this evaluation under *Regulatory APFs in NIOSH and Other Federal Agencies.*

[35]For example, refer to discussion presented in this evaluation under *Evaluation of Face-Seal Leakage Results from Nine Studies of Non-Powered, Air-Purifying Halfmasks.*

[36]Galvin, K., S. Selvin, and R. C. Spear: Variability in Protection Afforded by Half-Mask Respirators Against Styrene Exposure in the Field, *Am. Ind. Hyg. Assoc. J.* 51:625-639 (1990), p. 625.

Additionally, a major respirator manufacturer has stated:

> Ideally, respirator performance as described by 5th percentile values should be based on variability caused by the fit and filter efficiency of the respirator alone.[37]

Thus *hazardous leakage* of a contaminant into a respirator can result when either or both of *excessive filter leakage* or *excessive face-seal leakage* occur. Employers are responsible for testing for face-seal leakage with procedures known as *fit tests*, which can be either *qualitative* (QLFT) or *quantitative* (QNFT).[38] In several OSHA rule-makings, NIOSH has suggested numerous factors that affect respirator effectiveness for individual wearers in the workplace.[39,40]

NIOSH recognizes that the likelihood of each respirator wearer achieving adequate protection during each respirator wearing is a strong function of the inherent protective capabilities of the make and model respirator used. In addition, the Institute also recognizes that the likelihood of achieving adequate wearer protection is also a strong function of two types of determinant factors:

- the determinant factors affecting *excessive face-seal leakage* at the time of the initial and periodic fit factor screening (fit testing with QLFTs or QNFTs)

- the "point-of-use" determinant factors affecting both *excessive filter leakage* and *excessive face-seal leakage* during the time of each wearing.

As generally performed, QLFTs or QNFTs are performed to detect *only* face-seal leakage existing at the time of testing. They *are not capable* of detecting excessive filter leakage. No matter how effective they are or how well they are performed, fit tests can only help identify compromised protection resulting from the first type of factors for face-seal leakage. The fit tests cannot detect excessive filter or face-seal

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[37]Gosselink, D. W., Wilmes, D. P, and Mullins, H. E.: Workplace Protection Factor Study for Airborne Asbestos (a.k.a. The Shiloh Brake Study conducted by representatives of the 3M Company), presented at the American Industrial Hygiene Conference, Dallas, Texas (May 1986), p. 7.

[38]For example, but not limited to, 29 CFR 1910.134(e)(5).

[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.

leakage resulting from the second type of *point-of-use* factors occurring *after* initial fit testing and mask selection. These include, but are not limited to,

- airborne contaminants that can leak through filters
- incorrect mask position on the user's face
- incorrect headstrap tension
- incorrect headstrap position on and behind the user's head
- failure to use all the headstraps
- changes in a user's facial surface such as facial stubble and perspiration
- mask damage
- improper mask maintenance.

A major respirator manufacturer has correctly noted:

> . . . neither QNFT nor QLFT can guarantee that the wearer will don the respirator in the same fashion in the workplace as when being fit tested and, therefore, that the same respirator fit factor will be achieved under actual working conditions. Control of fit is primarily up to wearer himself. Consequently, in a real sense, neither QNFT nor QLFT by themselves have a direct bearing in assuring proper employee health protection, but rather can only assure that the respirator selected by the employee can fit properly.[41]

This statement supports the critical importance of adequate training for each user so they will know how to properly don, adjust, and wear their respirator. It also emphasizes that adequate fit testing must be performed by an employer so that a user will not have to wear a mask that leaks at the face seal.

Point-of-use factors can create a considerable risk of undetected excessive leakage at the face seal or through the filter when a mask is worn in a hazardous environment. Even for those minimal number of particulate contaminants with "adequate warning properties," there is risk to the wearer. By the time a user has smelled or tasted a hazardous contaminant, it may already have done some damage to the user's health. Thus, each wearer must have the capability of reliably and effectively fit checking his or her mask for proper fit each time the mask's protection must be depended on. This is the purpose of *fit-check tests* that must be performed by users each time they don their respirator.

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[41] 3M Company: *Comment of Minnesota Mining and Manufacturing Company with Respect to the Permanent Lead Standard Quantitative Fit Test Provision*, OSHA Docket No. H–049A, Exhibit 6–16, (July 1, 1981), p. 3.

Table L—Process Elements for Evaluating Respirator Performance and Determining APFs.

Process Element
1—Select respirators to be tested.
2—Select test environment.
3—Select test subjects.
4—(Optional) Perform fit-test screening (QLFT or QNFT) that is supposed to reject those subjects unable to obtain an adequate fit.
5—Measure respirator performance under test conditions.
6—Analyze respirator-leakage data and determine APFs for each respirator class.

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Table M—Simplified Elements of Respirator Selection and Usage Illustrating the Required Application of APFs for Air-Purifying Masks.

1—Identify intended respirator uses. Identify physical nature and toxicity of contaminant(s).
2—Measure concentration levels of contaminant(s) where worker exposures can occur. Compute the concentration level to OSHA PEL ratio (i.e., concentration level as a multiple of applicable PEL).
3—Identify prospective respirator wearers in a given workplace.
4—**Using APF tables** and other necessary information from a Respirator Decision Logic, select respirator(s) that can provide assured protection as required to exposed workers. **Selected respirator must have an APF *larger* than PEL multiple from Step 2 above.**
5—Using the selected respirator(s) and QLFT or QNFT, fit-test screen the adequacy of the face seal(s) on each prospective wearer. This is to identify those respirator facepieces that cannot achieve the class APF for selected device(s) on the prospective wearers. No filter testing is performed, since it is assumed that the filters that will actually be worn on the facepieces have essentially zero leakage.
6—Provide and assign a respirator to those workers that passed the fit-test screening.
7—Each wearer must perform a point-of-use "fit check" before each use of their assigned respirator. This is done to identify those wearers with inadequate protection due to point-of-use factors such as poorly-fitted or improperly adjusted facepieces or changes in the user's skin that are preventing a proper fit (e.g, beard stubble).
8—Properly wear the respirator in the hazardous environment. For tight-fitting masks, do not wear a respirator when conditions prevent a proper seal of the facepiece to the wearers skin. For respirator-related causes, respirator users should leave a hazardous area (e.g., failure of the mask to provide adequate protection, respirator malfunction, detection of leakage of air contaminant into the respirator).

6—Review and evaluation of professional practices used during the 1970s and 1980s for respirator face-seal evaluations and APF determinations.

As part of its efforts to develop APF values as part of this evaluation, NIOSH reviewed and evaluated professional practices used during the 1970s and 1980s for respirator face-seal performance evaluations and APF determinations. All NIOSH conclusions stated in this section are based on the best available evidence regarding professional practices used during these two decades.

The concept of respirator-class *protection factors* is over 25 years old. Since the early 1980s they have been called *assigned protection factors* (APFs) by respirator specialists. Hyatt[42] noted in 1976 that the first official definition of the term *[assigned] protection factor* was made by the U. S. Bureau of Mines in their Approval Schedule 21B published in 1965.[43] For over 7 years from 1965 to 1972, assigned protection factors were part of filter-type respirator certifications issued by the Bureau of Mines. Hyatt also reported that two years later in 1967, the Atomic Energy Commission (AEC) Director of Regulation published proposed [assigned] protection factors.[44] Hyatt reported that due to concerns relative to the lack of adequate test data for all types of devices, the AEC-proposed [assigned] protection factor table was withdrawn.

It is important to recognize that most current respirator-class APFs are founded on the professional precepts, technical policies, and respirator protection factor values[45] developed during the late 1960s through the 1970s as the product of AEC-fund-

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[42]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), p. 7.

[43]U. S. Department of the Interior, Bureau of Mines: Respiratory Protective Apparatus—Tests for Permissibility; Fees: Schedule 21B, Filter-Type Dust, Fume, and Mist Respirators (30 CFR Part 14), *Federal Register* 30(#616), (January 19, 1965) as amended at 34 FR 9617 (June 12, 1969).

[44]U. S. Atomic Energy Commission: Proposed Rule Making, Standards for Protection Against Radiation—10 CFR Part 20, *Federal Register* 32(#215), (November 4, 1967).

[45]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), Table I, pp. 4–5.

ed and NIOSH-funded research at the Los Alamos Scientific Laboratory (LASL).[46,47,48,49,50,51]

Hyatt stated in 1977 that "These [1976] respirator protection factor values are based on quantitative fit tests with Bureau of Mines' approved respirators on men during the period 1971 through 1973."[52] Hyatt also stated in 1977:

> New quantitative fit test data on NIOSH/MESA approved respirators made with male and female test panels representative of the facial sizes of the U. S. adult workers during the past three years is available and has been reviewed by several investigators. My analysis of this new data indicates that the respirator protection factors in the [Joint NIOSH/OSHA Standards Completion Program, 1975] "Respirator Decision Logic" should be reviewed and revised. . . .
>
> Respirator protection factors in the "Respirator Decision Logic" recommends a protection factor of 10 for quarter-mask and half-mask facepieces and 50 for full facepiece respirators operated with a negative pressure during inhalation. . . . The new respirator fit test data demonstrates that full facepiece respirators now available should be assigned a protection factor of 100 for men. However, this (sic) data indicates (sic) that the protection factor for women should be reduced. . . .
>
> My recommendation for an interim solution is to assign a protection factor of 10 for quarter-mask and half-mask facepieces and 100 for full facepiece devices operated with a negative pressure in the facepiece for men only. For women respirator users, I recommend a protection factor of 5 for quarter-mask and half-mask facepieces and 50 for full facepieces operated with a nega-

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[46]Hyatt E. C. et al.: *Respirator R and D Related to Quality Control; LASL Project P–37*, Los Alamos Scientific Laboratory, Quarterly Report July 1 thru September 30, 1971, No. LA–4908–PR (March 1972).

[47]Hyatt E. C. et al.: *Respiratory Studies for the National Institute for Occupational Safety and Health—July 1, 1972 through June 3, 1973*, Los Alamos Scientific Laboratory, Progress Report, No. LA–5620–PR (May 1974).

[48]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, Progress Report, #LA–5805–PR (December 1974).

[49]Douglas, D. D. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—July 1, 1974–June 30, 1975*, Los Alamos Scientific Laboratory, Progress Report, No. LA–6386–PR (August 1976).

[50]Lowry, P. L. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—July 1, 1975–December 31, 1976*, Los Alamos Scientific Laboratory, Progress Report, No. LA–6722–PR (February 1977).

[51]Lowry, P. L. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—January 1–December 31, 1977*, Los Alamos Scientific Laboratory, Progress Report, No. LA–7317–PR and HEW publication No. (NIOSH) 78–161 (June 1978).

[52]Hyatt, E. C.: Letter to J. F. Finklea of NIOSH, Los Alamos, New Mexico (September 14, 1977).

tive pressure in the facepiece. This may be impractical because the current practice is to assign the same protection factor for both men and women.[53]

Regarding the face-seal-performance data and technical criterion used for determining respirator-class APFs recommended to NIOSH and OSHA, an important LASL report stated in 1976:

> A reasonable basis for assigning a [assigned] protection factor to a single class of respirators would be to require that 95% of the [test] subjects must meet the performance criteria to assign a given protection factor. In addition, the 5% of the people not meeting the [APF] performance criteria and the 5% not included in the panel must be identifiable by a stringent qualitative or quantitative fitting test or by anthropometric facial measurements. It is recommended that this criteria be used in assigning a given protection factor to a single class of respirators such as half-mask high-efficiency filter respirators. This is the criteria that is used in making recommendations where the results of respirator [face-seal] performance measurements are discussed in Sec. VI.[54]

It is important to note that the face-seal-performance measurements made on half-masks by the LASL researchers were performed on test subjects who had *not been properly fit tested* with qualitative or quantitative fit tests. These measurements subsequently were used as the basis for the LASL APF recommendations. The LASL researchers stated the following regarding their measurements:

> Before entering the test chamber, the subject donned the respirator and tested the fit. When wearing a half-mask respirator, the subject tested the fit by either the positive or negative pressure method.[55]

The 1976 LASL report also stated that face-seal-performance results from each and every NIOSH-certified respirator in a class must meet the preceding criteria when determining a class APF.[56] This criterion is supported by remarks made at a

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[53]Ibid.

[54]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), p. 10.

[55]Hyatt E.C., J. A. Pritchard, and C. P. Richards: Respirator Efficiency Measurement Using Quantitative DOP Man Tests, *Am. Ind. Hyg. Assoc. J.* 33(10):634–643 (1972), p. 637.

[56]Ibid., Section VI, pp. 10–14.

1975 OSHA seminar presented by the senior LASL respirator researcher at that time.

The following APF criteria were also used for 1970s-vintage APFs recommended by LASL to NIOSH and OSHA and subsequently incorporated into NIOSH's first APF recommendations,[58] numerous OSHA regulations, OSHA's *Industrial Hygiene Manual*,[59] and OSHA's *Industrial Hygiene Technical Manual*:[60]

> 95% of [the test] subjects must meet given [A]PF criteria to assign [A]PF for that respirator [and] all types of respirators in one class must meet criteria to assign a [A]PF to one class of respirator. Example; if less than 95% of subjects fail to obtain a PF of 100 on only *one* of 6 types of FF [fullface] approved, then the [A]PF assigned to FF class must be lowered, say to [A]PF of 50.[61]

In 1980, the American National Standards Institute (ANSI) Z88.2–1980 respirator-use standard stated:

> Respirators shall be selected according to the characteristics of the hazards involved, the capabilities and limitations of the respirators, and the ability of each respirator wearer to obtain a satisfactory fit with a respirator. Taking into account the capabilities and limitations of respirators and the results of respirator-fitting tests, a table of respirator [assigned] protection factors has been prepared (see Table 5 [Table C in this evaluation]). A respirator [assigned] protection factor is a measure of the degree of protection provided by a respirator to a wearer.[62]

The ANSI standard required the successful completion of respirator-fitting tests before use of the standard's APF values. This was stated as follows:

> A qualitative or quantitative respirator-fitting test shall be used to determine the ability of each individual respirator wearer to obtain a satisfactory fit with a negative-pressure respirator. (The National Institute for Occupational Safety and Health recommends that only a program of quantitative-fit testing can provide adequate worker protection.) . . .

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[57]Hyatt, E.: *Respirator Protection Factors*, OSHA Seminar Outline (December 17, 1975).

[58]NIOSH: *A Guide to Industrial Respiratory Protection*, DHEW (NIOSH) Publication No. 76–189, Cincinnati, Ohio (June 1976), Appendix F, pp. 137–148.

[59]OSHA: *Industrial Hygiene Manual*, Chapter III—OSHA Standard Method for Determination of Respiratory Protection Program Acceptability (1979), pp. 89–90.

[60]OSHA: *Industrial Hygiene Technical Manual*, Chapter V—Respiratory Protection, Issued by OSHA Instruction CPL 2–2.20 A, (March 30, 1984), pp. 75–77.

[61]Hyatt, E.: *Respirator Protection Factors*, OSHA Seminar Outline (December 17, 1975), p. 8.

[62]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1980, New York, New York, (1980), p. 20.

If a qualitative respirator-fitting test has been used in respirator selection, a person shall be allowed to use only the specific make(s) and model(s) of respirator(s) for which the person obtained a satisfactory fit, and the respirator protection factor listed under "qualitative test" in Table 5 shall apply [Table C of this evaluation]. Under no circumstances shall a person be allowed to use any respirator if the results of the qualitative respirator-fitting test indicate that the person is unable to obtain a satisfactory fit.[63]

In 1982, researchers at Los Alamos National Laboratory (LANL) reiterated the criteria of their organization[64] in the following statements on [Assigned] Protection Factors:

The [Assigned] Protection Factor is the number assigned to a particular type of respirator, or to an entire class of respirators, representing the degree of protection that the respirator is thought to provide for the majority of users. In the past, the [A]PF has been selected to represent the lowest level of protection provided by the class of respirators selected.

The following information must be available for the derivation of a [Assigned] Protection Factor: the results of face-to-facepiece sealing tests (fit factor) on a representative number of test subjects, and a knowledge of the efficiency of the air-cleaning elements, if any, to be used with respirator in the workplace.[65]

In early 1983, Myers et al. stated the definitions and measures of respirator performance "currently used by the NIOSH Testing and Certification Branch respirator research staff."[66] They noted that "these definitions and relationships are in some instances at variance or different than those advocated by Hack, et al. [and Hyatt/LASL]" Regarding their APF definition Myers et al. stated:

The "assigned protection factor is a measure of the minimum anticipated workplace level of respiratory protection that would be provided, by a properly functioning respirator, to a large percentage of properly fitted and trained users. . . . The assigned protection factor should be based on

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[63]Ibid., pp. 20 and 24.

[64]The Los Alamos Scientific Laboratory had been renamed as the Los Alamos National Laboratory.

[65]Hack, A., C. Fairchild, and B. J. Skaggs: The Forum—Letter to the Editor, *Am. Ind. Hyg. Assoc. J.* 43(12):A–16 (1982).

[66]Myers, W. R., Lenhart, S. W., Campbell, D. and G. Provost: The Forum—Letter to the Editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983).

workplace protection factors[67] [WPF] measurements made in a representative number of workplace settings and for a representative number of wearers.[68]

Regarding their proposed computational method for APFs, Myers et al. stated:

While no method for calculating assigned protection factors from such [workplace protection factor] data has been established, several methods might be considered. If the distribution of measured workplace protection factors is lognormal, the assigned protection factor could be computed from the following relation: . . .

If we want to calculate the assigned protection factor for which we would expect 90% of the workplace protection factors to be above, then Z_p would be 1.28. If however, we choose 95% instead of 90%, Z_p would be 1.64. . . .

A more conservative method of determining the assigned protection factor from such data is to compute a one-sided lower tolerance limit above which, for example, we may prodict (sic) with 90% confidence that 90% of the workplace protection factors lie, and equate the assigned protection factor to that limit.[69]

In the same 1983 Letter to the Editor, Myers et al. of NIOSH gave the definition for another type of protection factor:

The "program protection factor" is a measure of the respiratory protection provided to a worker by an established respirator program. . . . *In terms of worker health, the program protection factor is the most significant form of the protection factor.* It is a measure of the effectiveness of the complete respirator program. The program protection factor is a function of the workplace environment, the activity of the wearer, the fit of the respirator, respirator selection, the respirator design, training, maintenance, storage, supervision, program administration and monitoring, and any other variable that affects program effectiveness. *If any of these program elements are deficient, the program protection factor will be adversely affected.*[70] [underlines added]

However, none of the protection-factor studies performed by NIOSH or other researchers in the 1980s or early 1990s have evaluated *program protection factors.*

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[67]A measure of the actual protection provided by a respirator in a workplace under the conditions of the workplace by a properly functioning respirator when it is correctly worn and used. A WPF is defined as the ratio of the measured contaminant concentration outside a respirator facepiece (C_o) to the contaminant concentration inside the facepiece (C_i). The sampling restrictions placed on C_o and C_i are that both should be time-weighted average samples taken simultaneously after the respirator has been properly fitted to the wearer and while the respirator is properly worn and used during normal work activities.

[68]Myers, W. R., Lenhart, S. W., Campbell, D. and G. Provost: The Forum—Letter to the Editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983) , p. B–26.

[69]Ibid., p. B–26.

[70]Ibid., p. B–26.

Hence many of the variables that can adversely affect protection actually provided to workers in typical respirator programs are not reflected in *WPF studies.*

In 1985, the AIHA Respirator Technical Committee, chaired by H. P. Guy, prepared a "consensus terminology" for respirator performance in consultation with the principals from Los Alamos National Laboratory and NIOSH.[71] The Guy Committee recommended that the terminology be published in the *AIHA Journal* and ultimately adopted for manuscripts submitted to the *Journal.* The Guy Committee provided the following APF definition:

> The minimum expected workplace protection level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users. The maximum use concentration for a respirator is generally determined by multiplying a contaminant's exposure limit by the protection factor assigned to the respirator.[72]

The Guy Committee also recommended the following definition for *workplace protection factors*:

> A measure of the protection provided in the workplace, under the conditions of the workplace, by a properly selected, fit tested and functioning respirator when correctly worn and used. It is defined as the workplace contaminant concentration which the user would inhale if he were not wearing the respirator (C_O) divided by the workplace contaminant concentration inside the respirator facepiece (C_I). Both C_O and C_I are determined from samples taken simultaneously, only while the respirator is properly worn and used during normal work activities.[73]

Regarding NIOSH's 1987 recommended APF values,[74] NIOSH stated:

> When WPF data existed, NIOSH utilized the point estimate equation proposed by Myers et al. [13] to help establish the APF's recommended in the decision logic. The point estimate equation is as follows . . .

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[71]Guy, H. P.: Letter to the Editor—Respirator Performance Technology, *Am. Ind. Hyg. Assoc. J.* 46(5):B–22 to B–24 (1985).

[72]Ibid., p. B–22.

[73]Ibid.

[74]*NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87–108, Cincinnati, OH (May, 1987), Tables 1–3, pp. 2–4, 13–18, and 27–29.

When WPF data existed, NIOSH selected a confidence limit of p=0.95.[75] Thus for a given set of data and given class of respirators, NIOSH would expect that 95% of the WPF's would exceed the calculated point estimate.[76]

NIOSH has concluded that APFs based on APF definitions from Myers et al. and the Guy Committee are derived from WPF data that were obtained *after* each test subject has been properly fitted and trained. "Properly fitted" for these APF definitions has generally been interpreted as fit screening with OSHA-approved qualitative or quantitative fit tests. As reported by respirator researchers in the 1980s, WPF values are measurements of the actual protection provided in the workplace by a properly-functioning respirator when correctly worn by a properly trained user *after* proper fit testing. This is in marked contrast to the LASL laboratory face-seal data for halfmasks that were obtained *before* proper fit testing was performed.

NIOSH has concluded that the Hyatt/LASL-recommended APFs were values that *at least 90% of all workers* were expected to achieve *before* proper fit testing was performed. That is, up to 5% of a face-seal-performance test panel not achieving an APF plus the 5% of all American workers with extreme facial sizes *not represented* on a test panel were expected to *not be able to achieve* a given LASL-recommended APF. However, for a given respirator, it was expected and required that these 10% maximum of all potential wearers would be identified and *not permitted to wear the respirator in the workplace.*

NIOSH has concluded that the Hyatt/LASL and ANSI 1980 APF recommendations were predicated on the requirement that *100% of respirator users in the workplace* must attain protection exceeding a class APF *after proper fitting* (i.e., fit testing) has been performed by the employer. That is, the Hyatt/LASL and 1980 ANSI APFs expressed the level of respiratory protection expected to be achieved by *100% of properly-fitted users* (i.e., those with satisfactory fits exceeding the class APF).

A noted respirator expert stated the following in 1989 with regard to the impact of workplace-testing results on the Hyatt/LASL APFs developed in the 1970s:

> The subject of testing the efficiency of respirators while worn in the workplace has become a hot topic of conversation. . . . This subject has been brought into close scrutiny by the significant work of several investigators which shows essentially no correlation between the "Simulated Workplace Protection Factor" (SWPF) determined in a semi-laboratory situation, that is, quantitative respirator fit testing (QNFT) results, as compared to the WPFs obtained in the workplace.

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[75]This is an incorrect statement. NIOSH personnel did not compute *confidence limits* at a *confidence level* for the NIOSH-recommended APFs based on WPF data. The statement should read, ". . . NIOSH selected a *population proportion* of p = 0.95."

[76]*NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87-108, Cincinnati, OH (May, 1987), p. 29.

By inference, these data are equally at odds with the protection factors established by OSHA for various types of respirator, which were based on QNFT data obtained by the Los Alamos National Laboratory in the 1970S. Until recently, the SWPFs gathered during QNFT were more or less assumed to translate directly into the protection afforded by a particular respirator, or class of respirators, while worn in the workplace.

Apparently this is now a questionable assumption which has thrown the entire concept of fit testing into doubt.[77]

Earlier, in a 1982 evaluation of qualitative fit tests (QLFTs), NIOSH had statistically analyzed numerous data sets that had been submitted to OSHA in support of the du Pont isoamyl acetate, irritant smoke, and 3M Company saccharin tests.[78] The 1982 NIOSH conclusions regarding the efficacy of these QLFTs included the following statements:

A substantial number of the studies submitted to Docket H–049A we believe were inappropriately conducted, analyzed, or reported. As a result many of the data sets are unreliable indicators of how the proposed qualitative screening tests will perform in respirator programs that can be reasonably expected in the lead industries. . . .

The use of the Du Pont isoamyl, 3M saccharin, or irritant smoke protocols could substantially increase the likelihood of assigning inadequate respirators to workers, when compared to the very low risk of the presently required quantitative method. . . .

The Du Pont isoamyl acetate, 3M saccharin, and stringent irritant smoke protocols cannot assure that respirator wearers with fit factors less than 100 [required for halfmask testing] will be efficiently rejected by any of the three screening tests.[79]

In 1989, a noted respirator expert stated the following with regard to the efficacy of both qualitative and quantitative fit tests:

. . . I believe it is more instructive to examine the role and function of respirator fit testing, and face some realities. First of all, it is unfortunate that fit testing results apparently cannot be used as a reliable indication of respirator performance in the workplace. Life would be simpler if the converse were to continue to be true.

But looking at fit testing logically, both in the semi-laboratory and in the workplace, it's unrealistic to make any claims other than that these are the results which were obtained on this person, wearing this respirator, on this data, using this standardized protocol. Any claims beyond this, in my mind, are neither technically nor professionally defensible. . . . In my opinion

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[77]Pritchard, J. A.: Open Forum: Respirator Testing—Old Values, *Ind. Safety and Hyg. News* (May 1989).

[78]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).

[79]Ibid., pp. 7–8.

we are left with respirator fit testing, whether qualitative or quantitative, playing the role as a means of obtaining the best possible fit of a given respirator on a given person at a given time. We should not make any representation as to the ultimate efficiency in the workplace.[80]

In 1990, another noted respirator expert stated the following regarding one qualitative fit test (QLFT) that has been widely-used in the 1980s:

If a person wearing a respirator in an atmosphere containing the airborne sodium saccharin particles detects the penetration of the sodium saccharin particles by taste, then the respirator is declared to have failed the test. OSHA has listed this test in several hazardous substance standards including those for respirator fitting test. However, evidence has been uncovered recently during the proceedings of an ANSI sucommittee (sic) on respirator fit testing that there may be insufficient data to validate the adequacy of this respirator fitting test.[81]

Previously in 1981, Revoir had expressed serious reservations regarding the saccharin and other qualitative fit tests proposed to OSHA:[82]

OSHA should not promulgate a rule making to permit employers to use the isoamyl acetate vapor and the protocol for this test for selecting specific makes and model of negative pressure type respirators for assignment of lead aerosols unless the faults in the protocol are eliminated. Eliminating these faults should not be a difficult task. . . .[83]

OSHA should not promulgate an interim rule to permit the use of QLFT which uses the saccharin aerosol as the test agent until more work has been carried out to eliminate problems associated with the saccharin aerosol. . . .[84]

Before OSHA promulgates an interim rule to permit the use of the saccharin aerosol QLFT by employers who must comply with the provisions of the OSHA Standard on Occupation Exposure to Lead, OSHA has the obligation of assuring that any problems associated with the size of the saccharin aerosol particles in the test atmospheres are resolved.[85]

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[80]Pritchard, J. A.: Open Forum: Respirator Testing—Old Values, *Ind. Safety and Hyg. News* (May 1989).

[81]Revoir, W. H.: *Comments on OSHA's Proposal to Modify Existing Provisions for Controlling Employee Exposure to Toxic Substances Found in 29 CFR 1910.1000(3) and 29 CFR 1910.134(a)(1).* Comments submitted to OSHA (May 30, 1990), p. 14.

[82]Revoir, W. H.: *Comments Concerning Respirator Fit Testing*, statement made at the OSHA Informal Public Hearing on Respirator Fit Testing, Washington, D.C. (September 23, 1981), pp. 11–22.

[83]Ibid., p. 14.

[84]Ibid., p. 18.

[85]Ibid., p. 20.

Most QLFT and QNFT protocols are the same as the one used in OSHA's quantitative-fit-test procedure in the lead health standard (29 CFR 1910.1025). The OSHA protocol is essentially the same as that developed in the early 1970s at the Los Alamos Scientific Laboratory (LASL) for respirator-performance research, which was supported in part by NIOSH. Originally, NIOSH and LASL had hoped to test respirator performance during simulated-workplace use of the respirators. However, as reported in 1976, LASL was unable to accomplish this:

> The LASL Human Studies Review Committee's only major objection was to stressing of test subjects. Part of the original test procedure called for test subjects to be stressed by treadmill, while undergoing a quantitative respirator leak evaluation. The purpose of this stressing was to simulate actual workplace use of the respirators. We accordingly abandoned the "stress" portion of the exercises, and substituted a period to be spent in a hot humid chamber, to work up a sweat, as a substitute for physical activity. . . .
>
> The use of the humid chamber was abandoned because of the time pressure on completion of the required number of tests.[86]

As with the LASL protocol, the current OSHA fit-test protocol does not use a "hot humid chamber, to work up a sweat, as a substitute for physical activity" as LASL intended. Regarding the OSHA test protocol, a noted respirator expert stated in 1990:

> The exercise time limits are very short. The required exercises are sedentary and do not replicate movements of workers that may occur in workplaces.[87]

In 1987, NIOSH cautioned with regard to the efficacy of both qualitative and quantitative fit tests:

> No qualitative or quantitative fit tests have been demonstrated to be capable of effectively identifying inadequately fitting respirators (i.e., respirator-wearer combinations that provide less protection than the APF). The presently used tests (e.g., ANSI-recommended, OSHA-approved) may fail to identify individual wearers with inadequate respiratory protection. Thus fit tests should be used with caution and with recognition of their possible deficiencies. As appropriate, periodic

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[86]Douglas, D. D. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health, July 1, 1974—June 30, 1975*, Los Alamos Scientific Laboratory Progress Report LA-6386-PR, Los Alamos, New Mexico (August 1976), pp. 35–36.

[87]Revoir, W. H.: *Comments on OSHA's Proposal to Modify Existing Provisions for Controlling Employee Exposure to Toxic Substances Found in 29 CFR 1910.1000(3) and 29 CFR 1910.134(a)(1).* Comments submitted to OSHA (May 30, 1990), p. 20.

evaluations of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection.[88]

NIOSH has concluded that this 1987 statement continues to best summarize the questionable efficacy of QLFTs and QNFTs. NIOSH also concluded that the OSHA fit-test protocol (and those similar to it) represents, at best, respirator wearers undergoing no physical activity and no rapid motions of the head. That is, at best the protocol is representative only of sedentary use of a respirator.

NIOSH has concluded that the Hyatt/LASL approach for determining class APFs for air-purifying respirators contains a *critical assumption* that has not been satisfactorily substantiated and must be considered questionable. The Hyatt/LASL approach assumes that the required *proper fit testing*[89] conducted by a respirator wearer's employer *will be 100% efficient at identifying those prospective wearer's who cannot achieve a given APF*. However, NIOSH concluded that *proper fit tests* are not 100% efficient at identifying those prospective wearer's who cannot achieve a given APF. At this time there is insufficient evidence to provide reasonable assurance of their efficacy. Thus any of these fit tests should be selected by respirator-program administrators and utilized by fit-test operators with due caution and appreciation of their possible deficiencies. Respirator wearers should be explicitly informed that these fit tests may fail to identify individual wearers with inadequately-fitting respirators.

NIOSH concluded that the Hyatt/LASL approach for determining APFs embodies a basically sound requirement. That is, that 100% of respirator users in the workplace must attain protection exceeding a class APF after proper fitting (i.e., fit testing) has been performed by the employer. Meeting this requirement is a technical matter of developing proper fit test methodologies, whether they be quantitative or qualitative, that can adequately screen out those prospective wearers that are incapable of achieving an adequate fit with a given respirator.

NIOSH has concluded that due to excessive face-seal leakage, while wearing air-purifying, NIOSH-certified respirators in the workplace as part of a state-of-the-art respirator program, from less than 1% to substantially more than 10% of American workers will not achieve with their respirator facepieces the APF-level protection computed according to the recommendations of Hyatt/LASL. This is because currently available quantitative and qualitative fit tests have not been satisfactorily demonstrated to be capable of effectively identifying (screening out) those wearers with

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[88] *NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87–108, Cincinnati, OH (May, 1987), p. 2.

[89] Qualitative or quantitative fit testing accepted by OSHA or generally considered acceptable for professional practice.

inadequately-fitting respirators. These percentages consider only face-seal leakage. Any additional leakage through filters or sorbent elements will increase the percentage of wearers not achieving APF-level protection. It should be recognized that those wearers with inadequate respiratory protection *will not be identifiable* except possibly for those contaminants with adequate warning properties or those very few contaminants for which an overexposure can be biologically detected (e.g., urine- or blood-monitoring techniques).

Additionally, it should be also recognized that the Hyatt/LASL APFs do not consider uncertainty present in the underlying performance data that is due to sampling errors. However, this is not necessarily a critical weakness in the approach. With the Hyatt/LASL approach it is not particularly relevant nor critical to know with a high degree of certainty the precise percentage of all workers expected to achieve a given APF before proper fit testing is performed. That is, it is basically irrelevant whether 5, 9, 10, 12, or 15% are incapable of achieving a satisfactory fit. This is because the purpose of subsequent fit testing is to screen out 100% of these individuals.

NIOSH concluded that APFs computed according to the definition used by Myers et al. and other researchers in the 1980s can result in *less protection* to at least 1 in 20 respirator users when compared to APFs computed according to the criterion of Hyatt/LASL in the 1970s *even if the fit testing in 100% effective.* This occurs because Myers et al. APF values are predicated on the less strict requirement that *only an estimated 95%, not an assured 100%, of respirator users in the workplace* must attain a class APF *after proper fitting* (i.e., fit testing) has been performed by the employer.

NIOSH has concluded that the Myers et al. approach implicitly considers it acceptable to permit at least 5% of respirator wearers in the workplace to receive protection less than the computed APF (unknowingly in most cases). This approach creates an equivalent situation to one that would result if OSHA were to permit 5% of American workers to exceed permissible exposure limits (PELs).

The results from any WPF must be evaluated both in terms of *internal validity* and *external validity.* With regard to *internal validity,* suppose a researcher were to conclude that the WPF-performance of respirator A is better than some performance criterion. If the conclusion was based on random errors occurring during WPF measurements, rather than truly superior performance, the conclusion would have *no internal validity.* Variability in WPF results exist and this variability casts doubt on the internal validity of any conclusions drawn from WPF results.

However, there is a widely accepted solution to the problem of questionable internal validity. The answer is to perform a statistical analysis that takes into account not only the differences among WPF percentile point estimates, but also considers the variability of the WPF results.

One type of statistical analysis for WPF data was proposed in 1978. Leidel and Busch suggested the use of 2- and 3-parameter lognormal distributions and tolerance limits for the reporting and interpretation of respirator leakage data.[90] However, these authors specifically omitted any recommendation for the use of lognormal tolerance limits for APF computations. They recognized that APFs based on tolerance limits would tacitly permit some wearers to receive less than APF-level protection.

In 1983, Myers et al. proposed the use of 1-sided lower tolerance limits for APF estimates.[91] However, except for one WPF study reported in 1984,[92] subsequent respirator researchers have not reported tolerance limits for their WPF results and APF estimates. In 1987, the ISEA stated with regard to the tolerance limit approach for determining APFs:

> The proposed rule requires that during analysis of the workplace protection data, 95% of the test subjects must achieve a workplace protection factor with *95% confidence*. There is too much variability in the test methods to require the use of confidence intervals. When the confidence interval is added to the prediction, no field test performed to date indicates any tested respirator can meet its assigned protection factor. For example, a half mask respirator with a minimum workplace protection factor (WPF) of 22 in the DuPont [sic] asbestos study would have a WPF of 6 using the NIOSH [confidence interval] methods.[93]

If one were to able to conduct multiple WPF respirator-performance studies under conditions similar to the initial study reported by a research team, the resulting study-to-study 5th-percentile WPF *point estimates*[94] would vary considerably due to *sampling errors*. In general, the smaller the number of test subjects, the larger the potential sampling error and uncertainty are associated with a computed point estimate.

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[90]Leidel, N. A. and K. A. Busch: Statistical Methods for Analysis of Respirator Data, paper presented at the 1978 American Industrial Hygiene Conference, Los Angeles, CA (May 10, 1978), pp. 12–13.

[91]Myers, W. R., Lenhart, S. W., Campbell, D. and G. Provost: The Forum—Letter to the Editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983), p. B–26.

[92]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), pp. 180–181.

[93]Industrial Safety Equipment Association: *Key Issues on NIOSH Notice of Proposed Rulemaking for Testing and Certification of Respirators for Use in Mines and Mining*, enclosure transmitted in a letter "To Our Customers and Distributors" from C. D. Cowan of the 3M Company, St. Paul, Minnesota (October 9, 1987), Item I.A.2, p. 2.

[94]A *5th-percentile WPF point estimate* from a sample of WPFs estimates the WPF value for which 5% of all similarly-obtained WPFs will be *less than or equal to*. Correspondingly, it estimates the WPF value for which 95% of all similarly obtained WPFs *will exceed*.

The computation of a *tolerance limit* enables one to create an *interval estimate* for the range of values around the point estimate within which we are confident (at a specified *confidence level*) that the actual 5th-percentile WPF lies. The interval estimate defines the *error band* for the actual 5th-percentile WPF. It is similar to the *margin of error* typically reported with the results of public opinion polls.

A 1-sided lower tolerance limit computed at the 95% confidence level for the 5th-percentile WPF would be denoted as $LTL_{1,.95,.05}$. A 1-sided lower tolerance limit is a type of confidence limit below which we expect a stated proportion of a population to lie.[95] With a tolerance limit one can then assess the amount of uncertainty or margin of sampling error associated with a point estimate of the actual 5th-percentile WPF.

Respirator researchers may conclude that their WPF data substantiate an APF of 10 for non-powered, air-purifying halfmasks if their *point estimate* for their 5th-percentile WPF exceeds 10. However, this approach to reaching research conclusions does not consider the uncertainty in their point estimate due to sampling errors. By not computing a 1-sided lower tolerance limit for their actual 5th-percentile WPF, they may reach erroneous conclusions regarding their study results, since the actual 5th-percentile WPF may be *lower* than the point estimate for this value. In this case the actual proportion of wearers expected to exceed the 5th-percentile WPF point estimate would *exceed 5%*.

For example, Lenhart and Campbell studied the performance of a non-powered, HEPA-equipped halfmask on 25 test subjects.[96] For their data they reported a 5th-percentile WPF point estimate of 18 and concluded that the use of an APF of 10 "for the negative pressure halfmask is not discredited" and "an assigned protection factor of 10 is appropriate for the half-mask negative pressure air-purifying respirator evaluated in this study."[97] They also computed a 1-sided lower tolerance limit for the actual 5th-percentile WPF and stated that "at a confidence level of 90% ($\gamma = 0.9$) approximately 95% ($P = 0.95$) of the negative pressure respirator workplace protection factors exceed a value of 10."[98]

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[95]Leidel, N. A. and K. A. Busch: *Statistical Design and Data Analysis Requirements.* Chapter 8 of *Patty's Industrial Hygiene and Toxicology*, Volume III, *Theory and Rationale of Industrial Hygiene Practice*, Second Edition, Volume 3A, *The Work Environment*, Cralley, L. J. and L. V. Cralley, Editors, John Wiley & Sons, Inc., New York, (1985), Sections 6.7 and 6.13.

[96]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).

[97]Ibid., pp. 180–181.

[98]Ibid., p. 181.

For their data, a NIOSH computation of the $LTL_{1,.90,.05}$ yields an APF value of 8.9 at the 90% confidence level. However, a 95% confidence level, not 90%, is the accepted value for professional practice in most scientific research work. At the 95% confidence level a NIOSH computation of $LTL_{1,.95,.05}$ yields an APF value of 7.1, which is substantially lower than the observed WPF point estimate of 18 for the 5th percentile. That is, for these results that *best* we can conclude with 95% confidence is that the 5th-percentile WPF *exceeds* 7.1. The difference in WPF values between the 5th-percentile point estimate of 18 and $LTL_{1,.95,.05}$ of 7.1 is the *margin of error* associated with the point estimate.

Additionally, none of the WPF studies reported in the literature have selected their test subjects according to anthropometric restrictions. As a result, in any given WPF study the test subjects may represent substantially less than 95% of facial sizes in American workers.

NIOSH has concluded that due to excessive face-seal leakage, while wearing air-purifying, NIOSH-certified respirators under ideal conditions in the workplace, from less than 1% to substantially more than 10% of American workers will not achieve a class APF computed according to the recommendations of Myers et al. These percentages consider only face-seal leakage. Any additional leakage through filters or sorbent elements will increase the percentage of wearers not achieving APF-level protection. These wearers with inadequate respiratory protection *would not be identifiable* except possibly for those contaminants with adequate warning properties or those very few contaminants for which an overexposure can be biologically detected (e.g., urine- or blood-monitoring techniques).

Since essentially all respirator-performance data reported since 1983 were measured as WPF values, the 1-sided lower tolerance limit approach might still be a viable means of determining APFs. However, because of public health considerations, the proportion of wearers not achieving the WPF would have to be set substantially lower than 5%. Values such as 0.1% to 1% might be considered. Confidence levels should be set at 95% or 99%. Most importantly, if this APF-determination method is used, both purchasers and users must be fully informed that a given percentage of wearers are not expected to achieve the APF and will not be able in many cases to know who these inadequately-protected wearers are. The issue of informed consent should be investigated if this approach is considered.

In addition to examining WPF study results for *internal validity*, it is also essential to examine the *external validity* of WPF and APF results from any given study. That is, how valid are the research results outside of the research-study sample? Suppose a researcher were to conclude that the WPF-performance of respirator A is better than some performance criterion. If the conclusion was based on activities than are irrelevant to tasks and circumstances in the real world, then the conclusion

would have *no external validity*. External validity includes topics such as possible *non-sampling errors* and *biases*[99] in WPF results. It requires that the respirator-use tasks and conditions of use are representative of actual conditions in typical workplaces. Unlike internal validity, for which there are objective statistical computations to justify conclusions, evaluating external validity is largely a subjective judgment.

For those researchers that wish to generalize their respirator-performance study findings to larger groups, a two-stage process in involved during which external validity problems can arise.[100,101] First, researchers must define a *target population* of persons, settings, or times (e.g., efficacy of respirators worn by most users in the U.S. for specific respirator classes under actual working conditions of typical respirator programs). Second, researchers must draw respirator-wearer samples to *represent* these populations. However, samples usually cannot be drawn systematically in a formal randomized manner and are drawn instead because they are convenient and give an intuitive impression of representativeness. However, the settings and conditions of any given research study may severely hamper the *generalizability* of the results.

Cook and Campbell have suggested that it is useful to distinguish between (1) target populations, (2) formally representative samples that correspond to known populations, (3) samples actually achieved in field research, and (4) achieved populations.[102] They have noted:

> To criticize the study because the achieved sample of settings was not formally representative of the target population may appear unduly harsh in light of the fact that financial and logistical resources for the experiment were limited, and so sampling was conducted for convenience rather than formal representativeness. . . . *it is worth noting that accidental samples of convenience do not make it easy to infer the target population*, nor is it clear what population is actually achieved.[103]

NIOSH has concluded that the majority of respirator-performance studies reported in the professional literature have not considered the uncertainty or margin or error

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[99]*Biases* are effects that deprive a statistical result of representativeness by *systematically* distorting it.

[100]Bracht, G. H. and G. V. Glass: The External Validity of Experiments. *Amer. Educ. Res. J.* 5:437–474 (1968).

[101]Cook, T. D. and D. T. Campbell: *Quasi-Experimentation—Design and Analysis Issues for Field Settings*, Houghton Mifflin Company, Boston, MA (1979), pp. 70–80.

[102]Ibid., p. 71.

[103]Ibid., p. 71.

associated with computed APFs. Thus the *internal validity* of the APFs is subject to question. It has been said that "the science of statistics deals with making decisions based on observed data in the face of uncertainty."[104] If decisions regarding the observed levels of 5th-percentile sample WPF values (or other percentiles such as the 1st or one tenth of 1%) are not made with regard to the margins of error associated with them, then the credibility of those decisions is suspect. In all modern scientific professions, the accepted standard of practice regarding research data is to consider the uncertainty in the data when making comparative decisions (i.e., establish internal validity with *confidence intervals* and *hypothesis testing*).

With regard to the research settings and study conditions of WPF research conducted by NIOSH staff in the 1980s and into the 1990s, it was stated in 1984:

> The methods and materials identified for collecting the workplace protection factor [WPF] data represent an optimized set of conditions in which the respirator is used while its field performance is being measured. Therefore, the best possible results should be obtained.[105]

Additionally, a noted respirator expert stated in 1989:

> Since the administrative deficiencies that reduce respiratory protection will be suppressed in a closely monitored field test, the WPF [workplace protection factor] may not reflect actual working conditions.[106]

Gaboury and Burd also stated in 1989:

> As mentioned before, these 5th percentile WPFs represent what can be achieved in the workplace under good worker compliance and tight administrative controls. Real life WPFs may be less than 275 [for a helmeted PAPR with organic vapor/HEPA cartridges] and 9 [for non-powered halfmasks with organic vapor cartridges and DM or DFM prefilters] respectively for the tested respiratory protective devices for the following reasons:
>
> — Close surveillance of workers under normal working conditions is not usually performed by supervision (sic);
> — Cleaning of the respirators during the rest period is not always done prior to the worker returning to the workplace;

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[104]Bowker, A. H. and G. J. Lieberman: *Engineering Statistics*, 2nd edition, Prentice-Hall, Inc., Englewood Cliffs, New Jersey (1972), p. 1.

[105]Myers, W.R., M. J. Peach, III, 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), p. 237.

[106]O'Leary, C. C.: New Concepts—Open Forum: Respirator Testing, *Ind. Safety and Health News* (May 1989).

— In the real world no respirator is used 100% of the time while in the workplace.[107]

After 39 years of professional experience in respiratory protection, Revoir stated in 1990:

Major problems frequently encountered by employers in using respirators to protect employees against respiratory hazards in workplaces include:

Respirator Selection.
Selecting the proper respirator for protecting persons against harmful air contaminants in workplaces is a difficult task. Employers often fail to consider all the factors necessary for making the correct decision such as workplace characteristics and conditions, nature of the process, location of the hazardous area relative to a safe area, employee activities, length of time a respirator must be worn, properties of the respiratory hazard (physical, chemical, toxicological), actual concentration of hazardous substance in workplace atmosphere, permissible exposure levels, physical and functional capabilities and limitations of each type of respirator, and assigned protection factors for various types of respirators. Frequently employers select respirators by reading brief descriptions of respirators in catalogs or sales bulletins. Employers often select respirators based upon advice from salespersons employed by safety products distributors who may be poorly trained in respiratory protection technology. . . .

Respirator Fit Testing.
Many employers do not conduct either qualitative or quantitative fit testing of respirators to insure that each employee is provided with a respirator that provides an adequate seal to his/her face. Carrying out a proper fit test is tedious and time-consuming.[108]

In a report prepared for OSHA by Centaur Associates, survey results estimated the actual working conditions in typical U.S. respirator programs.[109] For the approximately 3.6 million wearers covered by OSHA's respirator-use regulation, Centaur Associates estimated the following levels of noncompliance with respirator-use regulations by American employers in the early 1980's:

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[107]Gaboury, A. and D. H. Burd: Workplace Protection Factor Evaluation of Respiratory Protective Equipment in a Primary Aluminum Smelter, presented at the International Society for Respiratory Protection Conference, San Francisco, CA (November 1989).

[108]Revoir, W. H.: *Comments on OSHA's Proposal to Modify Existing Provisions for Controlling Employee Exposure to Toxic Substances Found in 29 CFR 1910.1000(3) and 29 CFR 1910.134(a)(1).* Comments submitted to OSHA (May 30, 1990), pp. 22–23.

[109]Centaur Associates, Inc.: *Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards, Volume II,* contract report prepared for the U. S. Department of Labor, Occupational Safety and Health Administration under Contract No. J–9–F–20067, Washington, D.C. (March 30, 1984), Section 5, The Costs of Compliance.

- Almost 80% of negative-pressure respirator wearers were not receiving fit testing.[110]

- Over 70% of 123,000 manufacturing plants did not perform exposure-level monitoring, when selecting respirators to use in the plants.[111] The level of noncompliance increased to almost 90% for the smallest plants.

- 75% of manufacturing plants did not have a written program.[112]

- 56% of manufacturing plants did not have a professional respirator-program administrator (i.e., qualified individual supervising the program).[113]

- almost 50% of wearers in manufacturing plants did not receive an annual examination by a physician.[114]

- almost 50% of wearers in manufacturing plants did not receive respirator-use training.[115]

- 80% of wearers in manufacturing plants did not have access to more than one facial-size mask, even though nearly all reusable masks were available in at least three sizes.

Additionally, Hyatt had noted earlier in 1976 that:

The majority of those purchasing and using respirators do not conduct a fitting program to determine if the respirator provides an adequate face seal.[116]

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[110]29 CFR 1910.134(e)(5).

[111]29 CFR 1910.134(b)(8).

[112]29 CFR 1910.134(b)(1).

[113]29 CFR 1910.134(e)(2).

[114]29 CFR 1910.134(b)(10).

[115]29 CFR 1910.134(e)(5).

[116]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA-6084-MS (1976), p. 17.

NIOSH has concluded there is no reason to believe that the actual quality of respirator programs provided to American workers has improved substantially since Hyatt's 1976 assessment and the 1984 Centaur Associates' report or are substantially better than the 1990 assessments of Revoir. NIOSH has concluded that all respirator workplace studies reported in the 1980s and early 1990s are *respirator-performance* studies, not *respirator program evaluation* studies. That is, they evaluate *workplace protection factors*, not *program protection factors.*[117]

WPF studies frequently are conducted primarily to demonstrate "adequate protection" from a particular make and model respirator. Thus, in effect, WPF studies generally are designed and conducted to measure *only respirator performance* in the most favorable light possible. This is done to avoid reducing or "biasing" (i.e., systematically distorting) the observed respirator protection resulting from poorly-performed or inadequately-performed respirator program elements that are typically found in actual programs. A major objective in respirator-performance (WPF) studies is to minimize the effects of human errors, even though these errors may typically occur in actual workplace use of respirators. However, it must be recognized that in terms of worker health, WPFs are not the most significant form of the protection factor.

NIOSH has concluded that respirator wearers in most laboratory and workplace respirator-performance studies are generally given substantially more and better training, fitting, and use observation than is actually received in real-life respirator programs. Thus, many respirator-performance studies are conducted under the effects of ideal respirator programs that are notably unrealistic compared to the way respirators are utilized in most workplaces. The laboratory protection factors (PFs) and working protection factors (WPFs) reported in any given study and subsequent APF recommendations are representative only of protection levels obtained under conditions similar to those of the study. Therefore NIOSH concludes that the APF conclusions from most laboratory and workplace respirator-performance studies reported to date have *questionable external validity* concerning WPF results achieved in many real-life respirator programs.

NIOSH's evaluation has shown that there are considerable differences between the approach to determining APFs used during the 1970s (i.e., Hyatt/LASL) and that used during the 1980s (i.e., Myers, et al.). A summary of NIOSH's evaluation of these differences is given in Table N of this evaluation. NIOSH has concluded that both APF approaches yield APFs such that while workers are wearing air-purifying, NIOSH-certified respirators in the workplace as part of a state-of-the-art respirator

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[117]Myers, W. R., Lenhart, S. W., Campbell, D. and G. Provost: The Forum—Letter to the Editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983).

program, from less than 1% to substantially more than 10% of American workers will not achieve APF-level protection with their respirator facepieces. These percentages consider only face-seal leakage. Any additional leakage through filters or sorbent elements will increase the percentage of wearers not achieving APF-level protection.

Table N—Summary of Evaluation of Professional Practices Used During the 1970s and 1980s for Face-Seal Evaluations and APF Determinations.

Process Element	Comments on 1970's Laboratory Evaluations and APFs	Comments on 1980's Workplace Evaluations and APFs
1—Select respirators to be tested.	Many if not most available models in each respirator class were tested. Hence the worst performers in each class generally were tested and considered when setting APFs.	Respirators tested were not necessarily the worst in each class, perhaps even the better ones were tested. Thus the worst in each class were not necessarily considered when setting APFs.
2—Select test environment.	Laboratory test chambers with subjects undergoing limited maneuvers to stress fit of respirators. Small-size test aerosols used to measure mask performance.	Workplaces under optimal, ideal use conditions. Performance was measured during routine job activities. Contaminants occurring in workplace were used to measure mask performance.
3—Select test subjects.	Test panels were selected with intent of representing 95% of facial sizes in U.S. population.	Any available facial sizes were used. Smaller and larger facial sizes may not have been tested, which are the sizes most expected to show poor respirator performance due to face-seal leakage.
4—Perform fit-test screening (QLFT or QNFT) to eliminate those subjects unable to obtain an adequate fit.	Generally a QLFT-type irritant fume fit test was used for fullface masks only. No fit testing was used before halfmask performance testing.	Generally the saccharin QLFT was used. A few studies used other QLFTs or QNFT.
5—Measure respirator leakages under test conditions.	These results were later shown in the 1980's to have no correlation with results measured in the workplace.	Two to three *measurement biases* were present in most studies. Thus the reported WPFs generally *overestimated* the actual WPFs and reported APFs.
6—Analyze leakage data and determine APFs for each respirator class.	*After* proper fit testing has been conducted by the employer, 100% of respirator wearers are required to achieve a class APF in the workplace. Class APF set at 5th percentile PF observed in panel subjects wearing worst respirator(s) in each class. It is expected that up to 10% of American workers *can not achieve* the class APF with the worst respirator (i.e., up to 5% of test subjects not achieving APF plus 5% of U.S. facial sizes not represented on test panel) *before* proper fit testing is performed. However, proper fit testing has not been demonstrated to be capable of identifying 100% of those fits less than class APFs. Thus from less than 1% to substantially more than 10% of American workers *will not achieve* a computed APF while wearing air-purifying, *laboratory-tested respirators* under *ideal conditions* in the workplace.	*After* proper fit testing has been conducted by the employer, *only* 95% of respirator wearers are required to achieve a class APF in the workplace. APFs for measured respirators are set at 5th percentile WPF observed in test subjects *after* proper fit testing has been performed. Additionally, no consideration made for large uncertainty in 5th percentile WPF estimates due to statistical sampling error. Panels may represent substantially less than 95% of U.S. facial sizes. Thus from less than 1% to substantially more than 10% of American workers *will not achieve* a computed APF while wearing air-purifying, *workplace-tested respirators* under *ideal conditions* in the workplace.

7—Evaluation of face-seal leakage results from nine studies of non-powered, air-purifying halfmasks.

As discussed earlier in this evaluation,[118] the safety and efficacy of an air-purifying respirator is determined by the efficacy of the face seal in combination with the efficacy of the air-purifying element. As part of this evaluation, NIOSH reviewed and evaluated face-seal leakage data from nine studies of non-powered, air-purifying halfmasks. The Institute conducted a statistical analysis of some published and unpublished studies to evaluate the value of 10%-maximum face-seal leakage that is the accepted value for professional practice for non-powered, air-purifying halfmasks.[119,120,121,122] This analysis was performed because non-powered halfmask facepieces are used daily by several million respirator wearers.[123]

Respirators are a public health *exposure control method* with the sole purpose of preventing occupationally-related illness and death. As such, it is important to evaluate the *failure rates*[124] of the control method as it is implemented in representative applications. Other public health research on control methods typically measure and report failure rates (e.g., study of contraceptive failure rates for birth control meth-

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[118]Refer to discussion presented in this evaluation under *Introduction to Respirator-Performance Evaluations, APF Determinations, and Use of APFs.*

[119]*NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87–108, Cincinnati, OH (May, 1987), Tables 1–3, pp. 2–4, 13–18, and 27–29.

[120]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1980, New York, New York, (1980), Table 5, pp. 21–23.

[121]Birkner, L. R.: *Respiratory Protection: A Manual and Guideline*, American Industrial Hygiene Association, Akron, Ohio (1980).

[122]Birkner, L. R.: *Celanese Corporation Respiratory Protection Manual and Guideline*, Celanese Corporation, New York, N.Y. (August 1978), Section 61, pp. 3–4.

[123]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).

[124]In epidemiologic usage, a *rate* is the frequency of a characteristic or disease expressed per unit of size of the population or group in which it is observed. In this case the *characteristic* is a failure of the control method.

ods[125]). As with birth control methods, the ideal public health goal for respirator wearers is a *zero control failure rate.*

For respirator performance, *control failure rate* will be defined as the number of users per 100 users that fail to achieve individual working protection factors equal to or exceeding the assigned protection factor for their respirator (i.e., WPFs ≥ APF). Where respirators are used, the reasonable expectation of both purchasers and users is that *none* of the users will receive less protection than the class APF (when the masks are properly selected, fit tested by the employer, and properly worn by the users).

One type of statistical analysis suitable for WPF failure-rate analysis computes the following two values:

- A *point estimate* for the *number of users* that fail to achieve a given WPF per 100 users (failure rate) and

- A *1-sided, 95% upper confidence limit* ($UCL_{1,95}$) for the actual number of user WPFs less than a given WPF per 100 users (actual failure rate under the conditions of the study).[126]

If one were to able to conduct multiple WPF respirator-performance studies under conditions identical to any given study reported by a research team, the resulting study-to-study failure-rate *point estimates* would vary considerably due to *sampling error.* Generally, the smaller the sample size in a study, the larger the potential sampling error. Thus computation of *confidence limits* is essential so that one can create a *confidence interval* (*interval estimate*). This is a range of values around the point estimate within which we are confident (at a specified *confidence level*) that the actual failure rate lies. With a confidence interval one can then assess the amount of uncertainty or *margin of error* associated with the point estimate of the actual failure rate in each study. Regarding the *95% confidence level* associated with each particular $UCL_{1,95}$, statistical theory predicts for any given sample of WPFs that in 19 of 20 similarly conducted studies the similarly computed UCLs will exceed the actual

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[125]Trussell, J. and K. Kost: Contraceptive Failure in the United States: A Critical Review of the Literature, *Studies in Family Planning* 18(5):237–283 (1987).

[126]Leidel, N. A. and K. A. Busch: *Statistical Design and Data Analysis Requirements.* Chapter 8 of *Patty's Industrial Hygiene and Toxicology,* Volume III, *Theory and Rationale of Industrial Hygiene Practice,* Second Edition, Volume 3A, *The Work Environment,* Cralley, L. J. and L. V. Cralley, Editors, John Wiley & Sons, Inc., New York, (1985), Section 6.8, p. 493–497.

failure rate. This statistical analysis for WPF data is both informative and relevant from a public health standpoint.

NIOSH performed this statistical analysis for some published and unpublished WPF data sets reported for non-powered, air-purifying halfmasks over the last decade. This evaluation included studies by Galvin et al.,[127] Gaboury and Burd,[128] Nelson and Dixon,[129] Lenhart and Campbell,[130] Colton and Mullins,[131] Colton et al.,[132] Johnston and Mullins,[133] Gosselink et al.,[134] and Dixon and Nelson.[135] Since this respirator class currently has an accepted APF of 10 for professional practice (i.e., 10% or less leakage at the face seal only), the results of NIOSH's control failure-rate analysis for these halfmasks against this APF of 10 are given in Table O of this evaluation.

In addition to sampling errors, the results in presented in Table O also need to be examined with regard to their *external validity limitations.*[136] That is, the possi-

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[127]Galvin, K., S. Selvin, and R. C. Spear: Variability in Protection Afforded by Half-Mask Respirators Against Styrene Exposure in the Field, *Am. Ind. Hyg. Assoc. J.* 51:625-639 (1990).

[128]Gaboury, A. and D. H. Burd: Workplace Protection Factor Evaluation of Respiratory Protective Equipment in a Primary Aluminum Smelter, presented at the International Society for Respiratory Protection Conference, San Francisco, CA (November 1989).

[129]Nelson, T. J. and S. W. Dixon: *Respirator Protection Factors for Asbestos, Parts I and II*, paper presented at the 1985 American Industrial Hygiene Conference, Las Vegas, Nevada (May 23, 1985).

[130]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).

[131]Colton, C. E. and H. E. Mullins: *Workplace Protection Factor Tests—Brass Foundry*, paper presented at the 1990 American Industrial Hygiene Conference, Orlando, Florida (May 1990).

[132]Colton, C. E., A. R. Johnston, H. E. Mullins, and C. R. Rhoe: *Respirator Workplace Protection Factor Study on a Half Mask Dust/Mist Respirator*, paper presented at the 1990 American Industrial Hygiene Conference, Orlando, Florida (May 17, 1990).

[133]Johnston, A. R. and H. E. Mullins: *Workplace Protection Factor Study for Airborne Metal Dusts*, paper presented at the 1987 American Industrial Hygiene Conference, Montreal, Canada (June 4, 1987).

[134]Gosselink, D. W., Wilmes, D. P, and Mullins, H. E.: Workplace Protection Factor Study for Airborne Asbestos (a.k.a. The Shiloh Brake Study conducted by representatives of the 3M Company), presented at the American Industrial Hygiene Conference, Dallas, Texas (May 1986).

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

[136]That is, the problems inherent in attempting to generalize from sample results to populations of respirator wearers. Refer to discussion for *external validity* presented in this evaluation under *Review and Evaluation of Professional Practices Used during the 1970s and 1980s for Respirator Faceseal Evaluations and APF Determinations.*

bility of *nonsampling errors* and *biases* must be explored. First, NIOSH noted that the computed failure rates were observed in WPF studies representing *optimal wearing conditions* in which the lowest possible failure-rate results should have been obtained. These optimal conditions include fit testing of all test subjects with OSHA-approved fit tests.

Second, none of the nine studies used a NIOSH-type deep probe to measure the in-mask concentrations. Failure to use this type of probe can *erroneously overestimate* all WPFs by up to 100% due to *measurement bias.*[137,138]

Third, eight of the nine studies[139] did not correct the observed WPF measurements for lung retention of inhaled aerosols. Failure to perform this correction can *erroneously overestimate* all WPFs by 10% to 30% due to *measurement bias.*[140,141,142,143]

Fourth, none of the eight studies[144] investigating WPFs in workplaces with aerosol contaminants corrected the observed WPF measurements for filter-holder wall deposition. In the Pallay et al. study, it was reported that this deposition averaged 18% for the ambient-air samples (outside a respirator) and 61% for the in-face samples (inside a respirator).[145] This magnitude of difference in the proportion of contaminant lost to the filter-holder wall can *erroneously overestimate* all WPFs by a substantial amount due to *measurement bias.* Results reported by Pallay et al. indi-

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[137]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).

[138]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).

[139]Studies numbers 2 through 8 in Table O of this evaluation.

[140]Holton, P. M. and K. Willeke: The Effect of Aerosol Size Distribution and Measurement Method on Respirator Fit, *Am. Ind. Hyg. Assoc. J.* 48(10):855–860 (1987), Figure 1, p. 856.

[141]Hounam, R. F., D. J. Morgan, D. T. O'Conner, and R. J. Sherwood: The Evaluation of Protection Afforded by Respirators, *Ann. Occup. Hyg.* 7:353– 363 (1964), pp. 361–362.

[142]Galvin, K., S. Selvin, and R. C. Spear: Variability in Protection Afforded by Half-Mask Respirators Against Styrene Exposure in the Field, *Am. Ind. Hyg. Assoc. J.* 51:625-639 (1990), p. 628.

[143]Pallay, B.: *Workplace Protection Factor Study of Half-Facepiece Particulate Air Purifying Respirators at Two Lead-Acid Battery Manufacturing Facilities*, paper presented at the 1991 American Industrial Hygiene Conference, Salt Lake City, Utah (May 22, 1991).

[144]Studies numbers 2 through 8 in Table O of this evaluation.

[145]Pallay, B.: *Workplace Protection Factor Study of Half-Facepiece Particulate Air Purifying Respirators at Two Lead-Acid Battery Manufacturing Facilities*, paper presented at the 1991 American Industrial Hygiene Conference, Salt Lake City, Utah (May 22, 1991).

cated that observed WPFs properly adjusted for wall deposition could typically be only one third to one fifth of the uncorrected values.[146]

Fifth, in 1981 it was stated that the saccharin QLFT "would reject any respirator having a leakage rate in excess of one percent [any PF less than 100]."[147] However, in the five studies of Table O that utilized the saccharin test, the true failure rates could have ranged from about 1 to 14 users per 100 users *for an APF of only 10.* Failure rates for an APF of 100 would be substantially higher.

Additionally, with respect to the issue of *external validity*, it should be noted that there are several reasons why the higher control failure rate estimates in Table O possibly *underestimate the highest* failure rates that can occur with NIOSH-certified halfmasks available to purchasers and users. These reasons relate to process elements 1 and 3 in Table L of this evaluation, which are necessary for evaluating respirator performance.

First, the studies presented in Table O were not based on a representative sample of all non-powered, halfmask facepieces certified under 30 CFR Part 11. Second, the reported results are from a very limited number of the scores of halfmask makes and models certified by NIOSH. Third, it was not the objective of any of the studies to test or identify the halfmasks with the *highest* control failure rates. Thus, other makes and models of untested halfmasks with higher control failure rates might easily have been excluded from the nine studies.

Fourth, the studies generally measured respirator performance on any available facial sizes. Based on the Institute's experience in this area and, absent information to the contrary reported in the studies, one can surmise that smaller and larger facial sizes were probably not included in the test subjects. Compared to average facial sizes, extreme facial sizes are generally expected to show substantially higher control failure rates due to excessive face-seal leakage. In summary, NIOSH concludes that it is highly probable that *higher control failure rates* would have been reported than those presented in Table O of this evaluation if the nine studies had been able to test non-powered halfmasks from more manufacturers and sample respirator performance on a wider range of facial sizes with each mask.

In three of the nine studies presented in Table O, the small-sample *point estimates* for the control failure rates were about 5 per 100 users, even though *every* measured respirator user had passed an OSHA-approved fit test (i.e., QNFT or QLFT). More importantly, the *1-sided, 95% upper confidence limits* ($UCL_{1,.95}$) for the true failure

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[146]Ibid.

[147]3M Company: *Comment of Minnesota Mining and Manufacturing Company with Respect to the Permanent Lead Standard Quantitative Fit Test Provision*, OSHA Docket No. H–049A, Exhibit 6–16, (July 1, 1981), p. 4.

rates ranged from about 9 to 14 users per 100 users in these three studies. That is, after necessary consideration of statistical sampling error for these three studies, the best one can conclude with 95% confidence is that the true failure rates for an APF of 10 was as high as 9 to 14 user failures per 100 users in these studies. These failure-rate results are in sharp contrast to Hyatt's requirement (and the expectations of most respirator purchasers and users) that *no user failures* will occur *after* OSHA-approved fit-test screening.[148]

Based on the preceding discussion and the results given in Table O for the nine studies, NIOSH concludes that:

(1) The failure rates in Table O were obtained under ideal conditions and it is highly likely that actual failure rates in typical American workplaces are substantially higher.

(2) The WPFs reported in eight of the nine studies had measurement biases and most likely were substantially overestimated because:

(A) A NIOSH-type deep probe was not used and failure to use this type of probe can *erroneously overestimate* WPFs by up to 100% and

(B) Lung retention was not corrected for and failure to perform this correction can *erroneously overestimate* WPFs by up to 25%.

(C) Filter-holder wall deposition was not corrected for and failure to perform this correction can *erroneously overestimate* WPFs by 300 to 500%.

(3) Because the individual WPFs reported in eight of the nine studies had measurement biases, both the computed point estimates for the control failure rates and the associated upper confidence limits are biased (i.e., incorrect). That is, the values reported in Table O *erroneously underestimate* the point estimates and confidence limits because of the inherent measurement biases in the WPF data values.

(4) In at least three studies of face-seal leakage for non-powered, air-purifying halfmask, the *actual control-failure rates* could have been as high as 9 to 14

[148]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), p. 10.

users per 100 users for the currently accepted APF value of 10 used for professional practice. However, in two of these three studies[149] the results were biased to an unknown degree. Thus the actual control-failure rates for these two studies could be *higher* than 14 users per 100 users.

(5) For the WPF data reported in studies #1 through #6 of Table O, which yielded the highest upper confidence limits for actual failure rates, the top two and two other of the six data sets were for halfmasks equipped with HEPA filters or organic-vapor sorbent cartridges.[150] The latter cartridges are expected to exhibit zero leakage as is expected for HEPA filters. Thus all the reported mask leakage should have occurred at the halfmask facial seals.

NIOSH concludes that there is a serious question whether an APF of 10 is valid for non-powered, HEPA-filter halfmasks, which for over 15 years has been an accepted value for professional practice. This conclusion is based on NIOSH evaluation of APF-determination methods used during the 1970s and 1980s[151] considered in combination with this evaluation of nine halfmask-performance studies conducted in the last decade. If the APF of 10 is invalid and is erroneously high, then the six APFs for non-powered, filter halfmasks recommended by NIOSH are erroneously high.

For non-powered halfmasks equipped with DM, DFM, HEPA filters, the APFs recommended by NIOSH in Table P of this evaluation have been computed using an APF of 10 to represent faceseal-only leakage. If this value of 10 is invalid and should actually be lower, then several of the APF computations summarized in Tables P and R of this evaluation are in error and six of the Institute's recommended APFs are erroneously high. The potential reductions in NIOSH-recommended APFs that might result from the use of an APF less than 10 can be estimated with the use of Figure II or III provided later in this evaluation.

Additionally, NIOSH questions why a failure-rate as high as 5% should be considered acceptable by respirator and public health professionals, as it apparently has since the 1983 proposal of Myers et al.[152] The Institute requests comments whether

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[149]Studies number 2 and 3 in Table O of this evaluation.

[150]Galvin et al. (1990), Gaboury and Burd (1989), Lenhart and Campbell (1984), and Colton et al. (1990).

[151]Refer to discussion presented in this evaluation under *Review and Evaluation of Professional Practices Used During the 1970s and 1980s for Respirator Face-Seal Evaluations and APF Determinations.*

[152]Myers, W. R., S. W. Lenhart, D. Campbell, and G. Provost: The Forum—Letter to the editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983).

it should be acceptable public health practice to permit as many as one (or more) wearers in twenty to unknowingly receive less than the designated minimum protection level (i.e., class APF)? The Institute is considering basing its APF determinations on a substantially lower maximum control-failure rate (e.g., 0.1 to 1 users per 100 users). Confidence levels should be set at 95% or 99%. A confidence level as low as 90% is unacceptable because possibility of erroneous decisions (10%) is unacceptably high. Most importantly, if this type of APF-determination method is used, both purchasers and users must be fully informed that this control method is expected to fail to achieve APF-level protection in a specified proportion of wearers. Additionally, they should be informed that in many cases the employer and wearers are unable to know who these inadequately-protected wearers are. The issue of informed consent given by respirator users should be investigated if this approach is considered.

More importantly, NIOSH concludes that respirator manufacturers and suppliers have not routinely informed respirator purchasers and users that a significant number of users are expected to unknowingly fail to attain APF-level protection, even under optimal use conditions due to excessive face-seal leakage. That is, neither supplier purchase guidance nor respirator-user instructions for NIOSH-certified masks routinely inform purchasers and users of this situation. Purchasers and users have not been provided with appropriate instructions regarding how to identify and adequately protect those wearers with facepieces failing to attain APF-level protection so as to permit the safe and effective use of NIOSH-certified respirators.

NIOSH concludes that APF values recommended by the Institute possibly may create a false sense of security in respirator users. In their use of NIOSH RAPFs, purchasers and users might erroneously assume that 100 in 100 respirator wearers will receive APF-level or better protection under *typical usage* conditions. Purchasers might then purchase NIOSH-certified respirators for use in conditions where they are less than effective for all wearers. This could create a hazard for those wearers that could receive inadequate protection.

Table O—Statistical Analysis of Control Failure Rates for Some Published and Unpublished WPF Studies for Non-Powered, Air-Purifying Halfmasks.

Study	Biased Control Failure Rate per 100 Wearers for APF of 10 (Note A)	Biased UCL on Actual Failure Rate per 100 Wearers (Note B)	Fit Test Used	NIOSH-Type Deep Probe Used? (Note C)	Lung-Retention Correction? (Note D)	Authors
1	5.0	8.9	Irritant smoke	No	Yes	Galvin et al. (1990)
2	4.7	12.7	QNFT, FF > 100	No	No	Gaboury/Burd (1989)
3	4.8 4.2 2.1 2.0 0.2	14.2 12.1 8.5 7.2 2.3	Saccharin	No	No	Nelson/Dixon (1985)
4	2.0	6.3	QNFT, FF > 250	No	No	Lenhart/Campbell (1984)
5	0.9 0.7	2.8 1.9	Saccharin	No	No	Colton/Mullins (1990)
6	0.7	3.2	Saccharin	No	No	Colton et al. (1990)
7	0.6 0.1 0.04	4.1 1.7 0.9	Saccharin	No	No	Johnston/Mullins (1987)
8	0.5 0.1 0.02 0.01	4.4 2.0 1.2 0.8	Saccharin	No	No	Gosselink et al. (1986)
9	0	0	Isoamyl acetate	No	No	Dixon/Nelson (1984)

[A] Small-sample point estimate for number of wearers with WPFs < 10 per 100 wearers. Because of uncorrected biases in the underlying data, corrected point estimates are expected to be *higher* than values reported here.

[B] Biased 1-sided, 95% upper confidence limit for true number of wearers with WPFs < 10 per 100 wearers. Because of uncorrected biases in the underlying data, corrected confidence limits are expected to be *higher* than values reported here.

[C] Failure to use this type of probe can *erroneously overestimate* WPFs by up to 100%.

[D] Failure to perform this correction can *erroneously overestimate* WPFs by up to 25%.

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8—Review and evaluation of reports, research findings, and recommendations concerning the nature of leakage through DM and DFM filters certified by NIOSH under 30 CFR Part 11.

As part of its efforts to prepare APFs values for this evaluation, NIOSH conducted a thorough review of relevant material pertaining to the issue of possible contaminant leakage through DM and DFM filters. The Institute's review included research data, findings, and recommendations that have been reported in the professional literature over the last two decades and in nonconfidential research reports and committee recommendations. The NIOSH conclusions stated in this section are based on the best available evidence from the last two decades regarding the efficacy of DM and DFM filters.

Over the last twenty years, numerous reports have appeared in the professional literature on the subject of leakage through NIOSH-certified DM and DFM filters. Substantial filter leakage has been reported to occur for contaminant sizes that typically range from about 0.05 to 0.40 micrometers (μm) count median diameter (CMD). Filter leakage of particles with aerodynamic mean sizes up to 2.5 μm has been reported through one type of NIOSH-certified DM filtering-facepiece mask.

In 1971, Mitchell et al. published the results of using a 0.05 μm CMD (geometric standard deviation (GSD) of 2.22) NaCl aerosol to test several DM and DFM filters that were approved at that time by the U.S. Bureau of Mines.[153] For three models of DM filters tested at 42.5 L/min/filter, they reported filter leakages of 3.8%, 40.0%, and 44.0%.[154] For three models of DFM filters also tested at 42.5 L/min/filter, they reported filter leakages of 6.5%, 12.5%, and 24.5%.[155]

In 1972, Ferber et al. reported the use of a 0.15 μm CMD (GSD of 1.9) NaCl aerosol to test 13 DM and 6 DFM filters that were commercially available and approved by the U.S. Bureau of Mines.[156] For the 13 DM filters tested at 42.5 L/min/filter, they reported filter leakages of 31%, 27%, 24%, 18%, 13%, 12%, 11%, and the rest

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[153]Mitchell, R.N., D. A. Bevis, and E. C. Hyatt: Comparison of Respirator Filter Penetration by Dioctyl Phthalate and Sodium Chloride, *Am. Ind. Hyg. Assoc. J.*, 32:357–364 (1971).

[154]Ibid., Table III, p. 362.

[155]Ibid., Table II, p. 361.

[156]Ferber, B. I., F. J. Brenenborg, and A. Rhode: Penetration of Sodium Chloride Aerosol through Respirator Filters, *Am. Ind. Hyg. Assoc. J.*, 33(12):791–796 (1972).

below 10% leakage.[157] For the 6 DFM filters also tested at 42.5 L/min/filter, they reported leakages of 13%, 12%, 10%, 8%, 7%, and 4%.[158]

In 1972, Hyatt et al. at LASL published the results of using a 0.82 μm MMD (GSD of 1.6) NaCl aerosol to test DM and DFM filters that were approved at that time by the U.S. Bureau of Mines.[159] For 7 DM filters tested at 32 L/min/filter, they reported average filter leakages of 11.5%, 10.7%, 5.3%, 4.0%, 2.7%, 0.9%, and 0.3% and for 6 DFM filters tested at 32 L/min/filter, they reported leakages of 15.3%, 14.8%, 10.1%, 5.7%, 3.2%, and 1.4%.[160]

In an April 1973 meeting with NIOSH, the Los Alamos Scientific Laboratory (LASL) recommended to the Institute that a small-sized sodium chloride aerosol be used for the Institute's certification testing of DM and DFM filters.[161] LASL recommended that the amount of permissible DM- and DFM-filter leakage be markedly reduced to the range of 1% to 5%. The LASL report stated that since before 1970 British respirator standards have required that filter testing be performed with a test aerosol of about 0.15 to 0.20 μm count median diameter.[162,163,164]

In May 1974, Hyatt et al. at LASL reported on the September 1972 preparation of a proposed respirator selection (protection factor) guide that was "distributed to appropriate agencies and manufacturers for comments."[165] They stated that "The first [LASL] selection guide (Table XVI) received many comments, and from these Table XVII was prepared." In addition to a column containing (assigned) protection factors

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[157]Ibid., Table II, p. 794.

[158]Ibid.

[159]Hyatt E. C. et al.: *Respirator R and D Related to Quality Control; LASL Project P-37*, Los Alamos Scientific Laboratory, Quarterly Report July 1 thru September 30, 1971, No. LA-4908-PR (March 1972).

[160]Ibid., Table II.

[161]Hyatt E.C., et al.: *Respiratory Studies for the National Institute for Occupational Safety and Health—July 1, 1972 through June 3, 1973*, Los Alamos Scientific Laboratory, Progress Report, No. LA-5620-PR (May 1974), p. 19.

[162]Ibid., p. 21, Table V—British Standard Methods Respirator Filter and Facepiece Leakage Tests.

[163]British Standard BS 2091: *Respirators for Protection Against Harmful Dusts and Gases*, British Standards House, London (1969).

[164]British Standard BS 4558: *Positive Pressure, Powered Respirators*, British Standards House, London (1970).

[165]Hyatt E. C. et al.: *Respiratory Studies for the National Institute for Occupational Safety and Health—July 1, 1972 through June 3, 1973*, Los Alamos Scientific Laboratory, Progress Report, No. LA-5620-PR (May 1974), p. 38.

for various respirator classes, the first Hyatt et al. guide contained a column for "filter efficiency, %" with values for both NaCl and DOP. The reported filter efficiencies against NaCl were 75% to 90% (25% to 10% filter leakage) for four DM-filter classes: single use, 1/4 or 1/2; dust filters on 1/4 and 1/2 facepieces, and dust filters on powered 1/2 facepieces.[166] Additionally, the reported filter efficiencies against NaCl were 95% to 99% (5% to 1% filter leakage) for three DFM-filter classes: fume filters on 1/4 and 1/2 facepieces and fume filters on powered 1/2 facepieces.[167]

The second LASL selection guide reported by Hyatt et al. (their Table XVII) had the filter-efficiency values removed and only "selection guide multiples of TWA for 8 hr. day" were reported.[168] Their second Table XVII contained a footnote 2 stating:

> Contaminants include gases, vapors, dusts, fumes, and mists. Each type of specific contaminant would have to be considered as to the size if it is a dust, fume, or mist, and the sorbent if a gas or vapor. Example, sulfuric acid mist criteria—concentrated sulfuric acid mist gives off SO_3, which is very fine and requires a high efficiency filter. It is known that dust filters are satisfactory for dilute sulfuric acid mist.[169]

Hyatt et al. also stated regarding their second Table XVII:

> Table XVI differs from Table XVII in several ways, a major one being the different protection factors (PF's) for various types of devices. . . . The selection guide of 10X time-weighted average (TWA) for both dust and fume respirators is based on new quantitative man tests on dust respirator facepieces equipped with high efficiency filters. This permits the measurement of facepiece leakage only, on both quarter and half facepieces. The data indicated that both types will pass the criteria for a protection factor of 10, based on facepiece leakage only.[170]

In 1975, the Executive Director of the Industrial Safety Equipment Association, Inc. (ISEA), sent comments from the Respirator Group of the ISEA. The ISEA "represents virtually all the manufacturers of respirators."[171] The ISEA provided their analysis of respirator filter and face-seal performance data obtained at the Los

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[166]Ibid., Table XVI, p. 40.

[167]Ibid., Table XVI, p. 40.

[168]Ibid., Table XVII, pp. 41–42.

[169]Ibid., p. 41.

[170]Ibid., p. 36.

[171]Wilcher, F. E.: Letter to J. Donald Millar of NIOSH from F. E. Wilcher, President, ISEA, Arlington, Virginia (September 23, 1986).

Alamos Scientific Laboratory in the early 1970s.[172] Regarding the performance of fume (DFM) filters they stated:

> Fume filters are designed to meet the criteria of an approval test involving a high load of lead oxide fume. . . . A comparison of the data of Table C–I for the half-mask facepiece respirators equipped with high efficiency filters with the data given in Table C–II indicates that the penetrations of the aerosols through the fume filters have a significant effect upon the determination of respirator protection factors.[173]

Regarding the performance of dust (DM) filters the ISEA Respirator Group stated:

> Dust filters are designed to meet the requirements of an approval test involving a high load of relatively coarse silica dust. . . . Comparing the data given in Table C–I for the half-mask facepiece respirators equipped with high efficiency filters with the data given in Tables C–III & C–IV shows that the penetrations of NaCl aerosol through the dust filters have a significant effect upon the determination of respirator protection factors. . . .
>
> A comparison of the protection factors given in Table D–I for respirators equipped with high efficiency filters and with the protection factors given in Tables D–II and D–III for respirators equipped with dust filters indicates that the dust filters permitted significant aerosol penetrations.[174]

In 1976, Douglas et al. at LASL reported on the effects of flow rates ranging from 16 to 77 L/min/filter on leakage of a 0.6 μm MMAD (GSD of 2.0, which is about 0.15 μm CMD) NaCl aerosol through DM filters (both mechanical nonwoven and electrostatic-type filter materials).[175] At about 50 L/min/filter, they observed filter leakages ranging from about 3% to almost 20% for five different types of DM-filter material with two of the five DM-filter media exceeding about 13% leakage.[176]

During 1978, NIOSH conducted a multiphase investigation to compare filter leakage results from test aerosols used in 30 CFR Part 11 and test aerosols that had been proposed by LASL several years earlier. The results of this investigation were

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[172]Wilcher, F. E.: *ISEA Analysis of Supporting Test Data (OSHA Exhibit 38) Utilized by E. C. Hyatt to Develop Respirator Protection Factors*, comments submitted by the ISEA to OSHA Docket SCP–1, Arlington, VA (October 1, 1975).

[173]Ibid., Section C, pp. 11–12.

[174]Ibid., Section C, p. 12 and Section D, p. 17.

[175]Douglas, D. D. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—July 1, 1974–June 30, 1975*, Los Alamos Scientific Laboratory, Progress Report, No. LA–6386–PR (August 1976), pp. 13–14.

[176]Ibid., Figure 7, p. 14.

presented in a 1980 NIOSH report[177] and published in 1986.[178] The NIOSH researchers used a 0.6 to 0.8 μm (GSD of 2, which is about a 0.14 μm count median diameter aerosol) NaCl aerosol without charge neutralization to test several NIOSH-certified DM and DFM filters at a flow rate of 32 L/min per filter. They reported the following initial test results from one filter tested per run at various relative humidities ranging from 10 to 90%: 10%, 7%, and 7% leakage through Norton 7500–6A DM filters; 3.3%, 2.4, and 1.0% leakage through 3M 9910 DM filter masks; and 1% or less for the other DM and DFM filters.[179] They reported the following test results after one hour of testing with the NaCl aerosol at 15 mg/m^3: 27%, 24%, and 17% leakage through Norton 7500–6A DM filters; 4.7%, 3.3%, and 3.5% leakage through 3M 9910 DM filter masks; 6.4% leakage through a Willson R–30 DM filter; 2.8% leakage through a 3M 9900 DM filter mask; and 1% or less for the other DM and DFM filters.[180] Reed et al. also used a 0.3 μm geometric mean diameter (GSD of 1.2) DOP oil aerosol to test several NIOSH-certified DM and DFM filters at a flow rate of 42.5 L/min per filter. They reported the following test results for mean filter leakage: 88% leakage for the Norton 7600–6A DM filter, 87% leakage for the AO R–30 DM filter, 69% leakage for the AO R–56 DFM filter, and 5% leakage for the MSA S DFM filter.[181] They stated:

> The initial penetration of DOP for DM filters started at about 3% and reached 88% after about five minutes. This rapid increase in DOP penetration results from degradation of the filter media and was noted for some DFM filters as well.[182]

In 1979, Smith et al. reported on the use of a 0.70 μm MMAD (GSD of 2, which is about a 0.14 μm count median diameter aerosol) NaCl aerosol to test several NIOSH-certified DM and DFM filters at a flow rate of 32 L/min per filter.[183] They reported

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[177]Reed, L. D., D. L. Smith, T. C. Mollman, and I. J. Frockt: *Comparison of Respirator Particulate Filter Test Methods*, NIOSH, Cincinnati, OH (August 1980).

[178]Reed, L. D., D. L. Smith, and E. S. Moyer: Comparison of Respirator Particulate Filter Test Methods, *J. Int. Soc. Resp. Prot.* 4(3):43–60 (1986).

[179]Ibid., Table VI, p. 58.

[180]Ibid., Table VI, p. 58.

[181]Ibid., Table IV, p. 52.

[182]Ibid., p. 52.

[183]Smith, D. L., O. E. Johnston, and W. T. Lockwood: The Efficiency of Respirator Filters in a Coke Oven Atmosphere, *Am. Ind. Hyg. Assoc. J.* 40(12): 1030–1038 (1979).

the following geometric mean NaCl leakages: 38% through a Willson DM filter, 31% leakage through an MSA DM filter, 28% through a Willson DM filter with acid-gas sorbent, 26% through a Willson DM filter with organic vapor sorbent, 24% leakage through an MSA DM filter with organic vapor sorbent, 23% leakage through an MSA DM filter with acid-gas sorbent, 4.3% leakage through a Willson DFM filter, and 1.5% leakage through an MSA DFM filter.[184]

In the early 1980s, the following consensus statements were made to NIOSH by respirator experts on the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee. These experts included several representatives from major respirator manufacturers.

> The second shortcoming of the [30 CFR Part 11] certification tests is that the actual aerosols used could not be related to those found in the workplace nor could they be considered as an aerosol having the greatest ability to penetrate the respirator filter media of those aerosols likely to found in the workplace. Many alternatives were discussed. The one most feasible aerosol evaluated was the extremely small ("worst case") sodium chloride aerosol having a particle size of approximately .12 (geometric count mean) microns in diameter and geometric SD [standard deviation] of less than 1.6. . . .
>
> The committee decided that in addition to the sodium chloride solid aerosol, the incorporation (sic) liquid aerosol should be also included to measure the respirator's efficiency in removing mists, should that certification be requested. The thermally generated approximately .3 micron DOP aerosol was chosen as the candidate for respirator certification for mists.
>
> Mists or liquid aerosols will affect filter media in a much different manner than a solid aerosol. With some filter media the liquid particles can have an extremely determental (sic) effect. For example, the committee has generated data that show an "[NIOSH-] approved" mist filter that can be less than 50% efficient when challenged with oil mist. . . .
>
> However to summarize, the data the committee obtained indicated that, in many cases, the efficiency of the respirator throughout the test when continuously measured was far less than indicated by the current [30 CFR Part 11] certification tests. The net result being that should the respirator wearer rely on a respirator currently certified for protection of certain particulates, he or she may not receive adequate protection if the environment contains a significant quantity of the "worst case" or hardest to filter contaminants. The committee recommended that NIOSH adopt a proposed alternatives (sic) attached to this report.
>
> The recommended particulate certification would consist of certifying the respirator for protection against either a liquid or a solid aerosol or both in filter efficiency classes of less than 5% [leakage], less than 1% or less than 0.03% [leakage]. . . .[185]

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[184]Ibid., Table VIII, p. 1036.

[185]Wilmes, D.: Recommendations to NIOSH for Revision of 30 CFR Part 11, memorandum from chairman of the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee for Respiratory Protection, St. Paul, MN (undated, ca. early 1980s), p. 2.

In 1987, Hinds and Kraske published filter leakage results for the 3M 8710 single-use, DM-filter respirator and MSA Type S DFM filters for aerosol size midpoints ranging from 0.14 to 11.3 μm and flow rates of 2 to 150 L/min/mask.[186] At 50 L/min/mask and against aerosol sizes about 0.2 μm diameter, they reported leakages through the 8710 DM filter of about 14 to 18% and about 4 to 5% leakage through MSA DFM filters.[187]

In 1989, Stevens and Moyer reported filter leakage results for four DM filters and four DFM filter challenged against 0.03 to 0.24 μm CMD (GSD of 1.4 to 1.6) NaCl aerosols at flow rates of 32 to 170 L/min/mask.[188] For flow rates in the range 32 to 85 L/min/mask, they reported maximum-leakage results of 11% to 29% for DFM filters and 1% to 6% for DFM filters.[189]

NIOSH concludes that for over two decades data have been available to indicate that substantial leakage can be expected to occur through some models of NIOSH-certified DM and DFM filters. There have been numerous reports of this filter leakage occurring when these filters were used against contaminant sizes ranging from about 0.05 to 0.40 micrometers (μm) (count median diameter).

Experts in the field of respiratory protection have cautioned that filter-protection limitations must be considered when determining assigned protection factors. In 1976, Hyatt cautioned:

> The [assigned] protection factor can only be applied when a comprehensive respirator program is being carried out and the respirator approval limitations are considered. Also, other factors must be considered, such as . . . the efficiency of a particulate-filter element for removal of specific types of aerosols.[190]

Hyatt also observed with regard to respirator-performance test results on dust filters using sodium chloride aerosol (0.6 μm MMAD):

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[186]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10):836–841 (1987), Figures 5 and 6, pp. 839–840.

[187]Ibid.

[188]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).

[189]Ibid., Table II, p. 262.

[190]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), p. 7.

The penetration measured on the dust respirators represents overall leakage through filters, facepiece seal, and exhalation valves. The results indicate that penetration through the quarter- and half-mask dust respirator filters are a major source of penetration when compared with the results in Table C for the same facepiece [equipped with a HEPA filter] and subject.[191]

Also in 1976 NIOSH stated:

Some filters used on the so-called "fume" respirators, look similar [to HEPA filters]. The basic difference is that the fume filter is less efficient (90–99% against 0.6–μm [MMAD] particles) . . . Less efficient are the so-called "dust" filters used on respirators designed for protection against "pneumoconiosis- and fibrosis-producing dusts" . . . This class of respirator accounts for as much as 90% of total sales. Their lower efficiency (80–90% against 0.6–μm particles [MMAD]) results from being designed to withstand heavy dust loadings without unacceptably increasing breathing resistance.[192]

The American National Standards Institute (ANSI) Z88.2–1980 respirator-use standard cautioned in 1980:

Limitations of filters, cartridges, and canisters used in air-purifying respirators shall be considered in determining [assigned] protection factors.[193]

For over two decades, statements have appeared in the professional literature regarding the filter-penetration problems caused by certain test aerosols used for quantitative fit testing (QNFT) and qualitative fit testing (QLFT) of face-seal efficacy. For example, the 1969 ANSI-recommended procedure for irritant-smoke fit testing[194] restricted its use to "a respirator equipped with a high-efficiency particulate filter" (to protect the wearer from irritant-smoke-leakage through DM- and DFM-filters) and noted:

Freshly produced smoke particles from this [smoke-generating] tube range from less than 0.1 to 3 microns [micrometers, μm] in diameter.[195]

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[191]Ibid., p. 21.

[192]NIOSH: *A Guide to Industrial Respiratory Protection*, DHEW(NIOSH) Publication # 76–189, Cincinnati, OH, (June 1976), p. 32.

[193]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1980, New York, New York, (1980), pp. 20 and 23, Table 5, footnote (a).

[194]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1969, New York, NY, (1969), p. 24.

[195]Ibid., p. 25.

Regarding this QLFT, NIOSH cautioned in 1976:

> This test can be used for both air-purifying and atmosphere-supplying respirators, but an air-purifying respirator must have a high-efficiency filter(s).[196]

Similarly, the 1980 ANSI-recommended procedures for aerosol QNFTs permitted the use of HEPA filters on the tested masks.[197] The 1980 ANSI-recommended protocol for irritant-smoke QLFT cautioned:

> When an air-purifying respirator is tested, it should be equipped with a high-efficiency filter.[198]

Another example is a QLFT based on a saccharin-water aerosol, which was introduced in the early 1980s.[199] OSHA permitted its use to comply with fit-testing requirements in the lead standard.[200] The following background information has been provided to NIOSH regarding this test:

> This test was designed and developed in the late 1970's and early 1980's as a validated qualitative fit test to be used with respirators with dust/mist filters. The test was developed because up to that time there was no fit test, qualitative or quantitative suitable for use with respirators with dust and mist filters.
>
> The quantitative fit tests then available were not suitable because the filter efficiency of this type of respirator filter would allow 10 to more than 20 percent of the test agent to pass through the filter masking any attempt to quantify the test aerosol that was passing through faceseal leakages. The qualitative fit tests available were also not suitable because they were either too small of a particle, such as irritant smoke, or a vapor, such as isoamyl acetate.[201]

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[196]NIOSH: *A Guide to Industrial Respiratory Protection*, DHEW(NIOSH) Publication # 76–189, Cincinnati, OH, (June 1976), p. 70.

[197]American National Standards Institute, Inc.: *American National Standard Practices for Respiratory Protection*, ANSI Z88.2–1980, New York, New York, (1980), p. 34.

[198]Ibid., p. 33.

[199]3M Company: *Comment of Minnesota Mining and Manufacturing Company with Respect to the Permanent Lead Standard Quantitative Fit Test Provision*, OSHA Docket No. H–049A, Exhibit 6–16, (July 1, 1981).

[200]29 CFR 1910.125(f)(3) and Appendix D.

[201]Wilmes, D. P.: Letter to R. W. Niemeier of NIOSH from the 3M Occupational Health and Environmental Safety Division, 3M Company, St. Paul, MN (May 17, 1991), p. 1.

The saccharin test agent has a relatively large size of 2.0 to 2.4 microns [μm] (count geometric mean, with 99.5% of the particles below 7.0 microns).[202] Given the data provided with the validation study for the QLFT, NIOSH estimates the saccharin test aerosol has a *mass median aerodynamic diameter* (MMAD) of about 4.5 to 5.0 microns.

Lastly, in 1992, Iverson et al. reported results for a proposed quantitative fit test for DM- and DFM-filter masks.[203] They reported that

> Submicron aerosol test agents used in many fit tests can be used with high-efficiency particulate (HEPA) filter elements but cannot be properly used with dust/fume/mist particulate filter elements because the aerosol is not completely stopped by these filter elements.[204]

Iverson et al. investigated the leakage of aerosols ranging from 0.7 to 15 μm at 32 L/min/mask through one type of NIOSH-certified, filtering-facepiece, DM-filter half-mask (Model 8710 from the 3M Company). They reported that a 2.5-μm aerosol particle met their QNFT criteria of 0.3 percent or lower filter leakage through their DM filter.[205]

NIOSH concludes that it has been well known for over two decades that face-seal-leakage test protocols based on certain aerosols for quantitative fit testing (QNFT) and qualitative fit testing (QLFT) required the use of HEPA-filters on the tested masks. This is because the test aerosols used in these protocols (e.g., less than about 2.5 μm aerodynamic diameter) will infiltrate NIOSH-certified DM and DFM filters.

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[202]3M Company: *Comment of Minnesota Mining and Manufacturing Company with Respect to the Permanent Lead Standard Quantitative Fit Test Provision*, OSHA Docket No. H-049A, Exhibit 6-16, (July 1, 1981), Attachment 1—Validation data for the Saccharin QLFT.

[203]Iverson, S. G., S. G. Danisch, H. E. Mullins, and S. K. Rudolph: Validation of a Quantitative Fit Test for Dust/Fume/Mist Respirators: Part I, *Appl. Occup. Environ. Hyg.* 7(3):161-167 (1992).

[204]Ibid., p. 161.

[205]Ibid., p. 163.

9—Derivation and evaluation of two leakage-function models for describing a *user's protection factor* while wearing a DM- or DFM-filter mask.

In order to evaluate the nature and extent of a possible hazard to respirator wearers due to contaminant leakage through NIOSH-certified DM and DFM filters, it is necessary to evaluate the combined effect of filter leakage and face-seal leakage on user protection factors (PFs) for filter-mask respirators. For the Institute to perform a quantitative evaluation of the efficacy of these filter masks, NIOSH examined two leakage-function models. These models describe a user's *protection factor* as a function of total *user-inhaled leakage*, *filter leakage*, and *face-seal leakage*. For both models the user protection factor for a given wearer shall be denoted by PF_{user}, total user-inhaled leakage by $L_{inhaled}$, filter leakage by L_{filter}, and face-seal leakage by $L_{face\ seal}$, where leakages are always given in fractional-leakage values, not percentage values. A protection factor is defined as the reciprocal of the corresponding fractional leakage (e.g., $PF_{user} = 1/L_{inhaled}$).

A *simple-additive model* relating $L_{inhaled}$ to the component leakages is given by

$$L_{inhaled} = L_{face\ seal} + L_{filter} \qquad (1)$$

Since $L_{face\ seal} = 1/PF_{face\ seal}$, after rearranging the terms the simple-additive model becomes

$$PF_{user} = [(PF_{face\ seal})^{-1} + (L_{filter})]^{-1}, \qquad (2)$$

where L_{filter} is given as *fractional leakage* (i.e., percentage leakage divided by 100). This is the same additive-leakage model used by a major respirator manufacturer.[206] It is based on assumptions that filter leakage and face-seal leakage are independent and additive. For the simple-additive model, Figure II illustrates the predicted effects on PF_{user} resulting from $PF_{face\ seal}$ values between 5 and 1,000 and L_{filter} values between 0.10 and 0.50.

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[206] 3M Company: *Comment of Minnesota Mining and Manufacturing Company with Respect to the Permanent Lead Standard Quantitative Fit Test Provision*, OSHA Docket No. H–049A, Exhibit 6–16, (July 1, 1981), p. 18.

A more sophisticated model developed by NIOSH is based on a relationship for filter and face-seal leakage that was first presented by Williams in 1980 and published in 1983.[207,208] This model was also given in 1984 by Campbell.[209] The derivation given in this evaluation for the *improved model* is based on that given by Campbell. This leakage-function model relies on the following assumptions:

- Pressure variations are sufficiently small such that the contaminated and filtered air can be considered incompressible.
- The cyclic performance of the respirator can be characterized by a representative constant volumetric flow rate.
- During each inhalation cycle, the inhaled concentration $C_{inhaled}$ reaches equilibrium sufficiently quick so that it can be considered a constant during the entire inhalation cycle.
- The workplace concentration C_o is spatially uniform and time independent.
- The contaminant concentration passing through the face seal $C_{face\ seal}$ equals the workplace contaminant concentration C_o (i.e., face-seal leakage $L_{face\ seal}$ = 1.00).

Start by considering a negative-pressure filter mask worn in a workplace contaminant concentration C_o. The contaminant concentration $C_{inhaled}$ in the volumetric air flow $Q_{inhaled}$ inhaled by the mask wearer is an air-flow-rate-weighted mixture of the contaminant concentration C_{filter} in the volumetric air flow Q_{filter} penetrating the filter and the concentration $C_{face\ seal}$ in the volumetric air flow $Q_{face\ seal}$ that has breached the face seal-to-skin interface. $Q_{inhaled}$ is the sum of Q_{filter} and $Q_{face\ seal}$. Then define the PF_{user} as

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[207]Williams, F. T.: An Analytical Method for Respirator Performance Prediction Utilizing the Quantitative Fit Test (QNFT), presented at NIOSH First International Respirator Research Workshop, Morgantown, West Virginia (September 11, 1980).

[208]Williams, F. T.: An Analytical Method for Respirator Performance Predic- . Utilizing the Quantitative Fit Test, *J. Int. Soc. Resp. Prot.* 1(3):109–125 (1983).

[209]Campbell, D. L.: The Theoretical Effect of Filter Resistance and Filter Penetration on Respirator Protection Factors, *J. Int. Soc. Resp. Prot.* 2(3):198–204 (1984).

$$PF_{user} = 1/L_{inhaled} = C_o/C_{inhaled}. \quad (3)$$

For these conditions, write a mass per unit time balance around the user's mouth and nose (i.e., total mass rate of contaminant inhaled into the user's body as a function of component mass rates approaching the mouth and nose). One obtains

$$(C_{inhaled})(Q_{inhaled}) = (C_{filter})(Q_{filter}) + C_{face\ seal})(Q_{face\ seal}). \quad (4)$$

These concentrations are related to the workplace contaminant concentration outside the respirator C_o as follows

$$C_{inhaled} = (L_{inhaled})(C_o), \quad (5)$$

$$C_{filter} = (L_{filter})(C_o), \text{ and} \quad (6)$$

$$C_{face\ seal} = (L_{face\ seal})(C_o). \quad (7)$$

From equations (3) through (7) and using the assumption that $C_{face\ seal} = C_o$ one can obtain

$$L_{inhaled} = (L_{filter})(Q_{filter}/Q_{inhaled}) + (Q_{face\ seal}/Q_{inhaled}). \quad (8)$$

From flow-rate balance around the user's mouth and nose one obtains

$$Q_{inhaled} = Q_{filter} + Q_{face\ seal}, \quad (9)$$

which can be substituted into equation (8) to yield

$$L_{inhaled} = L_{filter} + (1 - L_{filter})(Q_{face\ seal}/Q_{inhaled}). \quad (10)$$

Equation (10) can be solved by creating two equations for two sets of conditions. This will yield two equations in three unknowns: $L_{inhaled}$, $Q_{face\ seal}$, and $Q_{inhaled}$. Then an assumption will be used to eliminate $Q_{face\ seal}$. Case A is one in which a respirator is worn with a filter with essentially zero leakage (e.g., when a HEPA filter is fitted to the respirator during fit testing). In this case, equation (10) reduces to:

$$L'_{inhaled} = Q_{face\ seal}/Q_{inhaled}, \quad (11)$$

where the superscript (º) is used to indicate Case A with zero filter leakage. The second Case B is where the same respirator is worn with a DM or DFM filter against a contaminant size producing appreciable filter leakage. In this case, equation (10) yields

$$L_{inhaled} = L_{filter} + (1 - L_{filter})(Q_{face\ seal}/Q_{inhaled}). \quad (12)$$

Then, after assuming $Q_{face\ seal}$ is the same in both cases, combining equations (11) and (12) then yields

$$L_{inhaled} = L_{filter} + (1 - L_{filter})(L^{\circ}_{inhaled}). \quad (13)$$

Rearranging the right side of this equation yields

$$L_{inhaled} = L^{\circ}_{inhaled} + (L_{filter})(1 - L^{\circ}_{inhaled}). \quad (14)$$

Since $L_{inhaled} = 1/PF_{user}$ and for Case A, $L^{\circ}_{inhaled} = L_{face\ seal} = 1/PF_{face\ seal}$,

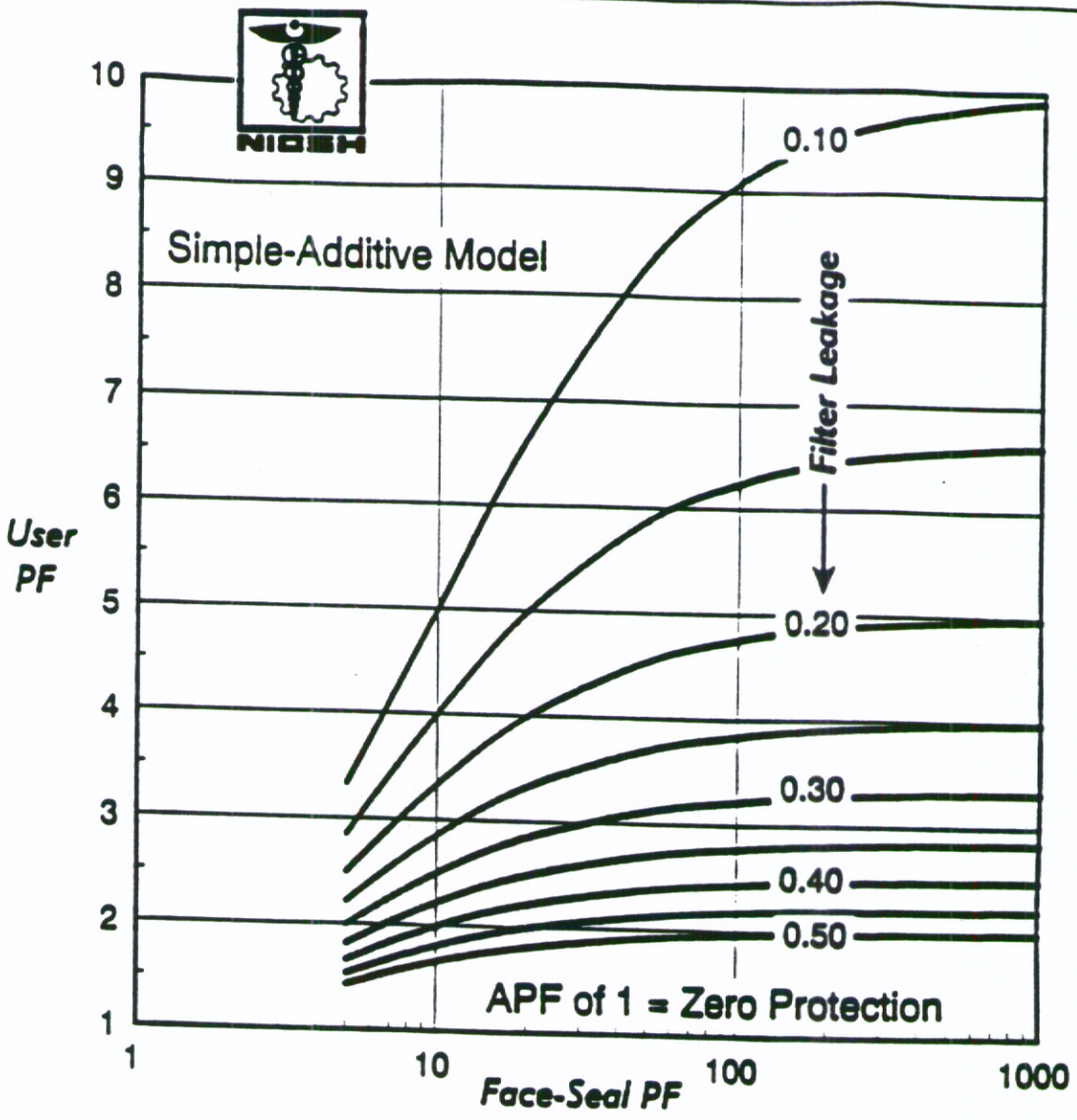
$$1/PF_{user} = 1/PF_{face\ seal} + (L_{filter})(1 - 1/PF_{face\ seal}), \quad (15)$$

thus

$$PF_{user} = [(PF_{face\ seal})^{-1} + (L_{filter}) - (L_{filter})/(PF_{face\ seal})]^{-1}. \quad (16)$$

As with Figure II for the simple-additive model, Figure III similarly illustrates for the *improved model* the predicted effects on PF_{user} resulting from $PF_{face\ seal}$ values between 5 and 1,000 and L_{filter} values between 0.10 and 0.50. There is a strong similarity between the two functions for PF_{user} in equations (2) and (16) respectively given by the simple-additive and improved models. In spite of additional complexity in assumptions and derivation, the improved model has only one extra term, the negative ratio $L_{filter}/PF_{face\ seal}$. *A comparison of user-PF values on Figures II and III for similar filter isoleakage curves indicates that the two models yield essentially identical user-PF values except in the face-seal PF range 5 to 10.* Even in that region the user-PF differences between the two models is about 10% at most. Note that the improved model yields *slightly lower* user PFs than those of the simple-additive model. The small differences between the two models result from the minimal effect of the negative ($L_{filter}/PF_{face\ seal}$) term. For face-seal PF values > 10, this term rapidly approaches zero, thus it has minimal effect on computed user-PF values.

Because the simple-additive and improved models for computing PF_{user} yield essentially the same results, one can consider the derivation given in this evaluation as primarily an interesting academic exercise rather than an essential step for analysis of filter-leakage data. However, because of its improved accuracy, additional sophistication, and technical considerations, NIOSH elected to use the improved model reflected in equation (16) as the basis for the Institute's analysis of filter-leakage data.



	5	10	20	50	100	200	500	1000
.05	4.00	6.67	10.00	14.29	16.67	18.18	19.23	19.61
.10	3.33	5.00	6.67	8.33	9.09	9.52	9.80	9.90
.15	2.86	4.00	5.00	5.66	6.25	6.45	6.58	6.62
.20	2.50	3.33	4.00	4.55	4.76	4.86	4.95	4.96
.25	2.22	2.86	3.33	3.70	3.85	3.92	3.97	3.98
.30	2.00	2.50	2.86	3.13	3.23	3.28	3.31	3.32
.35	1.82	2.22	2.50	2.70	2.78	2.82	2.84	2.85
.40	1.67	2.00	2.22	2.38	2.44	2.47	2.49	2.49
.45	1.54	1.82	2.00	2.13	2.17	2.20	2.21	2.22
.50	1.43	1.67	1.82	1.92	1.96	1.98	1.99	2.00

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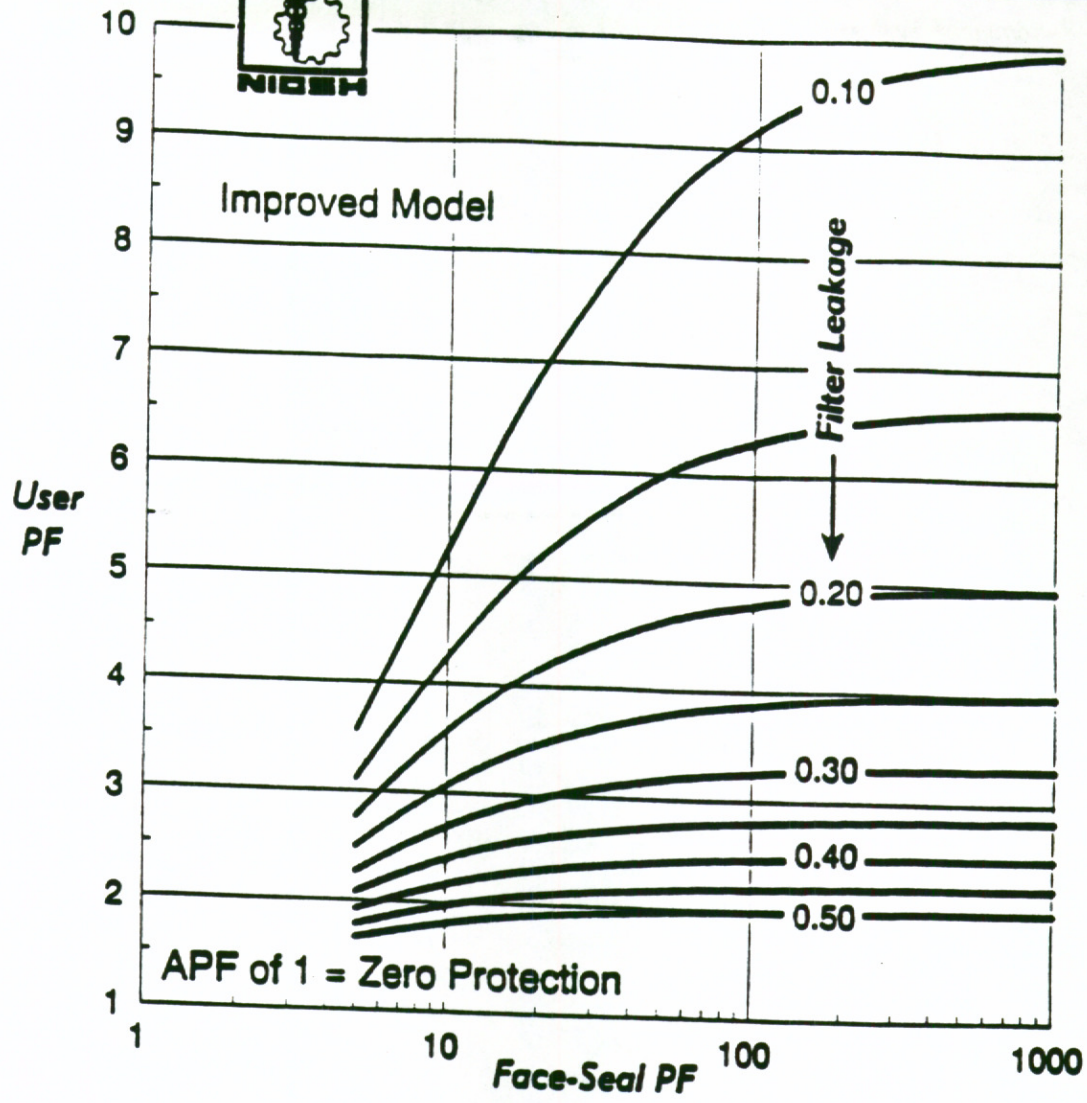
Figure II—Simple-Additive Model: Combined Effect of Face-Seal PF and Filter Leakage on User PF.



	5	10	20	50	100	200	500	1000
.05	4.17	6.90	10.26	14.49	16.81	18.26	19.27	19.83
.10	3.57	5.26	6.90	8.47	9.17	9.57	9.82	9.91
.15	3.13	4.26	5.19	5.99	6.31	6.48	6.59	6.63
.20	2.78	3.57	4.17	4.63	4.81	4.90	4.96	4.98
.25	2.50	3.06	3.48	3.77	3.88	3.94	3.98	3.99
.30	2.27	2.70	2.99	3.18	3.26	3.29	3.32	3.33
.35	2.08	2.41	2.61	2.75	2.81	2.83	2.85	2.85
.40	1.92	2.17	2.33	2.43	2.46	2.48	2.49	2.50
.45	1.79	1.96	2.09	2.17	2.20	2.21	2.22	2.22
.50	1.67	1.82	1.91	1.96	1.98	1.99	2.00	2.00

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Figure III—Improved Model: Combined Effect of Face-Seal PF and Filter Leakage on User PF.

10—Evaluation factors for DM- and DFM-filter-leakage data.

In order to evaluate the nature and extent of a possible hazard to respirator wearers due to contaminant leakage through NIOSH-certified DM and DFM filters, it is important to understand the factors affecting respirator-filter leakage. There are several major *technical* factors that determine the *actual leakages* through *dust and mist (DM)* and *dust, fume, and mist (DFM)* filter respirators. For over two decades it has been well known that these determinant factors include,[210] but are not limited to:

- *Leakage function* for each make and model filter (i.e., filter leakage as a function of particle size and air velocity through a filter).

- *Size distribution* for airborne contaminant (i.e., both the range and relative frequencies of different particle sizes challenging the filtering material).

- *Linear air velocity* through the filtering material, which is a function of the total filtering area and the wearer's volumetric flow rate through the mask filter(s).

- *Filter loading* (i.e., amount of contaminant deposited on the filtering material during use).

- *Electrostatic charge(s)* on the filtering material and on an airborne contaminant or test aerosol. These filter and aerosol charges are affected by the humidity conditions in the workplace, where the filters are stored before use, and how the contaminant or test aerosol are generated.

When comparing or evaluating leakage measurements (or APF values) from a filter-performance study, it is necessary to consider the effects from each of these five factors, particularly the first three. Regarding *filter leakage functions* for each make and model filter, note that the variability in observed leakage between different filter lots from the same manufacturer can be of comparable magnitude to that observed

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[210]Hyatt E.C., et al.: *Respiratory Studies for the National Institute for Occupational Safety and Health—July 1, 1972 through June 3, 1973*, Los Alamos Scientific Laboratory, Progress Report, No. LA-5620-PR (May 1974), p. 15.

between different brands of the same filter type.[211] These leakage functions can be considered to be leakage bands, ranges, or distributions that are a function of each (contaminant size, volumetric flow rate, filter lot) combination, rather than a single leakage value for each combination of (contaminant size, volumetric flow rate). Additionally, these functions can be characterized as "narrow band" or "wide band" functions, depending on how narrow or wide a range of contaminant sizes the substantial filter leakage occurs over. Refer to leakage functions reported by Hinds and Kraske,[212] Liu and Fardi,[213] or Stevens and Moyer[214] to gain an appreciation of different leakage functions. Also refer to Figures VI through IX presented later in this evaluation.

Regarding the effect of *particle size* on filter leakage, contaminant *count diameters* between about 0.05 and 0.5 μm *generally* produce the *highest leakage* values for DM and DFM filters (some authors report a size range of about 0.1 to 0.4 μm). Particle count diameters smaller or larger than this range generally produce considerably *lower leakage results*. If a *median diameter* for a size distribution is reported, then leakage values must be evaluated on the basis of *count median diameter* (*CMD*), not *mass median diameter* (*MMD*) or *mass median aerodynamic diameter* (*MMAD*).[215] If either one of the latter two is reported, it should be converted to a count median diameter. Typically a *CMD* is at least one fifth to one tenth the size of the corresponding *MMD* or *MMAD*, depending on the *geometric standard deviation* of the contaminant size distribution.[216] Refer to multiple particle-size results reported by Hinds and Kraske,[217] Liu and Fardi,[218] or Stevens and Moyer[219] to gain an appreciа-

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[211]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10):836–841 (1987), p. 840.

[212]Ibid., Figures 5 and 6.

[213]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Chapter 6—Experimental Results, pp. 250–307

[214]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).

[215]The *count median diameter* (*CMD*) is defined as the contaminant size for which half the total *number* of contaminant particles are larger and half are smaller. In contrast, the *mass median aerodynamic diameter* (*MMAD*) is defined as the aerodynamic diameter for which half the total *mass* of particles is contributed by particles larger than the MMAD and half by particles smaller than the MMAD.

[216]Hinds, W. C.: *Aerosol Technology*, John Wiley & Sons, New York (1982), p. 93, Figure 4.16.

[217]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10):836–841 (1987), Figures 5 and 6.

tion of the effect of particle size on DM and DFM filter leakage. Also refer to Figures VI through X presented later in this evaluation.

The *linear air velocity* through a filter, which is function of *volumetric flow rate* and filtering area, can have a substantial effect on filter leakage values. In *general, leakage increases* as *air velocity increases* through the filtering material. That is, as *volumetric flow rate increases* and *filtering area decreases.*

Prior to the late 1980s, most researchers performed filter-leakage studies at volumetric flow rates of about 16 to 50 liters per minute per filter (L/min/filter). Generally, this was done because 32 L/min is the volumetric flow rate for non-powered *respirators* tested against silica dust, silica mist, and lead fume under the requirements of 30 CFR Part 11.[220] That is, a test flow rate of 16 L/min/filter when two filters are used on a respirator and 32 L/min/filter when only a single filter is used. However, for DOP tests conducted on HEPA filters, Part 11 requires substantially higher volumetric flow rates of 85 L/min/mask (42.5 L/min/filter for 2-filter masks).

As a historical note, 32 liters/min/mask was the flow rate used in U.S. Public Health Service tests respirator-performance tests conducted over 60 years ago.[221] This flow rate was stated to be "the rate of breathing by a man doing vigorous work."[222] However, at that time the Bureau of Mines evaluated the maximum permissible resistance of gas masks at a flow rate of 85 liter/min.[223] NIOSH still uses the same flow rate today for the same resistance test.[224]

Thus for comparing the potential for excessive filter leakage of Part 11-certified filters against that of any new Part 84-certified filters, leakage data obtained at volumetric flow rates nearest to 85 L/min/mask are the most relevant. If leakage data

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[218](...continued)

[218]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Chapter 6—Experimental Results, pp. 250–307

[219]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).

[220]§§ 11.140–4 to 11.140–7.

[221]Katz, S. H., E. G. Meiter, and F. H. Gibson: *Efficiencies of Painters' Respirators Filtering Lead Paint, Benzol and Vitreous Enamel Sprays*, Public Health Bulletin No. 177, Treasury Department, U.S. Public Health Service (June 1928).

[222]Ibid., p. 7.

[223]Bureau of Mines: *Schedule 14A, Procedure for Establishing a List of Permissible Gas Masks* (August 25, 1923).

[224]30 CFR 11.102–1.

are reported only for lower volumetric flow rates (e.g., 28 or 32 L/min/filter), then the *expected higher* leakage values at 85 L/min/mask must be considered when evaluating a study depending on whether one or two filters are used per mask. All volumetric flow rate results reported and discussed in this evaluation have been converted to "as-used-on-mask" units (L/min/mask) when necessary.

Refer to multiple flow-rate results reported by Hinds and Kraske,[225] Liu and Fardi,[226] or Stevens and Moyer[227] to gain an appreciation of the substantial effect of volumetric flow rate on DM and DFM filter leakage. Also refer to Figures VI through IX presented later in this evaluation.

In order to evaluate what volumetric flow rates through filters are most relevant to actual workplace usage, one needs to know what volumetric flow rates are achieved by respirator users at various work rates. In 1990, this topic was commented on by Revoir as follows:

Breathing rates for healthy adult males determined by the late Dr. Leslie Silverman and his associates at Harvard University often are used to establish air-flow rates for performance testing of respirators. The breathing rates determined by Dr. Silverman and his associates that should be considered for respirator performance testing are listed as follows:

Work Classification	Work Rate (kg-m/min)	Breaths per minute	Minute volume (L/min)	Maximum Inspiratory Rate (L/min)	Maximum Expiratory Rate (L/min)
Medium work	622–830	23–30	37–55	100–149	107–154
Heavy work	1107–1384	35–41	75–104	194–254	211–314
Maximum exertion	1660	48	114	286	322

The [volumetric] air-flow requirement for an open-circuit self-contained breathing apparatus listed in 30 CFR Part 11 is 200 liters/minute which means that if the activity of a wearer is that equivalent to heavy work, the wearer's peak inspiration rate may exceed the air-flow rate of the

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[225]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10):836–841 (1987), Figures 5 and 6.

[226]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), § 6.3, pp. 296–299.

[227]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).

apparatus and this could result in leakage of contaminated air into the facepiece of the apparatus during the peak inhalation portion of the breathing cycle.[228]

In 1992, Johnson et al. used five work classifications to evaluate workplace-performance degradations caused by respirator usage.[229] The following is an abridged version of Table II from Johnson et al.:

Work Classification	Representative Activities	Physical Work Rate (Watts)	Respiratory Ventilation (L/min)	Peak Flow (L/min)
Very light	Lying, sitting, reading, answering phone, intermittent typing	0	8	31
Light	Washing clothes, polishing, light gymnastics, walking at 2 mph	10	15	59
Moderate	Climbing hills, shoveling fast	140	50	125
Heavy	Running at 9–10 mph unencumbered, skiing, playing squash	240	80	192
Very heavy	Sprinting	430	110	264

For most filter-mask users, peak inhalation flow rates are probably not the best indicator of filter leakage risk, since peak flow rates occur for such short periods of time. For filter masks, a more relevant indicator of leakage risk is the *time-averaged inhalation flow rate* (i.e., *minute volume*, the volume of air inhaled per minute or *respiratory ventilation*).

Silverman's results indicate that for typical periods defined as *medium work*, one can expect that filter-mask users will inhale at *average volumetric rates* of about 35 to 55 L/min/mask through their filter(s) with *peak volumetric rates* of 100 to almost 150 L/min/mask. Correspondingly, Johnson et al. defined *moderate work* as that with an average *respiratory ventilation* of 50 L/min/mask with a *peak flow* of 125 L/min/mask. For typical periods defined by Silverman as *heavy work*, one can expect that filter-mask users will inhale at *average volumetric rates* of 75 to about

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[228]Revoir, W. H.: *Comments on OSHA's Proposal to Modify Existing Provisions for Controlling Employee Exposure to Toxic Substances Found in 29 CFR 1910.1000(3) and 29 CFR 1910.134(a)(1).* Comments submitted to OSHA (May 30, 1990), p. 10.

[229]Johnson, A. T., R. A. Weiss, and C. Grove: Respirator Performance Rating Table for Mask Design, *Am. Ind. Hyg. Assoc. J.*, 53(3):193–202 (1992).

100 L/min/mask through their filter(s) with *peak volumetric rates* of about 200 to 250 L/min/mask. Similarly, Johnson et al. defined *heavy work* as that with an average *respiratory ventilation* of 80 L/min/mask with a *peak flow* of 192 L/min/mask. Also on the subject of respirator work rates, two respirator experts commented in 1984:

> The breathing rate at a moderate to heavy work rate would be greater than the rate at rest. Typical rates may be 60 LPM [L/min] at work versus 6 LPM at rest. Higher breathing rates may affect a respirator's efficiency.[230]

Therefore for filter testing, a range of volumetric flow rates from about 35 to 100 L/min/mask are most relevant to actual workplace usage of filter masks for use at medium (moderate) to heavy work rates.

Filter loading can also have a marked effect on filter leakage values. In general, *leakage decreases* as filter *loading increases*. That is, *clean filters* are generally the *least protective*. This effect applies to "mechanical" (non-electrostatic) filter media. For "electrostatic" filter media the loading effect can be reversed, with increasing leakage resulting from increased loading.[231,232] Wilmes stated in the early 1980s:

> The current [30 CFR Part 11] certification tests only give an integrated value throughout the time period and provide little information on how much penetration occurs at any particular time. This element is important in that many of the filter media in existence today and in use in respirators have either good initial filter efficiency but the efficiency "degrades" when the filter begins to load with particulates due to the masking or loss of electrostatic charge or alternately other types have poor initial filter efficiency but the efficiency increases as filter becomes load (sic) or clogged.[233]

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[230]Dixon, S.W. and T. J. Nelson: Workplace Protection Factors for Negative Pressure Half-Mask Facepiece Respirators, *J. Int. Soc. Respir. Prot.* 2(4): 347–361 (1984), p. 357.

[231]Hyatt E. C. et al.: *Respirator R and D Related to Quality Control; LASL Project P–37*, Los Alamos Scientific Laboratory, Quarterly Report July 1 thru September 30, 1971, No. LA–4908–PR (March 1972), pp. 15–16.

[232]Douglas, D. D. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—July 1, 1974–June 30, 1975*, Los Alamos Scientific Laboratory, Progress Report, No. LA–6386–PR (August 1976), pp. 17–19.

[233]Wilmes, D.: Recommendations to NIOSH for Revision of 30 CFR Part 11, memorandum from chairman of the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee for Respiratory Protection, St. Paul, MN (undated, ca. early 1980s), p. 2.

Refer to multiple loading-level results reported by Hyatt et al. for NaCl,[234] Douglas et al. for DOP and NaCl,[235] Shibata et al. for NaCl,[236] and Liu and Fardi[237] to gain a qualitative appreciation for the substantial effect of filter loading on filter leakage.

Lastly, the effects on filter leakage due to *electrostatic charges* on a filter and airborne contaminants or test aerosols *generally* are not nearly as great as seen with particle size and volumetric flow rate changes.[238] However, testing with a non-neutralized aerosol can underestimate a filter's leakage.[239] Additional comments on the preceding factors are given in this evaluation.[240]

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boratory, Progress Report, No.

nt Aerosol Technology for Meeting
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[237]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Chapter 6—Experimental Results, pp. 250–307

[238]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).

[239]TSI Incorporated: *Model 8110 Automated Filter Tester—Operation and Service Manual*, P/N 1980053 (Rev. C), St. Paul, Minnesota (November 1990), Appendix N, Part II, pp. N–9 to N–15.

[240]Refer to discussion presented in this evaluation for *Subpart V—Particulate Air-Purifying Respirators.*

11—Results reported from four recent studies of DM- and DFM-filter leakage.

In order to evaluate the nature and extent of a possible hazard to respirator wearers due to contaminant leakage through NIOSH-certified DM and DFM filters, it is important to evaluate the magnitude and nature of leakage through these filters. NIOSH obtained and evaluated filter-leakage research data from four research teams: (1) Hinds and Kraske[241,242] at the University of California at Los Angeles, (2) Liu and Fardi[243,244] at the University of Minnesota, (3) Stevens and Moyer[245] at NIOSH, and (4) Willeke and Chen[246,247,248] at the University of Cincinnati.

Hinds and Kraske used an oleic acid aerosol to test filter masks and respirators equipped with the following DM- and DFM-filter cartridges (SF and DF indicate utilization with single or dual filters respectively): MSA Type F (DM/DF) and Type S (DFM/DF) filter cartridges; North N7500–7 (DFM/DF) filters; American Optical AO®

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[241]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10): 836–841 (1987), Figures 5 and 6.

[242]Hinds, W. C.: Letter to L. W. Sparks of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01595, Los Angeles, CA (June 19, 1991).

[243]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Chapter 6—Experimental Results, pp. 250–307.

[244]Liu, B. Y. H.: Letter to L. W. Sparks of NIOSH transmitting filter information regarding filter-leakage data obtained during research activities supported in part by NIOSH Grant # R01 OH01485, Minneapolis, Minnesota (August 9, 1991).

[245]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), Tables II and III, p. 262.

[246]Chen, C. C., Ruuskanen, J., Pilacinski, W., and K. Willeke: Filter and Leak Penetration Characteristics of a Dust and Mist Filtering Facepiece, *Am. Ind. Hyg. Assoc. J.*, 51(12):632–639 (1990), Figure 6A, p. 636.

[247]Willeke, K. and C. C. Chen: Letters to N. A. Leidel of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01301, Cincinnati, OH (June 27 and July 15, 1991).

[248]Chen C. C., Lehtimäki, M., and K. Willeke: Aerosol Penetration Through Filtering Facepieces and Respirator Cartridges, Am. Ind. Hyg. Assoc. J., 53(9):566-574 (1992).

R56A (DFM/DF) filters; 3M 8710 (DM/SF) filter mask; American Optical AO® R1070 (DM/SF) filter mask; and Gerson 1710 (DM/SF) filter mask. Liu and Fardi used both dioctyl phthalate (DOP) and sodium chloride aerosols to test the following disposable DM- and DFM-filter masks: American Optical AO® R1070 (DM/SF); Moldex 2200 (DM/SF); and 3M 8710 (DM/SF), 9900 (DM/SF), and 9920 (DFM/SF). Stevens and Moyer also used both dioctyl phthalate (DOP) and sodium chloride aerosols to test the following DM- and DFM-filter cartridges: American Optical AO® R30 (DM/DF) and R56 (DFM/DF); North N7500–6A (DM/DF) and N7500–7 (DFM/DF); Pulmosan C–264–7 (DM/SF); and Willson® R–11 (DFM/DF).

Stevens and Moyer reported their filter leakage results as a function of volumetric flow rates per single filters (L/min/filter). For the data values reported in this evaluation, NIOSH doubled their reported flow-rate values to convert them to comparable L/min/mask flow rates (except for one facepiece that used only a single filter).

Lastly, Willeke and Chen used a corn oil aerosol to test filter masks and respirator facepieces equipped with the following DM- and DFM-filters: Gerson 1710 (DM/SF) filter mask; Moldex 2200 (DM/SF) and 3400 (DFM/SF) filter masks; MSA Type F (DM/DF) and Type S (DFM/DF) filters; 3M 7258 (DM/DF) prefilters; and 3M 8710 (DM/SF), 8715 (DM/SF), and 9920 (DFM/SF) filter masks.

The *percent filter-leakage* versus *respirator volumetric flow rate* results from these four studies are presented in Figures IV (DM filters) and V (DFM filters) of this evaluation. The capital letters on each graph are data markers for reported filter-leakage results from individual masks. The data markers are given as suffixes in the first column of the accompanying data tables. For example in Figure IV, each of the four "A" markers indicates one value in the data table for the HK–22 leakage results (i.e., 3.6, 5.2, 15.5, and 22.3 percent leakage) at the respective flow rates in L/min/mask indicated in the header row of the data table on the continuation page for Figure IV. In the first column of each data table, results reported by Hinds and Kraske are coded as HK, those from Liu and Fardi as LF, data from Stevens and Moyer as SM, and results from Willeke and Chen are coded as WC. The alphanumeric suffixes after the investigator codes are those used in their research reports.

For each research team, NIOSH plotted the highest-reported leakage values at each available volumetric flow rate (i.e., at the highest-leakage aerosol sizes). For example, the plotted values for the Hinds-Kraske results generally are for test-aerosol sizes in the range 0.14 to 0.37 μm diameter.

For Liu and Fardi, their DOP aerosol-leakage results are plotted. Their NaCl-leakage results were similar to or slightly lower than their DOP results, thus the former were not plotted on Figures IV and V to improve the clarity of the presentations (i.e. reduce visual clutter on the scatter plots). For Stevens and Moyer, their only their NaCl-leakage results are plotted. Since their DOP results were essentially

the same as for their NaCl results, the former are not presented in Figures IV or V to improve the clarity of the presentations.

To help the reader better understand the general effect of filter volumetric flow rate Q_{filter} on filter leakage L_{filter}, NIOSH statistically fitted logarithmic-regression curves[249] to each data series (each row in the data tables) shown in Figures IV and V. In all cases the correlation coefficient (degree of relationship) between the Q_{filter} and L_{filter} variables exceeded 0.93 and in many cases it exceeded 0.99, which indicated a high positive relationship between the two variables. However, note that these regression curves are presented primarily for *illustrative purposes*. They are not critical to NIOSH's determination of relevant filter-leakage values at relevant volumetric flow rates.

The data presented in Figures IV and V show that a *consistent pattern* of filter-leakage results was observed in each of four independent research studies conducted at four different laboratories. Their results were also consistent with those report in 1976 by Douglas et al. for five DM filters of that era[250] The mid-1980's results of Hinds and Kraske have been verified by the other three research teams. Each study reported consistently wide differences in the amount of filter leakage exhibited between different filter makes and models within each filter class. For DM filters at medium work rates, Figure IV indicates an approximately five-fold spread in percent leakage between those filter models exhibiting the least leakage versus the most leakage. For DFM filters at medium work rates, Figure V indicates an approximately two and a half-fold spread in percent leakage between filter models exhibiting the least leakage versus the most leakage.

As discussed previously in this evaluation, the quantitative effect on filter leakage due to use against contaminant sizes other than 0.1 to 0.4 μm depends both on the *filter-leakage function* for a given filter and the *size distribution* for the contaminant in question. For some filters the amount of leakage drops off relatively sharply to less than a few percent for contaminant sizes larger than about 0.3 μm (i.e., "narrow-band" leakage). However for other filters the leakage remains high even for contaminant sizes exceeding 1.0 μm diameter (i.e., "broad-band" leakage).

For the four DM-filter sets from Figure IV that exhibited the highest leakage values, Figures VI, VII, VIII, and IX indicate that all four exhibit *broad-band leakage* characteristics for breathing rates of 20 to 100 L/min (i.e., light to heavy work rates).

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[249]Mathematical model of the form $y = ax^b$ fitted through zero of each variable.

[250]Douglas, D. D. et al.: *Respirator Studies for the National Institute for Occupational Safety and Health—July 1, 1974–June 30, 1975*, Los Alamos Scientific Laboratory, Progress Report, No. LA–6386–PR (August 1976), Figure 7, p. 14.

Figure X summarizes the filter-leakage functions for three DM filters LF–M,[251] HK–23,[252] and HK–24[253] at a medium work rate (i.e., 50 L/min breathing rate).

Lastly, Figures XI through XIII illustrate the effect of DM-filter leakage on a user's protection factor PF_{user} as a function of *contaminant size* and *face-seal PF* values of 10 and 1,000 for DM filters HK–23 (Figure XI) and HK–24 (Figure XII) at a *medium-work breathing rate* (50 L/min characteristic volumetric flow rate) and WC-D at 30 L/min (Figure XIII). The PF_{user} values for Figures XI, XII, and XIII were computed with equation (16) in this evaluation.[254]

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[251]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Table 6–5, p. 271.

[252]Hinds, W. C.: Letter to Mr. Larry W. Sparks of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01595, Los Angeles, CA (June 19, 1991).

[253]Ibid.

[254]Under discussion under *Derivation and Evaluation of Two Leakage-Function Models for Describing a User's Protection Factor While Wearing a DM- or DFM-filter Mask.*

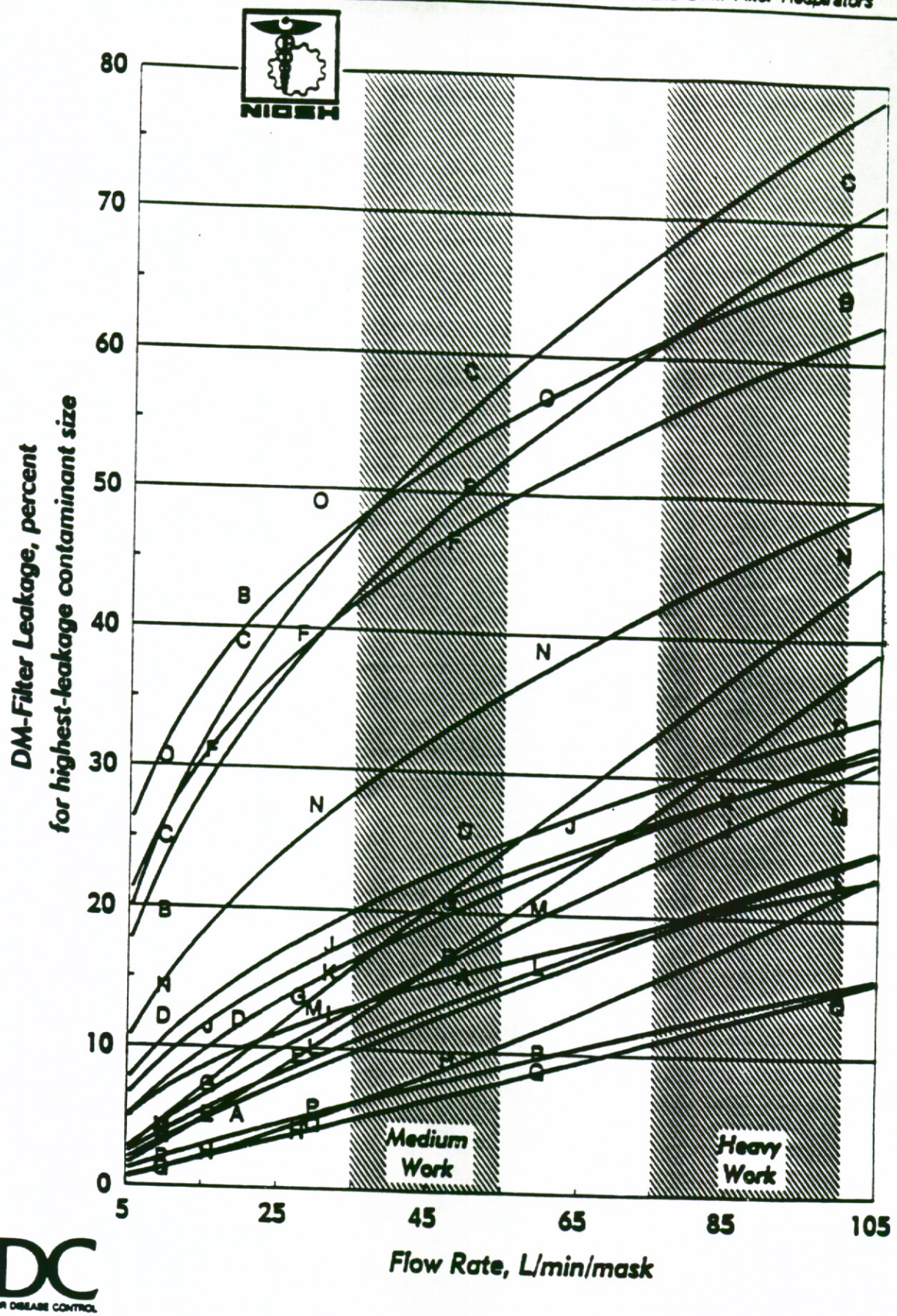

Figure IV—DM-Filter Leakage Values Reported in Four Recent Studies.

	Flow Rate, L/min/mask												
	10	16	20	28	30	32	42.5	48	50	60	64	85	100
HK-22=A	3.6		5.2						15.5				22.3
HK-23=B	19.7		42.2						50.5				64.5
HK-24=C	25.0		39.0						58.8				73.1
HK-31=D	12.1		12.0						25.9				34.0
LF-A=E		5.2		9.5				16.9					
LF-M=F		31.2		39.6				46.6					
LF-T1=G		7.3		13.7				20.8					
LF-T2=H		2.5		4.1				9.5					
SM-A=I						12.5						20.5	
SM-B=J		11.5				17.5					26.5	26.5	
SM-C=K						15.5						26.5	
WC-A=L	3.8				10.1					16.3			22.9
WC-B=M	4.3				12.9					20.5			27.5
WC-C=N	14.3				27.4					38.9			46.2
WC-D=O	30.7				49.1					57.1			64.6
WC-E=P	2.0				5.8					10.1			14.1
WC-F=Q	1.3				4.7					8.8			13.9

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Figure IV (Continued)—DM-Filter Leakage Values Reported in Four Recent Studies.

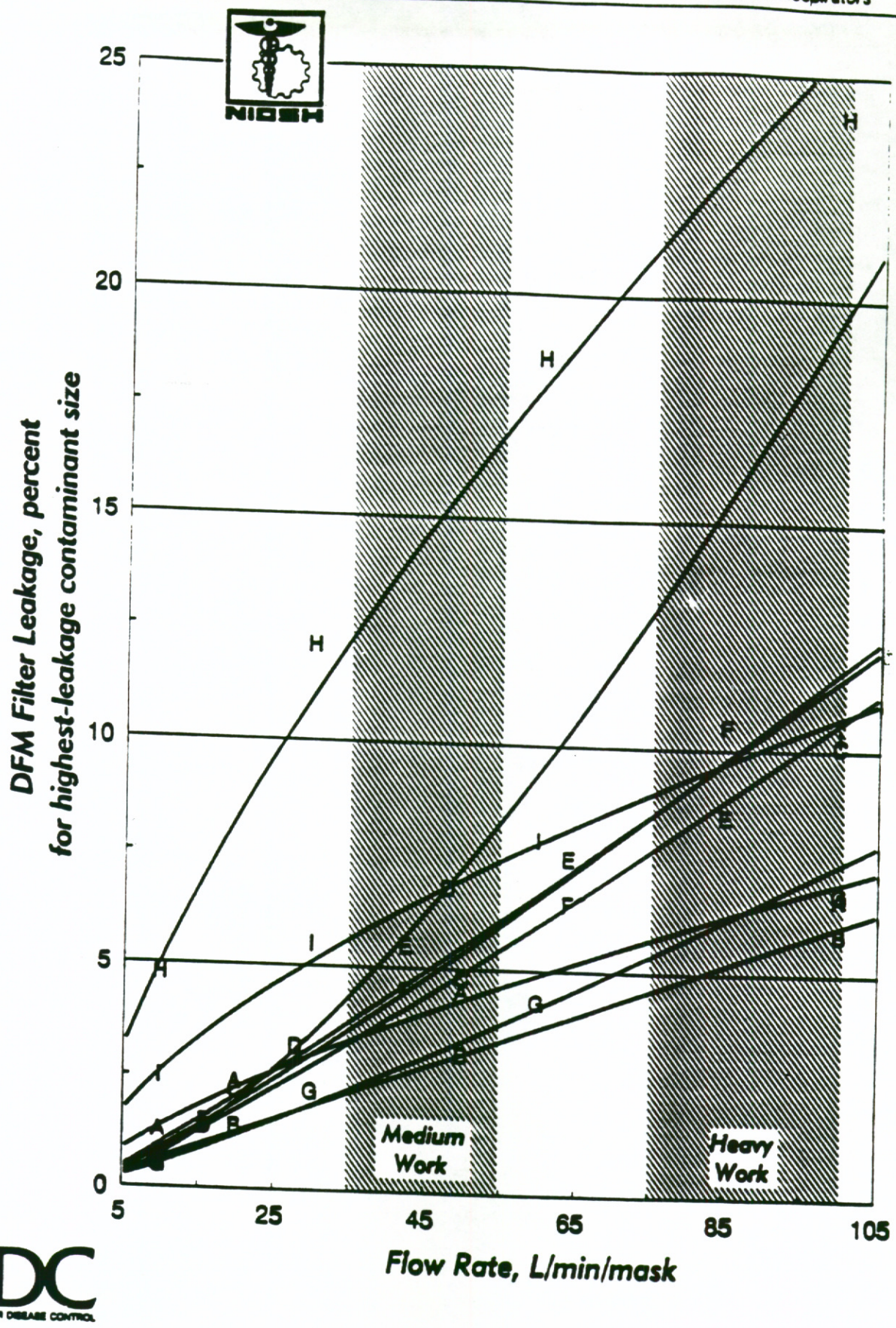

Figure V—DFM-Filter Leakage Values Reported in Four Recent Studies.

	10	16	20	28	30	42.5	48	50	60	64	85	100
HK-12=A	1.3		2.4					4.5				6.7
HK-13=B	0.6		1.4					3.1				5.9
HK-14=C	0.7		2.2					4.8				10.1
LF-T=D		1.4		3.2			6.8					
SM-A=E		1.5				5.5				7.5	8.5	
SM-C=F		1.5				4.5				6.5	10.5	
SM-D											12.5	
WC-A=G	0.5				2.2				4.3			6.8
WC-B=H	4.8				12.1				18.6			24.1
WC-C=I	2.5				5.5				7.9			10.3

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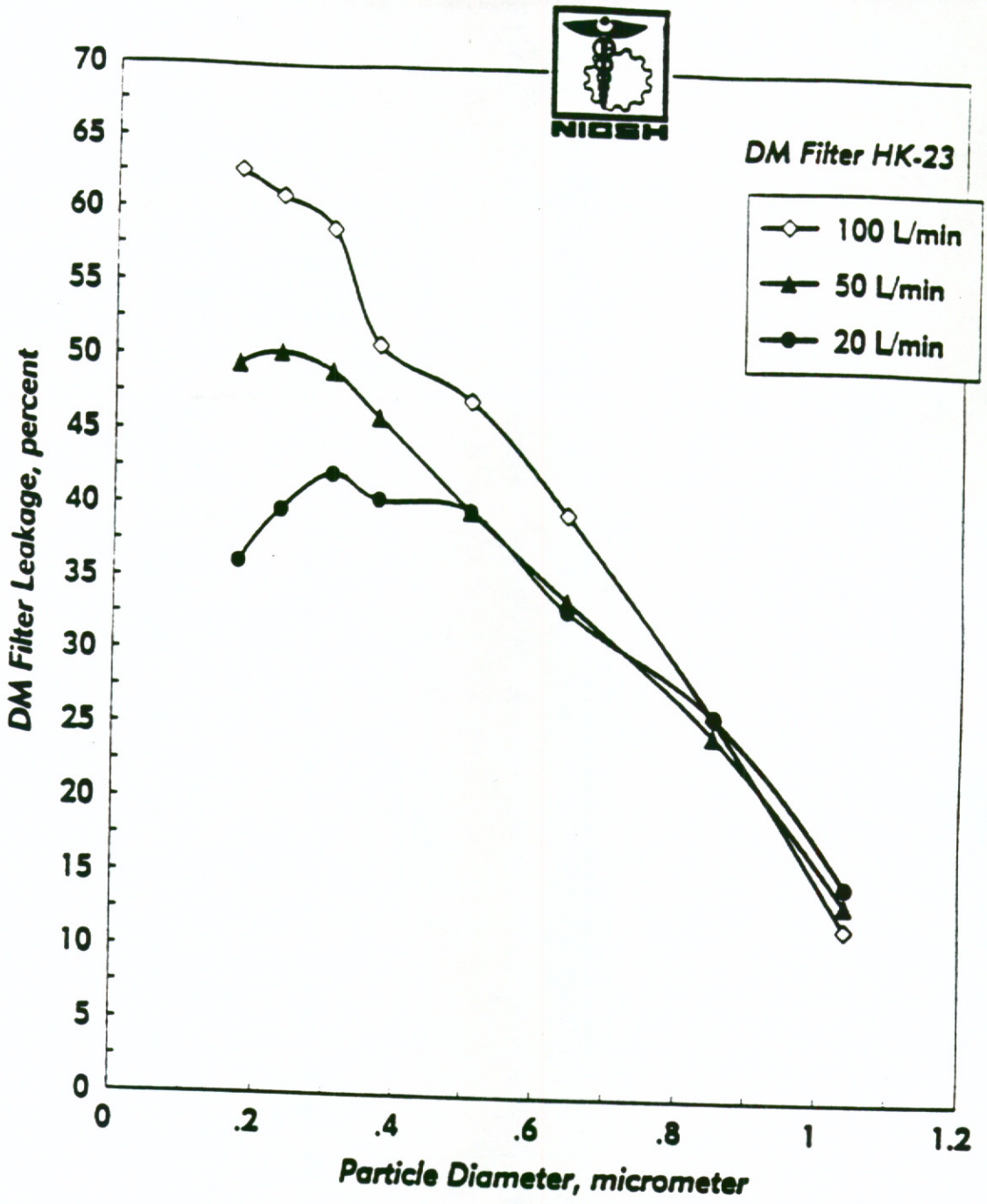
Figure V (Continued)—DFM-Filter Leakage Values Reported in Four Recent Studies.



	.173	.232	.305	.372	.506	.643	.849	1.04
100 L/min	62.7	60.9	58.7	51.0	47.4	39.8	28.1	11.9
50 L/min	49.5	50.3	49.1	46.1	39.9	33.9	24.9	13.8
20 L/min	36.1	39.7	42.2	40.5	39.9	33.2	26.2	14.8

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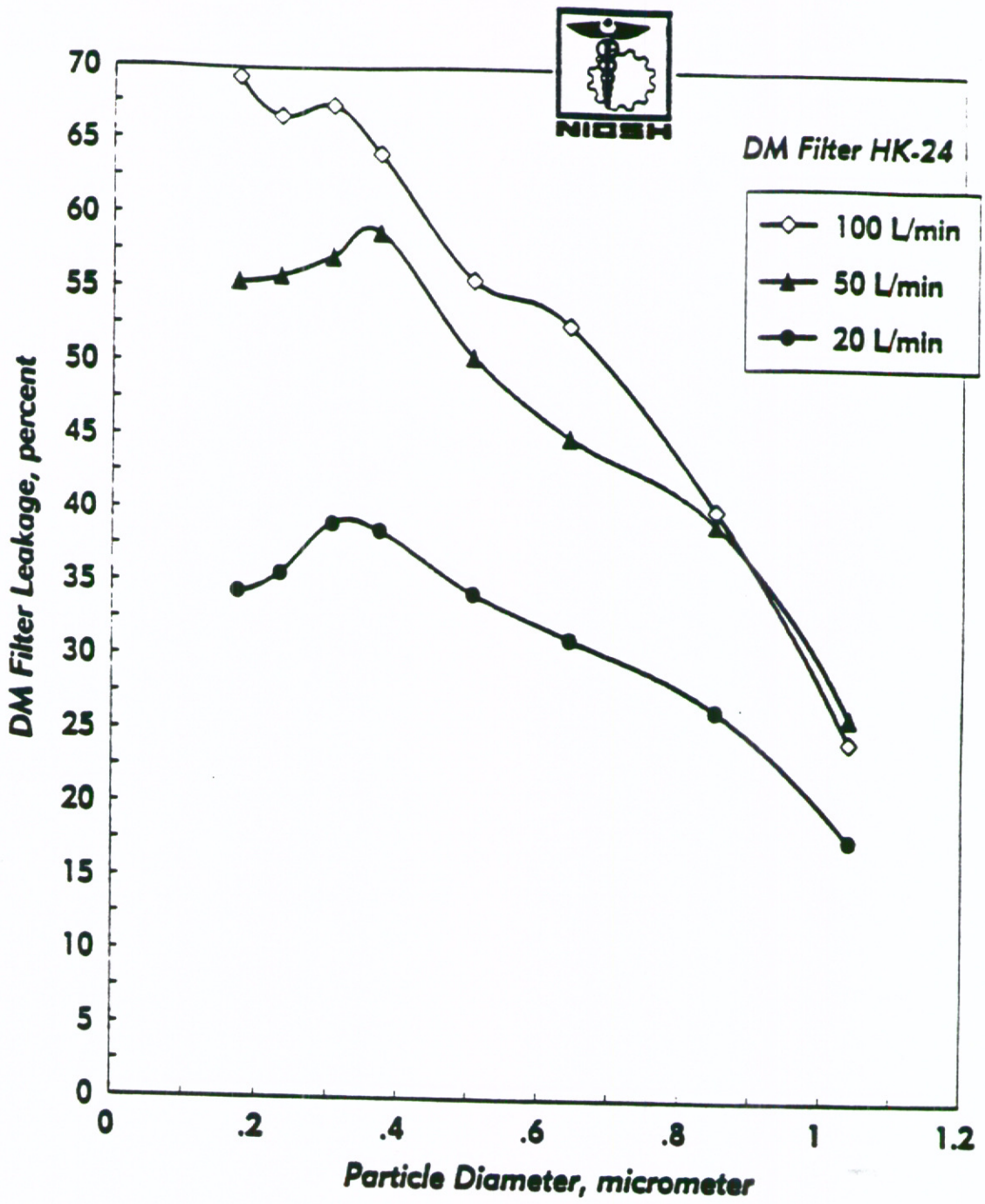
Figure VI—Effect of Particle Size on DM-Filter Leakage for DM filter *HK-23* Certified Under 30 CFR Part 11.



	.173	.232	.306	.372	.506	.643	.849	1.04
100 L/min	69.3	66.6	67.4	64.1	55.7	52.7	40.2	24.5
50 L/min	55.4	55.8	57.1	58.8	50.5	45.1	38.3	26.2
20 L/min	34.3	35.6	39.0	38.5	34.3	31.3	26.8	17.8

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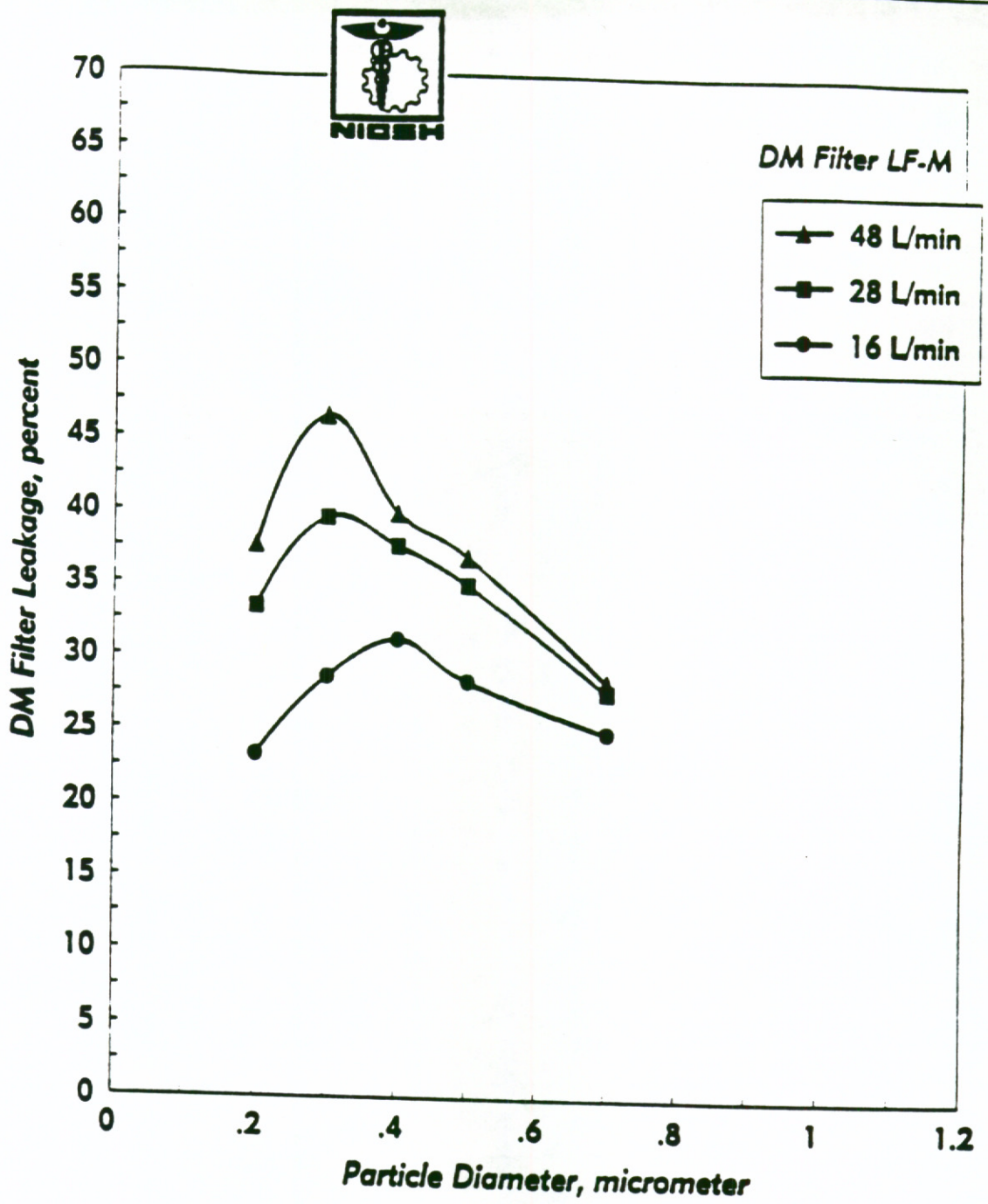
Figure VII—Effect of Particle Size on DM-Filter Leakage for DM filter *HK-24* Certified Under 30 CFR Part 11.



	.2	.3	.4	.5	.7
48 L/min	37.7	46.8	40.0	37.0	28.6
28 L/min	33.5	39.6	37.7	35.1	27.9
16 L/min	23.3	28.7	31.3	28.5	25.1

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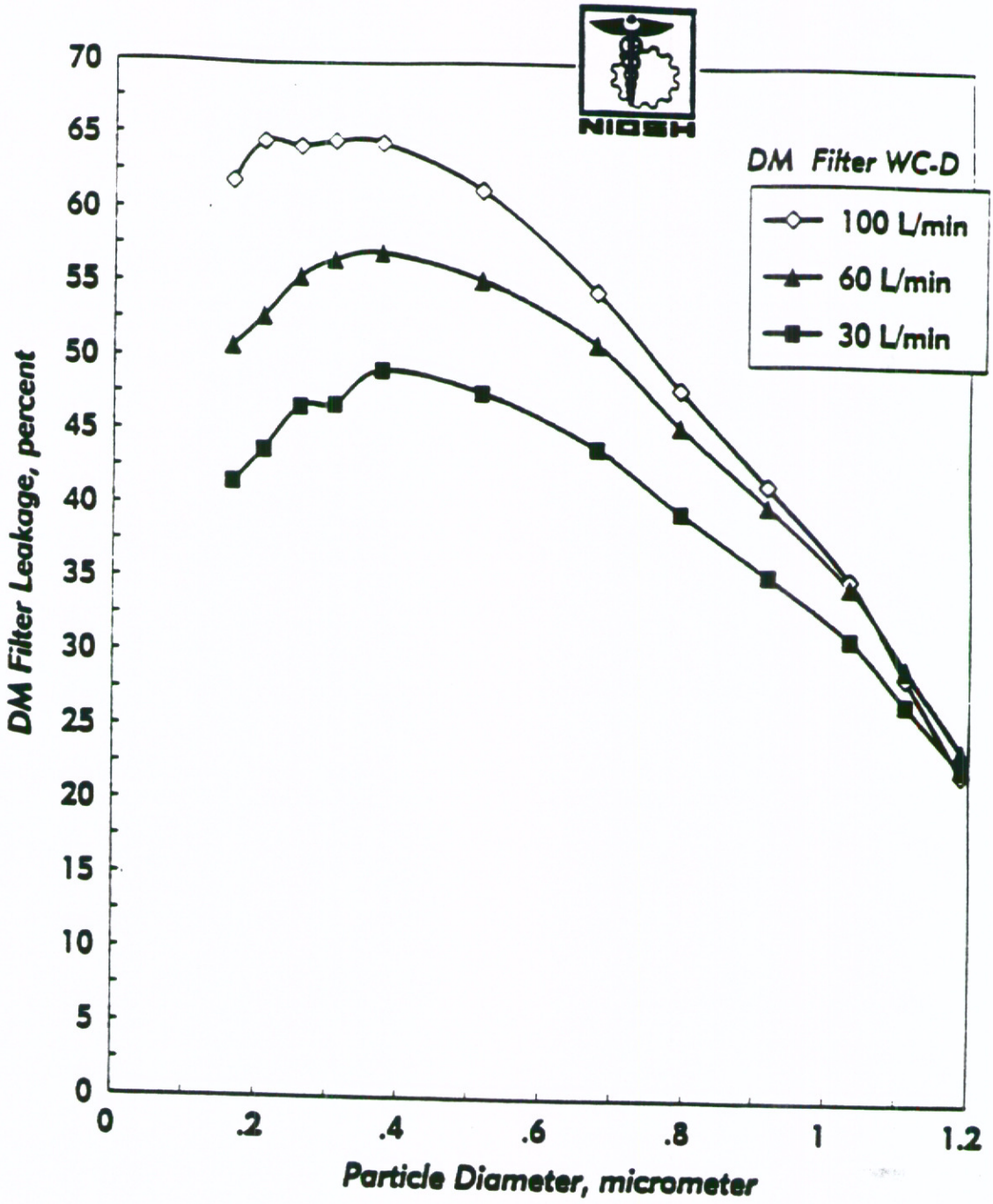
Figure VIII—Effect of Particle Size on DM-Filter Leakage for DM filter *LF–M* Certified Under 30 CFR Part 11.



	.166	.208	.259	.308	.374	.515	.676	.792	.915	1.03	1.11	1.19
100 L/min	61.8	64.5	64.2	64.6	64.5	61.4	54.7	48.2	41.7	35.3	28.8	22.3
60 L/min	50.7	52.7	55.4	56.6	57.1	55.4	51.2	45.7	40.3	34.8	29.4	23.9
30 L/min	41.5	43.7	46.6	46.8	49.2	47.8	44.1	39.8	35.5	31.3	27.0	22.7

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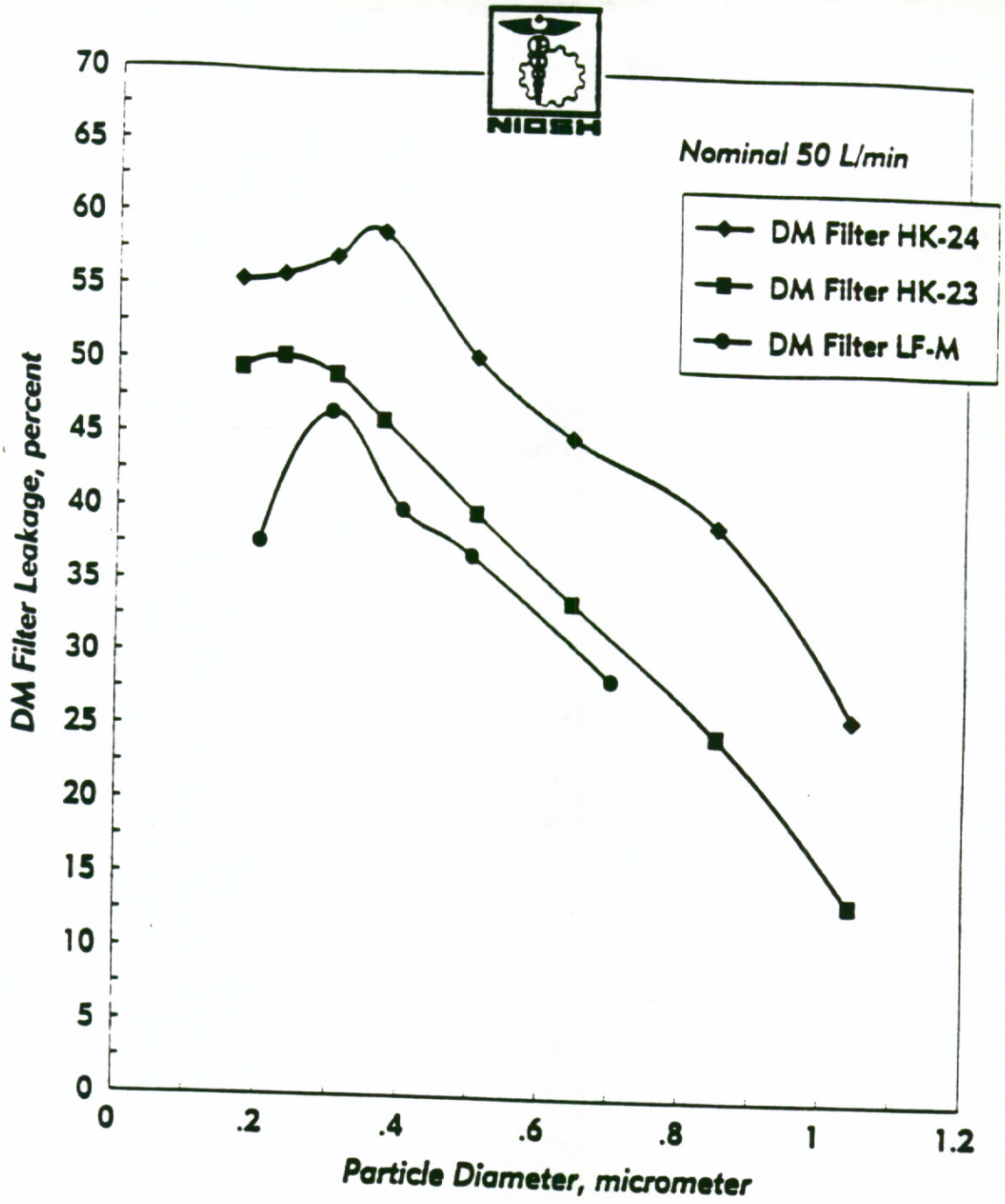
Figure IX—Effect of Particle Size on DM-Filter Leakage for DM filter *WC–D* Certified Under 30 CFR Part 11.



	.173	.2	.232	.3	.305	.372	.4	.5	.506	.643	.7	.849	1.04
DM Filter HK-24	55.4		55.8		57.1	58.8			50.5	45.1		39.3	28.2
DM Filter HK-23	49.5		50.3		49.1	46.1			39.9	33.9		24.9	13.8
DM Filter LF-M		37.7		46.8			40.0	37.0			28.8		

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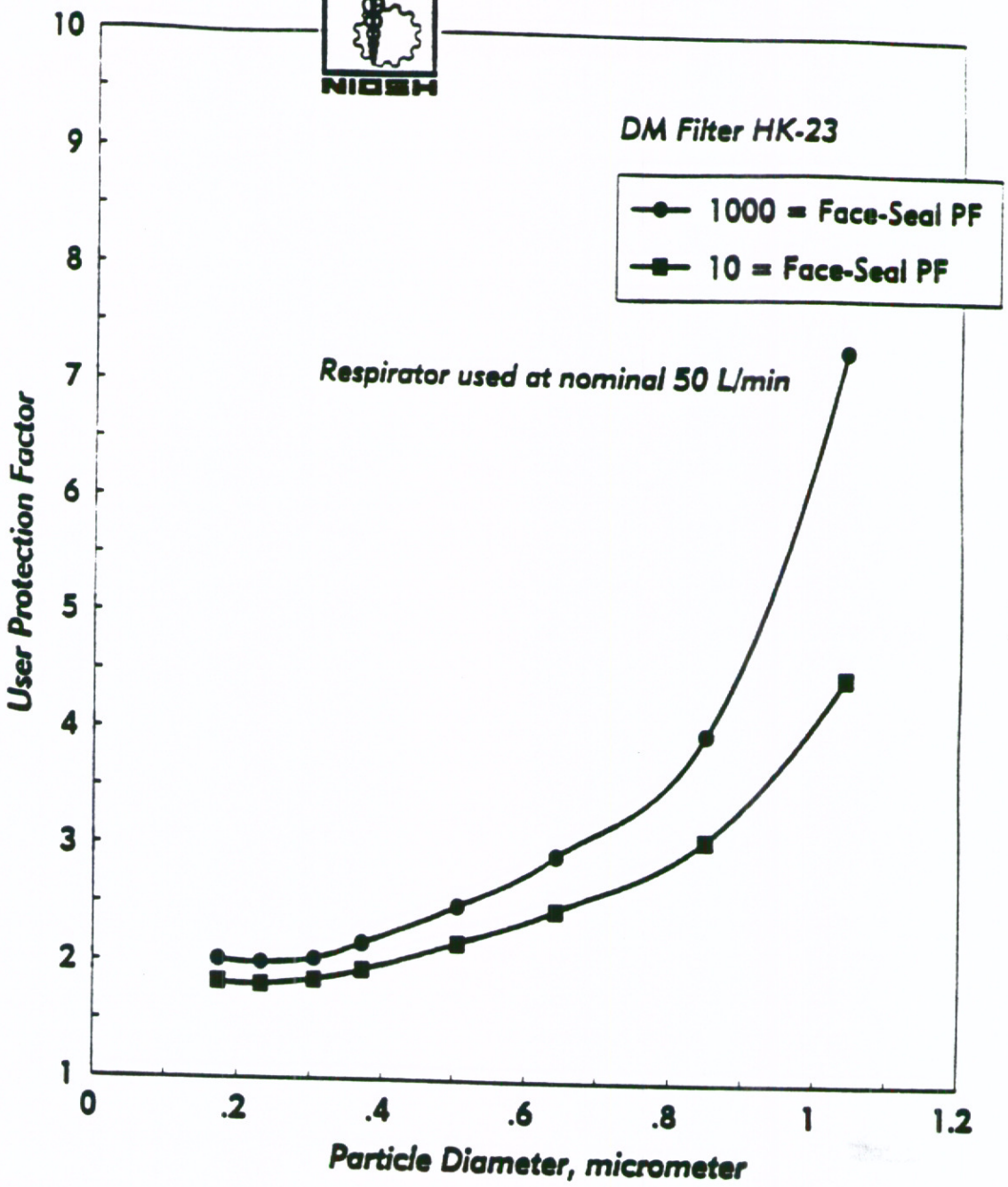
Figure X—Effect of Particle Size on DM-Filter Leakage at a Characteristic Breathing Rate of 50 L/min for Three DM Filters Certified Under 30 CFR Part 11.



	.173	.232	.305	.372	.506	.643	.849	1.04
1000 = Face-Seal PF	2.02	1.99	2.03	2.17	2.50	2.94	4.00	7.31
10 = Face-Seal PF	1.83	1.81	1.85	1.94	2.18	2.47	3.09	4.50

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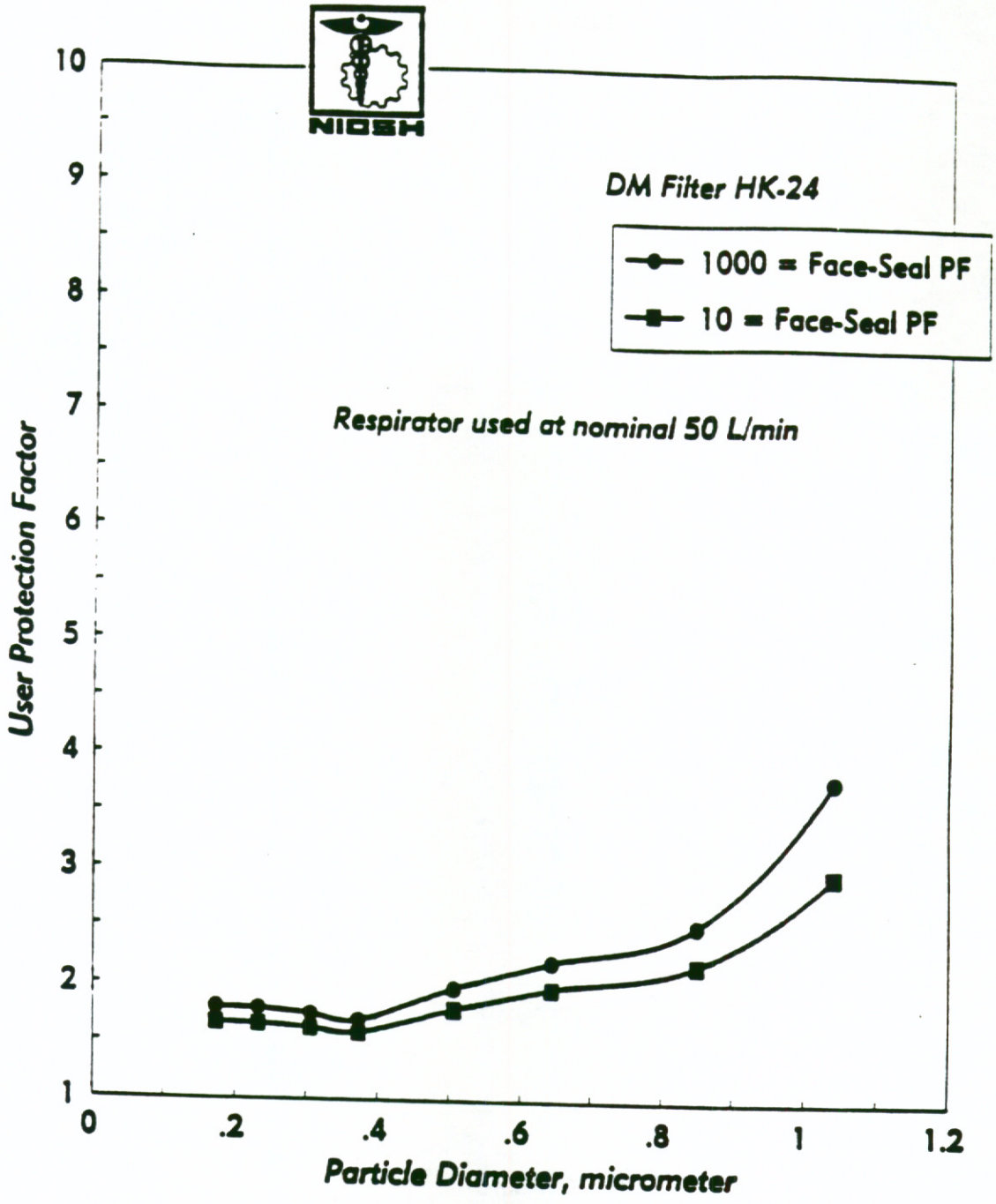
Figure XI—Effect of Particle Size and Face-Seal PF on User Protection Factors at a Characteristic 50 L/min for DM Filter *HK-23* Certified Under 30 CFR Part 11.



	.173	.232	.305	.372	.506	.643	.849	1.04
1000 = Face-Seal PF	1.80	1.79	1.75	1.70	1.96	2.21	2.54	3.81
10 = Face-Seal PF	1.57	1.56	1.53	1.59	1.80	1.96	2.20	2.96

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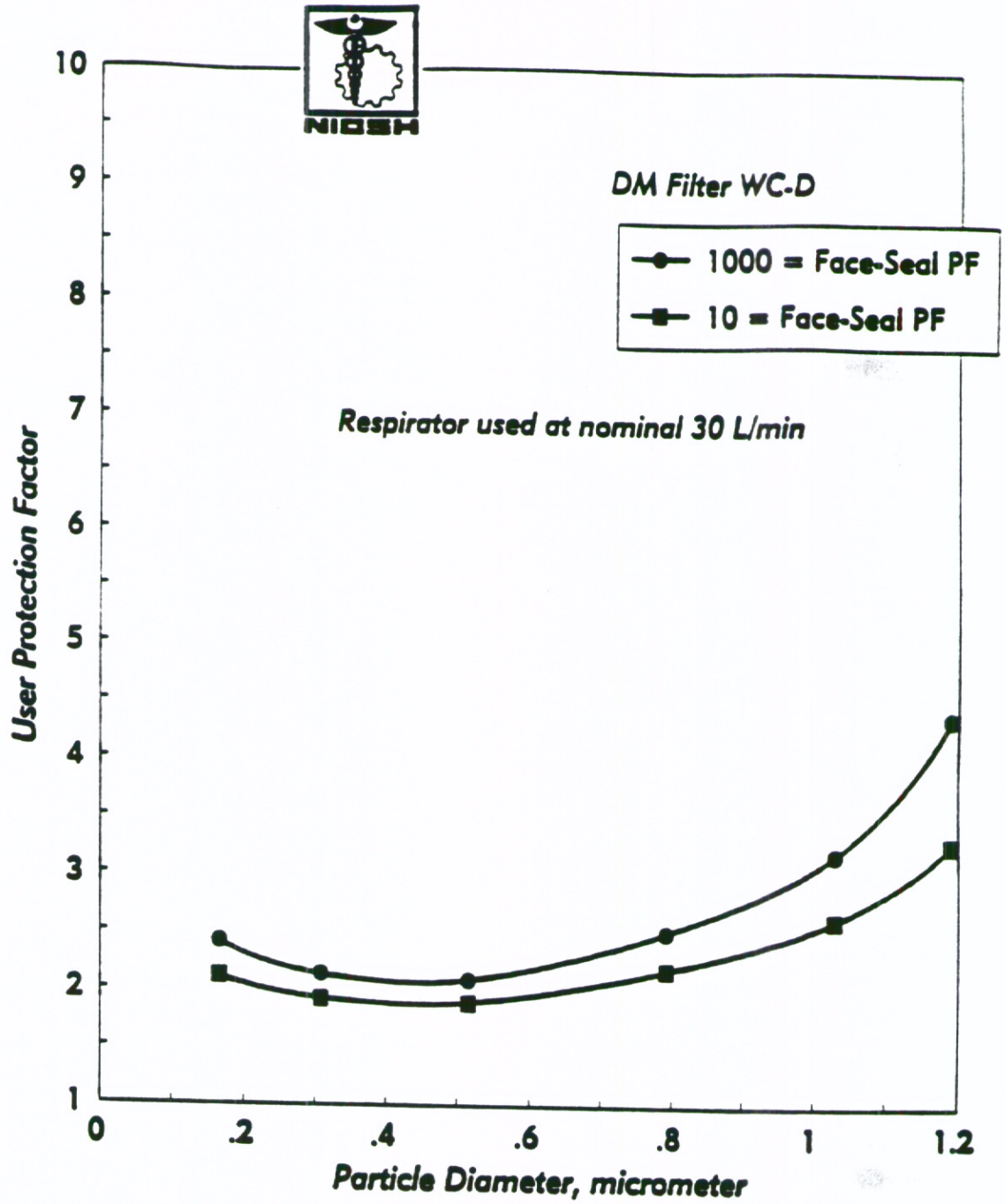
Figure XII—Effect of Particle Size and Face-Seal PF on User Protection Factors at a Characteristic 50 L/min for DM Filter *HK-24* Certified Under 30 CFR Part 11.



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	.165	.308	.515	.792	1.03	1.19
1000 = Face-Seal PF	2.41	2.13	2.09	2.51	3.19	4.37
10 = Face-Seal PF	2.11	1.92	1.89	2.18	2.**	3.28

Figure XIII—Effect of Particle Size and Face-Seal PF on User Protection Factors at a Characteristic 30 L/min for DM Filter *WC–D* Certified Under 30 CFR Part 11.

12—Evaluation of a possible hazard to respirator wearers due to leakage through DM and DFM filters.

As part of this performance evaluation, NIOSH conducted a thorough evaluation of the nature and extent of a possible hazard to filter-mask users due to contaminant leakage through DM and DFM filters certified by the Institute under 30 CFR Part 11. The NIOSH conclusions stated in this section are based on the best available evidence regarding leakage through DM and DFM filters as presented earlier in this evaluation.

As part of this evaluation, NIOSH addressed the following pertinent questions regarding DM- and DFM-filter leakage:

- What is the nature and extent of DM- and DFM-filter usage against toxic dusts, fumes, and mists?

- What do research results from four recent filter-leakage studies indicate with regard to whether DM- and DFM-filter leakage can present a hazard to respirator users?

- Do the hazardous contaminants that DM- and DFM-filters are used for protection against possess adequate warning properties to alert users if filter leakage occurs?

- Are the contaminant sizes that leak through DM- and DFM-filters more or less toxicologically potent than other respirable particle sizes?

- Does informative technical material produced by respirator manufacturers for purchasers and users address the issue of possible contaminant leakage through DM and DFM filters? Such material would include, but is not limited to, advertising, selection guides, respiratory protection catalogs, and respirator-user instructions.

- Do the approval-limitation and cautionary statements on respirator approval labels[255] required of respirator manufacturers address the issue of possible contaminant leakage through DM and DFM filters?

- Is information readily available to respirator purchasers and users regarding the sizes of contaminants present in workplaces where respirators are used?

- *What is the nature and extent of DM- and DFM-filter usage against toxic dusts, fumes, and mists?*

NIOSH-certified DM and DFM filters are produced and sold for protection against over 200 toxic dusts and mists regulated by OSHA.[256,257] Based on estimates provided to the Office of Management and Budget in the Institute's *Preliminary Regulatory Impact Analysis*, NIOSH estimates that several million workers depend on these filters for protection against toxic contaminants in their workplaces.[258] DM and DFM filters are NIOSH-approved for use against contaminants of such high toxicity that OSHA limits worker inhalation exposures to levels as low as 50 millionths of a gram per cubic meter (i.e., 50 billionths of an ounce per cubic foot).[259] DM filters are sold under 120+ different NIOSH certification numbers and DFM filters are sold under 50+ NIOSH certification numbers.[260]

- *Regarding the filter-leakage results reported in four recent filter-leakage studies, how representative are these results of the range of leakage values occurring in the populations of all 120+ NIOSH-certified DM filters and 50+ NIOSH-certified DFM filters?*

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[255]30 CFR 11.33

[256]Occupational Safety and Health Administration: Air Contaminants; Final Rule, 29 CFR Part 1910, *Federal Register* 54(12):2332–2983 (January 19, 1989), Table Z–1–A, pp. 2923–2958.

[257]3M Company: *1991 Respirator Selection Guide*, St. Paul, MN (1991), pp. 6–41.

[258]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).

[259]30 CFR 11.130

[260]National Institute for Occupational Safety and Health: *NIOSH Certified Equipment List as of December 31, 1990*, DHHS (NIOSH) Publication #91–105, Cincinnati, OH (January 1991), pp. D–1 through D–26.

Filter-leakage results from four recent research studies were presented in the previous section of this evaluation discussion (Figures IV through XIII and XVI and XVII). Numerous cases of excessive and unexpectedly high filter leakage were reported (e.g., for heavy work rates, up to 74% leakage through DM filters and up to 24% leakage through DFM filters).

There are four major reasons why the high-leakage data sets in Figures IV and V of this evaluation probably *underestimate* the highest hazardous leakages that can occur with NIOSH-certified DM and DFM filters available to purchasers and users *at any given volumetric flow rate*. Correspondingly, Figures IV and V probably *overestimate* the lowest leakages in each filter class that some manufacturers have been able to achieve for NIOSH-certified filters. That is, these figures do not contain the *highest* and *lowest* filter-leakage curves for DM and DFM respirators worn by American workers.

First, the data presented in Figures IV and V are not based on a representative sample of all DM and DFM filters certified under 30 CFR Part 11. The tested filter masks and cartridges represent only a few models from a few major respirator manufacturers.

Second, the high-leakage filter group presented in Figure IV, which represent some of the data reported by three research teams, were for DM filters obtained from a very limited subset of only four tested filters. For DFM filters, Hinds and Kraske along with Willeke and Chen reported results from only three manufacturers. Liu and Fardi reported DFM results from only one major manufacturer. Additionally, applicable results for only two DFM manufacturers were available from Stevens and Moyer. It was not the objective of any of the four research teams to test or identify the *highest- or lowest-leakage* DM or DFM filters certified by NIOSH. Thus, untested lower- and more hazardous higher-leakage filters from other manufacturers might easily have been excluded from these four studies. For example, if one were to evaluate only the DM-filter results from Stevens and Moyer, then the two substantially higher-leakage DM-filter models from the other three research groups would be overlooked.

Third, generally a very small sample of filters (e.g., five or less) was tested at each test-aerosol diameter. This small a sample results in large sampling errors in estimates of population means, that is, large uncertainties in the sample means reported for L_{filter} at each aerosol size.

Fourth, in the case of Stevens and Moyer, the investigators stated that "whenever possible, all filters tested were from the same lot to eliminate lot-to-lot variability."[261] Hinds and Kraske observed a wide range of L_{filter} values between their several filter makes and a similarly wide range of L_{filter} values observed from three different filter lots from the same manufacturer. They stated:

> Filter performance was found to vary significantly between types and between brands within a type. Based on three different filter brands the relative standard deviation for penetration measurements [L_{filter}] is 65% for dust, fume, and mist half-mask cartridges pairs (MSA, AO, and North) and 77% for single use respirators (3M 8710, American Optical R1070, and Gerson 1710). Three lots of MSA Type S filters (dust, fume, and mist cartridge pairs) had a relative standard deviation for penetration measurements of 57%. Note, that this relative standard deviation is of comparable magnitude to that for different brands of the same type.[262]

Thus the variability in filter-leakage results shown in Figures IV and V at any given volumetric flow rate is due to variability contributed by one or more of the following variabilities: between individual filters, between filter lots, between filter makes and models, between measurements conducted at a single laboratory, and between measurements conducted at different laboratories. The first three types of variability are actual differences in what is being measured (filter leakage), while the last two variabilities are differences in leakage-measurement equipment and techniques. Note that Figures IV and V *do not* display *confidence intervals* (i.e., probable range of values) for the *true leakages*, only *point estimates* are plotted.

NIOSH concludes that if the four research teams had been able to test NIOSH-certified filters from a wider range of manufacturers, sample from multiple lots of each make and model filter, and sample more filters from each lot, then it is highly probable that they would have observed L_{filter} values both lower and higher than those presented in Figures IV and V of this evaluation. Thus it is probable that the leakage values reported from the four recent studies *are not representative* of the best and worst filters in the populations of 120+ DM and 50+ DFM NIOSH-certified filters available in the United States.

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[261]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), p. 258.

[262]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental, *Am. Ind. Hyg. Assoc. J.*, 48(10): 836–841 (1987), p. 840.

- *What is the effect on DM- and DFM-filter leakage when the filters are used against contaminant sizes larger than the highest-leakage-size ("worst-case") contaminants (e.g., used against sizes of 0.25 to over 1.0 μm diameter)?*

For the four high-leakage DM-filter sets shown in Figure IV, Figures VI, VII, VIII, and IX indicate that all four tested filters exhibited *broad-band leakage* characteristics for volumetric breathing rates of 20 to 100 L/min (i.e., light to heavy work rates). That is, leakage through these filters remained high even for contaminant sizes exceeding 1.0 μm diameter (e.g., leakage of particles with aerodynamic mean sizes up to 2.5 μm has been reported through one type of NIOSH-certified DM filter[263]). Figure X summarizes the filter-leakage functions for three DM filters LF–M,[264] HK–23,[265] and HK–24[266] at a medium work rate (i.e., a characteristic breathing rate of 50 L/min). Two of these three DM filters exhibited 15% to almost 30% leakage at particle sizes just over 1.0 μm diameter.

Lastly, Figures XI through XIII illustrate the debilitating effect of DM-filter leakage on a user's protection factor PF_{user} as a function of *contaminant size* and *face-seal PF* values of 10 and 1,000 for DM filters HK–23 (Figure XI) and HK–24 (Figure XII) at a *medium-work breathing rate* (50 L/min characteristic volumetric flow rate) and WC-D (Figure XIII) at a *light-medium-work breathing rate* (30 L/min). The PF_{user} values for Figures XI, XII, and XIII were computed with equation (16) in this evaluation.[267]

It is important to note that regardless of how well a respirator user's face seal might be fitted, Figures XI, XII, and XIII demonstrate that a user's protection factors can remain very low at contaminant sizes up to and exceeding 1.0 μm diameter for at least three NIOSH-certified DM-filter masks.

NIOSH concludes that significant leakage through DM filters and the resulting unexpectedly low user protection factors are not limited to a narrow range of small,

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[263]Iverson, S. G., S. G. Danisch, H. E. Mullins, and S. K. Rudolph: Validation of a Quantitative Fit Test for Dust/Fume/Mist Respirators: Part I, *Appl. Occup. Environ. Hyg.* 7(3):161–167 (1992), p. 163.

[264]Liu, B. Y. H. and B. Fardi: *A Fundamental Study of Respiratory Air Filtration*, Final Report for NIOSH Grant # R01 OH01485–01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota (September 1988), Table 6–5, p. 271.

[265]Hinds, W. C.: Letter to Mr. Larry W. Sparks of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01595, Los Angeles, CA (June 19, 1991).

[266]Ibid.

[267]Under discussion under *Derivation and Evaluation of Two Leakage-Function Models for Describing a User's Protection Factor While Wearing a DM- or DFM-filter Mask.*

"worst-case" contaminant sizes. This conclusion is based on Figures VI through XIII in this evaluation. These eight figures indicate that significant leakage does occur through NIOSH-certified DM filters when they are used against contaminant sizes ranging from less than 0.2 μm to at least 1.0 μm in diameter.

- *What is the effect on DM- and DFM-filter leakage when these filters are used at medium work rates (i.e., user's breathing rate in the range 35 to 55 L/min) and heavy work rates (75 to 100 L/min).*

The effect of respirator usage at medium and heavy work rates upon filter leakage is shown in Figures IV through IX of this evaluation. NIOSH concludes that significant leakage through these filters is not limited to only medium and heavy work rates. This conclusion is based on Figures VI through IX for DM filters. NIOSH also concludes that significant leakage occurs through some NIOSH-certified DM filters even at very light work rates (in effect, sedentary usage) with volumetric flow rates as low as 5 L/min into a respirator. NIOSH concludes that the *existence* of a DM-filter-leakage hazard to a user is unrelated to the user's breathing rate over a wide range of very light to heavy work rates. However, the *magnitude* of the filter-leakage hazard generally becomes larger at higher work rates.

- *If a respirator user's DM or DFM filter exhibits significant leakage, can the adverse effect on overall mask protection be offset by a better-fitting face seal? That is, what are the interactive effects of significant filter leakage and face-seal efficacy on overall mask protection levels?*

Figures XI, XII, and XIII indicate that for users with face-seal PFs between 10 (10% face-seal leakage) and 1,000 (0.1% face-seal leakage) and filter leakages over 10%, those users will have *user PFs* substantially less than the minimum PF of 10 expected for non-powered, air-purifying halfmasks. For filter leakages above about 10%, Figure III demonstrates that user PFs remain relatively low even for face-seal PFs over 1,000 (i.e., less than 0.1% face-seal leakage). For example, for a DM filter with 20% leakage, a user's PF would go from about 3.5 at a face-seal PF of 10 to a maximum of about 5 for face-seal PFs over 1,000. This user-PF range is not substantially higher than the APF of 2 recommended for NIOSH for a non-powered halfmask with a DM filter. Another example would be a DFM filter with 5% leakage. A user's PF would go from about 7 for a face-seal PF of 10 to a maximum of about 20 for face-seal PFs over 1,000.

NIOSH concludes that for filters with leakages over 10%, negligible additional

protection is given to a respirator user by obtaining a well-fitting face seal (e.g., increasing a face-seal PF from 10 to 1,000). This conclusion is based on Figures III, XI, XII, and XIII. That is, the adverse effects of significant filter leakage on overall protection provided by a respirator to a wearer cannot be mitigated through measures such as comprehensive user training and superior fit testing (whether it be quantitative or qualitative).

- *What is the effect on filter leakage due to the use of new filters or those with relatively little contaminant loading?*

As discussed previously in this evaluation, the effect on hazardous filter leakage due to use with moderate to substantial loading (accumulated contaminant) can be to either increase or decrease the filter leakage, depending on the filter media used by the manufacturer.

- *Do the hazardous contaminants that DM- and DFM-filters are used for protection against possess adequate warning properties to alert users if filter leakage occurs?*

Most hazardous airborne contaminants that are dusts, fumes, or mists do not have *adequate warning properties*[268] to warn respirator users of any hazardous contaminant leakage that may infiltrate into their respirators. NIOSH concludes that DM- and DFM-filter mask users can be unknowingly exposed to hazardous contaminants leaking through their filters because they generally have no warning properties.

- *Are the contaminant sizes that leak through DM- and DFM-filters more or less toxicologically potent than other respirable particle sizes?*

There have been several statements in the professional literature noting that contaminant sizes known by manufacturers and respirator experts to leak through DM and DFM filters (e.g., 0.05 to 0.5 μm diameter) can be especially hazardous from a toxicological standpoint. That is, these particle sizes might be readily absorbed by a worker's body and therefore be more toxic compared to other particle sizes. Amdur stated in 1973:

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[268]Physiological effects in humans (e.g., odor, taste, eye irritation, respiratory-tract irritation) that have been demonstrated as being capable of consistently providing respirator wearers with timely, consistent, persistent, and reliable warning of hazardous airborne concentrations inside a respirator so that users can take necessary action to protect themselves (e.g., leaving the area where respirators are required, changing the filter element).

In the limited space available only one point will be emphasized here, namely, the toxicological importance of particles below 1 μm in size. Aerosols in the range 0.2–0.4 μm tend to be fairly stable in the atmosphere because they are too small to be effectively removed by forces of settling or impaction and too big to be effectively removed by diffusion. Since these are the forces that lead to deposition in the respiratory tract, it has been predicted theoretically and confirmed experimentally that a lesser *percentage* of these particles is deposited in the respiratory tract. On the other hand, since they are stable in the atmosphere, there are large numbers of them present to be inhaled, and to dismiss this size range as of minimal importance is an error in toxicological thinking which should be corrected whenever it is encountered.[269]

In the early 1980s respirator experts on the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee sent the following comments to NIOSH. These experts included several representatives from major respirator manufacturers.

Literature indicates that the most difficult size particle or (sic) any filter to remove lies within the size range of .1 – .3 microns [micrometers, μm]. While these particles are the most difficult to filter they are also the size that is most difficult for the respirator systems to retain. However, because of their physiological effect, this size particle is considered to be the most hazardous per unit of mass. The systemically toxic particles of this size are most easily absorbed into the body because of the large surface area per unit mass. Lung damaging particles of this size are considered more hazardous per unit mass because their great numbers affect a greater area of the lung.[270]

Lastly, in 1987 based on the work of Froines, et al.,[271] Hinds and Kraske made this comment on the disproportional adverse effects on respirator users than can result from smaller-size particle leakage:

For example, even though the mass concentration of lead aerosol is reduced by a factor of 20 by a respirator, if the particle-size distribution inside is smaller than outside, the fraction of inhaled aerosol absorbed into the blood may be as much as four times that for the larger outside distribution yielding performance equivalent to a protection factor as low as 5.[272]

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[269]Amdur, M. O.: *Industrial Toxicology*. Chapter 7 of *The Industrial Environment—Its Evaluation and Control*, National Institute for Occupational Safety and Health, Cincinnati, OH, (1973), pp. 69–70.

[270]Wilmes, D.: Recommendations to NIOSH for Revision of 30 CFR Part 11, memorandum from chairman of the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee for Respiratory Protection, St. Paul, MN (undated, ca. early 1980s), p. 3.

[271]Froines, J. R., et al.: Effect of Aerosol Size on the Blood Lead Distribution of Industrial Workers. *Am. J. Ind. Med.* 9:227 (1986).

[272]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental. *Am. Ind. Hyg. Assoc. J.* 48(10):836–841 (1987).

NIOSH concludes that smaller contaminant sizes can be more toxicologically potent than indicated by their proportional mass contribution to inhaled doses received by respirator wearers via filter leakage. Unfortunately for respirator wearers, the inhalation of smaller contaminant sizes by filter-mask wearers is expected to occur with the type of significant leakage known to occur through DM and DFM filters. The same effect occurs with leakage past a respirator's face seal.[273,274]

- *Does informative technical material produced by respirator manufacturers for purchasers and users address the issue of possible contaminant leakage through DM and DFM filters?*

Respirator manufacturers have not routinely informed respirator purchasers and users of the potential for significant leakage through NIOSH-certified DM and DFM filters of hazardous particles with aerodynamic diameters up to 2.5 μm. That is, respirator advertising, selection guides, product catalogs, and respirator-user instructions for DM- and DFM-filter masks do not inform purchasers and users of the potential for significant filter leakage that can compromise the safety and efficacy of these masks. NIOSH concludes that filter-mask purchasers and users have not been provided with appropriate instructions to permit the safe and effective use of these respirators against all sizes of hazardous contaminants.

- *Do the approval-limitation and cautionary statements on respirator approval labels required of respirator manufacturers address the issue of possible contaminant leakage through DM and DFM filters?*

There is no contaminant-size-qualifying language given on the labels for NIOSH-certified DM- and DFM-filters. These labels typically contain language to the effect:

Approved for respiratory protection against dusts, fumes, and mists having a time-weighted average less than 0.05 milligram per cubic meter.

The certification regulation defines *dusts, fumes, and mists* as:

Dust means a solid mechanically produced particle with a size ranging from submicroscopic to macroscopic. Fume means a solid condensation particle, generally less than 1 micrometer [μm]

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[273]Ibid.

[274]Holton, P. M. and K. Willeke: The Effect of Aerosol Size Distribution and Measurement Method on Respirator Fit, *Am. Ind. Hyg. Assoc. J.* 48(10): 855–860 (1987).

in diameter. Mist means a liquid condensation particle with a size ranging from submicroscopic to macroscopic.[275]

NIOSH concludes that the labels for NIOSH-certified DM- and DFM-filters create an erroneous perception for purchasers and users that these filters will protect against *all sizes* of dusts, fumes, and mists. The clearly implied, but apparently incorrect message to a purchaser or user of NIOSH-certified filters is that they will protect a user from *any size* dry dust or wet mist and *any size* fume generally below 1 μm diameter.

- *Is information readily available to respirator purchasers and users regarding the sizes of contaminants present in workplaces where respirators are used?*

If workplace contaminant-size information were available to the several million users who wear NIOSH-certified DM- and DFM-filter masks, then purchasers and users would be able to make informed decisions as to when to avoid the use of DM or DFM filters. However, determination of airborne-contaminant particle sizes appears to be far from a routine procedure in workplaces where employers provide respirators to workers. As previously noted in this evaluation, an OSHA contractor reported that over 70% of 123,000 manufacturing plants *performed no exposure-level monitoring* when selecting respirators to use in the plants[276] (in spite of OSHA regulatory requirements to do so[277]). More importantly, the sophisticated technical expertise and equipment necessary to measure contaminant size distributions in the workplace and interpret the results are not generally available to employers or users. Currently, airborne-contaminant sizing methods are primarily used only in workplace research studies.

Additionally, just as with workplace-concentration levels, particle-size distributions of airborne contaminants can vary substantially between workplaces and from day to

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[275]30 CFR 11.3(k, p, and y respectively).

[276]Centaur Associates, Inc.: *Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards, Volume II*, contract report prepared for the U. S. Department of Labor, Occupational Safety and Health Administration under Contract No. J–9–F–20067, Washington, D.C. (March 30, 1984), Section 5, The Costs of Compliance.

[277]29 CFR 1910.134(b)(8)

day in the same workplace.[278,279,280] This would substantially increase the burden of contaminant-size monitoring for employers if they elected to perform it.

NIOSH concludes that contaminant-size information for workplace exposures is not readily available to filter purchasers and users to enable them to make informed decisions as to when to avoid the use of DM or DFM filters. NIOSH also concludes that it is highly doubtful that employers would choose to do additional contaminant-size monitoring because few of them currently do the OSHA-required exposure-level monitoring.

In summary, after conducting the evaluation discussed in this section of the evaluation and based on the best available evidence, NIOSH concludes that contaminant leakage through some widely-used DM and DFM filters currently certified by the Institute can create a hazard for respirator users. Additionally, because of their widespread usage against several hundred toxic contaminants, the excessive leakage exhibited by some DM and DFM filters is a significant public health hazard.

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[278]Herrick, P.F., M. J. Ellenbecker, and T. J. Smith: Measurement of the Epoxy Content of Paint Spray Aerosol: Three Case Studies, *Appl. Ind. Hyg.*, 3(4):123–128 (1988).

[279]McCammon, Jr., C. S., C. Robinson, R. J. Worweiller, and R. Roscoe: Industrial Hygiene Characterization of Automotive Wood Model Shops, *Am. Ind. Hyg. Assoc. J.* 46(7):343–349 (1985).

[280]NIOSH: *Health Hazard Evaluation Report, HETA 84–115–1493*, Cincinnati, Ohio (July 1984).

13—NIOSH's control strategy for lower APFs for DM- and DFM-filter masks to reduce inhalation hazards to respirator users.

The remainder of this evaluation concerns the *control strategy* that NIOSH is considering to protect filter-mask users from hazardous filter leakage. NIOSH has concluded that APFs for currently-certified DM- and DFM-filter masks must reflect protection levels that respirator wearers will receive against *all* contaminant sizes.

Since the early 1970s, APFs previously recommended and utilized by organizations such as the LASL, NIOSH, OSHA, ANSI, American Industrial Hygiene Association (AIHA),[281] and private employers[282] must have relied on two critical assumptions. First, it must have been assumed that hazardous filter leakage never occurs through any NIOSH-certified filter during use. Second, it must have been assumed that DM- and DFM-filter masks are never used against a workplace contaminant that is at or near the highest-leakage size. However, substantiating data has not been given for these two critical assumptions. Absent substantiation for these assumptions, the Institute has concluded that it must assume:

- that NIOSH-certified DM- and DFM-filter masks will be used without knowledge of contaminant sizes and

- that mask usage will occur under higher filter-leakage conditions.

Thus, NIOSH determined that it must use known leakage values for DM and DFM filters obtained at higher-leakage contaminant sizes to calculate recommended APFs for these filter-mask respirators. NIOSH recognizes that many DM- and DFM-filter masks may be used against contaminant sizes, at inhalation volumetric flow rates, and at filter loadings for which these filters provide adequate protection. However, the Institute's control strategy is totally consistent with accepted standards of professional practice used for over 20 years by respirator experts to determine respirator-class APFs.

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[281]Birkner, L. R.: *Respiratory Protection: A Manual and Guideline*, American Industrial Hygiene Association, Akron, Ohio (1980).

[282]Birkner, L. R.: *Celanese Corporation Respiratory Protection Manual and Guideline*, Celanese Corporation, New York, N.Y. (August 1978), Section 61, pp. 3–4.

As previously noted in this evaluation, respirator-class APFs have always been governed by those makes and models of respirator facepieces with the higher face-seal leakage in each class (i.e., poorer performance).

Therefore, NIOSH maintains that it is not the average or typical filter leakage that must also govern APF determinations. Instead, it is the higher filter-leakages that can be reasonably expected to occur through each type of NIOSH-certified DM and DFM filter that must govern filter-mask APFs. This strategy is founded on the rationale that virtually no purchasers nor users know whether their particular combination of non-HEPA filter and contaminant size will result in hazardous, average, or superior protection. Thus in the absence of specific and reliable information as to which filters will or will not exhibit inadequate protection, prudent purchasers and users must assume that *any* NIOSH-certified filter they purchase or use may provide the least expected protection (e.g., the APFs recommended in Table P).

Because the nature and technology of industrial respirator filters prevents purchasers and users from assessing filter safety and protection under widely varying use conditions, NIOSH concluded that its assumptions for computing filter-mask APFs are necessary to protect the health and safety of all users.

As discussed earlier in this evaluation, respirators are not selected and used with prior knowledge of the contaminant size distribution existing in a given workplace.[283] Thus purchasers and users have essentially no way to protect against unknowingly using a NIOSH-certified DM or DFM filter against a contaminant with a size equal or near the high-leakage-size aerosol (e.g., 0.05 to 2.0 μm count median diameter). For example, as was discussed earlier in this evaluation, four NIOSH-certified DM filters have shown to have hazardous leakage through the filter element as high as 74% at heavy work rates.[284] This amount of gross leakage would yield an individual protection factor (PF) for a user of *under 1.5* for a halfmask or fullface mask *even if the face-seal fit was perfect.* A PF under 1.5 is strikingly lower than an APF of 10 for a filter halfmask or an APF of 50 for a fullface respirator, which are accepted values for professional practice.

To compute the APFs recommended in Table P for DM- and DFM- filter respirators certified under 30 CFR Part 11, NIOSH concluded that it must consider hazardous leakage through DM and DFM filters at small contaminant sizes. That is, NIOSH used known leakage values for higher-leakage contaminant sizes to calculate the recommended APFs for filter-mask respirators.

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[283]Refer to discussion presented in this evaluation under *Evaluation of a Possible Hazard to Respirator Wearers Due to Leakage Through DM and DFM Filters.*

[284]Refer to Figure IV in this evaluation and subsequent discussion under *Evaluation of a Possible Hazard to Respirator Wearers Due to Leakage Through DM and DFM Filters.*

14—General basis for APFs recommended in Table P.

Except for some respirators used against dusts, fumes, and mists (filter masks), NIOSH is considering APFs that were previously recommended in the 1987 *NIOSH Respirator Decision Logic (RDL)*.[285] A majority of the 1987 NIOSH recommendations (Tables J and K of this evaluation) were unchanged from those recommended in 1976 (Tables E and F of this evaluation).[286] However, for APF recommendations in NIOSH's 1987 RDL, NIOSH considered data from both WPF

[285] *NIOSH Respirator Decision Logic*, DHHS (NIOSH) Publication # 87-108, Cincinnati, OH (May, 1987), Tables 1-3, pp. 2-4, 13-18, and 27-29.

[286] NIOSH: *A Guide to Industrial Respiratory Protection*, DHEW (NIOSH) Publication No. 76-189, Cincinnati, Ohio (June 1976), Appendix F, pp. 137-148.

studies[287,288,289,290,291,292,293,294] conducted in the 1980s and from laboratory studies performed on anthropometric panels in the 1970s.[295]

In general, NIOSH considered only those studies published in peer-reviewed journals, since those studies were known to have undergone scientific review. For estimation of APFs recommended in 1987, when WPF data existed NIOSH considered point estimates of lower 5th percentiles from WPF sample distributions. Confidence intervals for these point estimates were not computed and not considered.

A recent review of the peer-reviewed literature and other reliable studies indicates that, except for DM and DFM filter respirators, there is minimal information from the period 1987–1991 to substantiate changes to the 1987 NIOSH APF recommendations.[296,297,298] However, note that earlier in this evaluation NIOSH present-

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[287]Myers, W.R. and M. J. Peach,: 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).

[288]Bentley, R.A., G. J. Bostock, D. J. Longson, and M. W. Roff: Determination of the Quantitative Fit Factors of Various Types of Respiratory Protective Equipment, *J. Int. Soc. Respir. Prot.* 2(4):313–337 (1984).

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

[290]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).

[291]Linauskas, S.H. and F. Kalos: Study of Efficiency and Current Use of Respiratory Protection Devices. [Report prepared for the Atomic Energy Control Board. Ottawa, Canada.] Atomic Energy of Canada Limited (1984).

[292]Myers, W.R., M. J. Peach, III, K. Cutright, and W. Iskander: Field Test of Powered Air-Purifying Respirators at a Battery Manufacturing Facility, *J. Int. Soc. Respir. Prot.* 4(1):62–89 (1984).

[293]Myers, W.R., M. J. Peach, III, 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).

[294]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).

[295]Refer to discussion presented earlier in this evaluation under *Review and Evaluation of Professional Practices Used During the 1970s and 1980s for Respirator Face-Seal Evaluations and APF Determinations.*

[296]Reed, L. D., S. W. Lenhart, R. L. Stephenson, and J. R. Allender: Workplace Evaluation of a Disposable Respirator in a Dusty Environment, *Appl. Ind. Hyg.* 2(2):53–56 (1987).

ed an evaluation of APF-determination methods used during the 1970s and 1980s[299] and an evaluation of face-seal leakage for some non-powered, air-purifying halfmasks.[300] When considered together, these two NIOSH evaluations also bring into question whether the "face-seal-leakage only" APF of 10 for non-powered, HEPA-filter halfmasks is sufficiently protective. If the 10 is invalid and is erroneously high, then the two APFs for non-powered, filter halfmasks recommended by NIOSH in Table P are erroneously high.

The APFs recommended in this evaluation reflect *only* the protection that *might* be achieved under the conditions of an ideal or optimal respirator program combined with correct wearing by *every user*. The recommended APFs *do not consider* whether certain types of respirators certified by NIOSH can be reliably fit tested periodically *and* reliably fit checked by a wearer each time they don their mask. The recommended APFs *cannot* be considered to be the typical protection that will be achieved under most routine respirator programs. NIOSH expects that only a small minority of users wear respirators under optimal-program conditions. Thus only a minority of users are expected to actually achieve those APFs recommended in Table P. There is always some possibility that the *protection factor* attained by a particular wearer with a particular mask will be less than the class APF for the mask.

The APFs recommended in this evaluation are based *solely on respirator capabilities* for a few models from each respirator class that were measured under ideal laboratory or ideal field conditions. They *do not necessarily indicate* performance attained during actual working conditions in many American workplaces.

NIOSH's certification-test methods do not incorporate nor evaluate the many combinations and permutations of fit tests and fit checks that must be used in the workplace to assure each respirator's proper fit on individual wearers as required by OSHA in 29 CFR 1910.134. For example, if an air-purifying, filter mask is constructed such that it cannot be reliably fit checked by the wearer each time it is donned, then an APF less than the NIOSH APF might be indicated. If faceseal leak-

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[297](...continued)

[297]Cohen, H. J.: Determining and Validating the Adequacy of Air-Purifying Respirators Used in Industry, Part I—Evaluating the Performance of a Disposable Respirator for Protection Against Mercury Vapor, *J. Int. Soc. Respir. Prot.* 2(3):296–304 (1984).

[298]Galvin, K., S. Selvin, and R. C. Spear: Variability in Protection Afforded by Half-Mask Respirators Against Styrene Exposure in the Field, *Am. Ind. Hyg. Assoc. J.* 51(12):625–631 (1990).

[299]Refer to discussion presented earlier in this evaluation under *Review and Evaluation of Professional Practices Used During the 1970s and 1980s for Respirator Face-Seal Evaluations and APF Determinations.*

[300]Refer to discussion in this evaluation under *Evaluation of Face-Seal Results from Nine Studies of Non-Powered, Air-Purifying Halfmasks.*

age was a significant contributor to a mask's computed APF, then an APF less than the NIOSH APF would be strongly indicated.

Continuing the example, the U. S. Court of Appeals for the District of Columbia Circuit ruled in 1987 that OSHA had correctly assigned an APF of 5 to those "disposable respirators" that could not be fit checked by wearers for adequate inhalation protection against cotton dust.[301] That is, certain filtering-facepiece halfmasks for which it is "difficult, if not impossible, for the wearer to cover the entire [filtering] surface area, but not the seal between the respirator and the wearer's face" during the fit check recommended by the manufacturer.[302] The federal court stated that

> OSHA recognized that, in the case of [certain filtering-facepiece] disposable respirators, the worker's hands cannot effectively block intended air intake, and that intake only, while leaving unobstructed air taken in because of the respirator's improper fit.[303]

The federal court also noted that

> Absent assurance of a respirator's proper fit, the NIOSH and ANSI ratings can reliably indicate only the efficiency of the filter, not the effectiveness of the entire respirator as it is used on the job.[304]

A second control strategy that might have been used by NIOSH for determining the values in Table P would have attempted to determine levels of protection typically attained by most users in actual respirator programs. That is, protection levels similar to the *program protection factors* (PPFs) proposed by Myers et al. in 1983.[305] In contrast to APFs, for which only respirator hardware capabilities are considered under optimal use conditions, by definition PPFs incorporate the adverse effects on personal protection levels due to factors such as, but not limited to,

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[301] *National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration*, 825 F.2d 482 (D.C. Cir. 1987)

[302] Ibid., p. 489, footnote 6.

[303] Ibid., p. 492.

[304] Ibid., p. 493.

[305] Myers, W. R., S. W. Lenhart, D. Campbell, and G. Provost: The Forum—Letter to the editor, *Am. Ind. Hyg. Assoc. J.* 44(3):B25–26 (1983), p. B–26.

- respirator selection
- respirator design and protection potential
- variability, suitability, and acceptability of respirator fit on each wearer's face
- periodic fit testing by the employer
- fit checks performed by wearers
- training of supervisors and wearers
- user motivation to properly don and wear their mask
- respirator maintenance and storage
- supervision of wearer's to ensure correct use
- program administration and monitoring

and any other *program variable* that affects effectiveness of personal protection afforded each and every wearer. It appears that this type of protection factor would be most relevant and indicative of protection that most users will actually attain. NIOSH anticipates that this second control strategy would likely yield protection values that are *lower* than the APFs recommended in Table P. However, at this time there is a notable lack of information upon which to base PPFs. The necessary type of research data to determine PPFs is years to decades away. Thus the Institute was not able to pursue this second control strategy for determining the values in Table P.

For at least two decades, as extensively discussed earlier in this evaluation, the accepted standard of professional practice for determination of respirator-class APFs has been performance levels exhibited by the *poorer*-performing devices in each class.[306] Class APFs *have not been determined* by use of "typical," "representative," or "average" respirator protection in each class. Unfortunately, this approach prevents purchasers and users from benefiting from superior protection available from most masks in any given class. When using class minima to define class APFs, the

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[306]Refer to discussion presented in this evaluation under *Review and Evaluation of Professional Practices Used During the 1970s and 1980s for Respirator Face-Seal Evaluations and APF Determinations.*

potential protection afforded by most mask models in a class will exceed the class APF under ideal conditions. This approach to class APFs also eliminates a major incentive to respirator manufacturers to produce more protective devices in each respirator class, since class APFs are in effect "held hostage" to lower values produced by poorer performing devices of one or two manufacturers (particularly for the air-purifying masks).

15—Computation of APF values for DM- and DFM-filter masks recommended in Table P.

For a given user wearing a given mask, equation (16) derived earlier in this evaluation[307] estimates the PF_{user} for: (1) a specified user face-seal PF ($PF_{face\text{-}seal}$) (e.g., obtained from a quantitative fit test on the mask as equipped with a HEPA filter) in combination with (2) a specified filter leakage (L_{filter}) (e.g., for a DM or DFM filter). To compute APF values for DM- and DFM-filter masks, one must have an estimate for the relevant $PF_{face\text{-}seal}$. This specialized PF value is computed from a face-seal leakage value for each specific facepiece and operating mode (e.g., obtained from a quantitative fit test on a mask as equipped with a HEPA filter).

For example, a HEPA-equipped, non-powered, air-purifying halfmask respirator is used with an APF of 10, which is the currently accepted value for professional practice. Since $APF_{HEPA\text{-}filter\ mask}$ equals $PF_{face\text{-}seal}$, the latter term is considered to be 10 (or a maximum face-seal leakage of 10% for this facepiece and operating mode). This value was recommended by Hyatt with the following comment:

> Based on the results in Table V and the above discussion, we recommend a PF of 10 for respirators A, C, D, E, F, and G, which practically constitute all [NIOSH] approved half-mask respirators equipped with a high-efficiency filter. It is emphasized that this is based on face seal only.[308]

Thus it is a simple step to substitute a HEPA-filter-mask APF value into the term $PF_{face\text{-}seal}$ to obtain an $APF_{filter\ mask}$ function for any filter-mask APF as follows

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[307]Refer to material presented in this evaluation under *Derivation and Evaluation of Two Leakage-Function Models for Describing a User's Protection Factor While Wearing a DM- or DFM-Filter Mask.*

[308]Hyatt E.C.: *Respirator Protection Factors.* Los Alamos Scientific Laboratory, Informal Report No. LA–6084–MS (1976), p. 14.

$$APF_{filter\ mask} = [(APF_{HEPA\text{-}filter\ mask})^{-1} + (L_{filter}) - (L_{filter})/(APF_{HEPA\text{-}filter\ mask})]^{-1}. \quad (17)$$

Note that equation (17) is based on the *improved model* leakage function derived earlier in this evaluation.[309] Use of the improved model yields *slightly lower* $APF_{filter\ mask}$ values than those that would result from use of the simple-additive model (equation (2) of this evaluation).

To compute the APF Values for DM- and DFM-filter masks recommended in Table P, it was then necessary for NIOSH to determine relevant L_{filter} values for use in equation (17). NIOSH evaluated recent DM- and DFM-filter-leakage data from four research teams, which were presented earlier in this evaluation.[310] For experimental studies involving filter leakage measurements, measurement biases can occur due to the complex nature of test equipment, test aerosols, and leakage measurements. Because similar hazardous filter-leakage results were obtained in four independent laboratory studies, NIOSH concluded that the DM- and DFM-filter results presented in Figures IV and V were suitable for computing the filter-mask APFs.

As discussed earlier in this evaluation, respirator volumetric flow rates for filter testing of about 35 to 100 L/min/mask are the most relevant flow rates for evaluating the effect of hazardous filter leakage during actual workplace usage of these filter masks at medium to heavy work rates.[311] Filter-leakage results at *medium* work rates should be determined at volumetric flow rates of about 35 to 55 L/min/mask, while *heavy* work-rate leakages should be determined at about 75 to 100 L/min/mask.

For the 17 DM-filter data sets A through I, Figure IV indicates that four filters (B, C, F, and O) fall in a hazardous "high-leakage" band distinct from the other 13 DM filters. Because the hazardous high-leakage filter results in the upper band were reported from three different research teams (HK, LF, and WC), they do not appear to be possible aberrations or outliers. NIOSH decided that it was reasonable to use the four high-leakage test results to determine the characteristic L_{filter} value for computing DM-filter APFs.

For the four high-leakage DM-filter data sets B, C, F, and O, Figure IV indicates that at 35–55 L/min/mask (medium work rate) these test filters yielded about 45 to

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[309]Refer to material presented in this evaluation under *Derivation and Evaluation of Two Leakage-Function Models for Describing a User's Protection Factor While Wearing a DM- or DFM-Filter Mask.*

[310]Refer to material presented in this evaluation under *Results Reported from Four Recent Studies of DM- and DFM-Filter Leakage.*

[311]Refer to discussion presented in this evaluation under *Evaluation Factors for DM- and DFM-Filter-Leakage Data.*

almost 60% leakage, i.e., a characteristic value of about *50% filter leakage at medium work rates* for the highest-leakage contaminant sizes. For these data sets over the range 75–100 L/min/mask (heavy work rate), these four test filters yielded about 55 to 75% leakage or a characteristic value of about *65% filter leakage at heavy work rates* at the highest-leakage contaminant sizes. Thus NIOSH selected a characteristic L_{filter} value of 50% for DM filters (at medium work rates) for use in equation (17) of this evaluation.

Unlike the DM-filter results in Figure IV, the nine DFM-filter data sets A through I shown in Figure V do not show a separate high-leakage grouping. Only DFM-data set H is substantially higher than the other 8 DFM-data sets. Because DFM-data set H constitutes leakage results from a single model filter reported by a single laboratory, NIOSH concluded it would not be reasonable to use it as the basis for the relevant L_{filter} value for DFM-filter APFs.

For 8 DFM-filter data sets A through G plus I, Figure V indicates that at 35–55 L/min/mask (medium work rate) these test filters yielded about 2.5 to 7.5% leakage or a characteristic value of about *6% leakage at medium work rates* for the highest-leakage contaminant sizes. For these data sets over the range 75–100 L/min these 8 filters yielded about 5 to 12% leakage or a characteristic value of about *9.5% leakage at heavy work rates* at the highest-leakage contaminant sizes. Thus NIOSH selected a characteristic L_{filter} value of 6% for DFM filters (at medium work rates) for use in equation (17). After the two characteristic L_{filter} values of 50% (DM filters) and 6% (DFM filters) were determined by NIOSH, they were then used in equation (17) of this evaluation to compute the recommended APFs of Table P for DM and DFM filters used on non-powered and powered filter masks. Table P of this evaluation summarizes the specific values of the input variable values used to compute the $APF_{filter\ mask}$ values leading to the recommended APF values for DM and DFM filters in Table P. These are the $APF_{HEPA\text{-}filter\ mask}$ values and the characteristic L_{filter} values discussed in this evaluation, which were then used in equation (17). The last column of Table P presents the APF value recommended in Table P. NIOSH rounded each computed $APF_{filter\ mask}$ value *up or down* to the *nearest* integer. For example, in the first row of Table P for a non-powered, quarter or halfmask with DM filter(s), $APF_{HEPA\text{-}filter\ mask}$ is 10, L_{filter} value is 0.50, and $APF_{filter\ mask}$ is computed as

$$APF_{filter\ mask} = [10^{-1} + 0.50 - (0.50)/(10)]^{-1}. \qquad (18)$$

These values yield an $APF_{filter\ mask} = 1.82$, which was then rounded to the nearest integer, for a recommended APF of 2.

Note that use of a rounding procedure results in the same APF as if a lower L_{filter} of 0.44 had been used in equation (17). Additionally, at high L_{filter} values such as

occurs for DM filters, the *simple* and *improved* models for PF_{user} yield essentially the same result. Thus a recommended APF of 2 for non-powered, DM-filter halfmasks is *insensitive* to which leakage-function model is chosen for the computations.

Determination of the two characteristic L_{filter} values of 50% leakage (DM filters) and 6% leakage (DFM filters) was based on NIOSH's conclusion that filter leakages at medium work rates were the most relevant values for APF computations. NIOSH concluded that the use of heavy-work-rate leakages would be unrealistic and unreasonable due to the limited number of users that will use DM- and DFM-filter masks at heavy work rates. For DM filters, the use of a 65%-leakage value for characteristic filter leakage at heavy work rates would reduce the computed *APF* for these filters to 1.46 from the 1.82 (non-powered halfmasks) computed for a 50% filter-leakage value. For DFM filters, the use of a 9.5%-leakage value for characteristic filter leakage at heavy work rates would reduce the computed *APF* for these filters to 5.39 from the 6.49 (non-powered halfmasks) computed for 50% filter leakage.

When determining the relevant characteristic L_{filter} values for computing its recommended APFs, NIOSH would be following a control strategy of anticipating severe filter-use conditions. However, as discussed in the preceding paragraphs, the assumed filter-use conditions underlying the selected L_{filter} values are those that can be reasonably anticipated in American workplaces. That is, the contaminant sizes, user work rates, face-seal leakages, and filter loadings considered by NIOSH during its characteristic L_{filter} determinations *are not* unlikely, improbable, questionable, or implausible.

Lastly, the filter-leakage data presented in Figures IV and V also indicate that some respirator manufacturers have been able to design and market DM and DFM filters that exhibit a substantially less hazard to users than do most other filters in their class. These data indicate to NIOSH that the high filter leakage shown by most of the tested filters *cannot* be attributed to the archaic performance and design restrictions in the current 30 CFR Part 11 regulations. That is, the data indicate some manufacturers have been able to design and manufacture filters with relatively low leakage values and still obtain certifications under 30 CFR Part 11 requirements (e.g., undergo the unrealistically high filter loading of 30 CFR 11.140–4 and still be able to pass the maximum-resistance requirements of 30 CFR 11.140–9(b)). If all of the DM and DFM filters tested in the four studies had exhibited filter leakage as low as the most protective filters in each class, NIOSH would have been able to propose an APF of about 6 for non-powered, DM-filter masks and about 8 for DFM-filter masks instead of the values 2 and 6 respectively.

For over 15 years respirator manufacturers have had the ability to produce DM-filters that *yield less than 5% leakage*. Held et al. reported in 1974 regarding the results of research funded in part by NIOSH:

LASL tested 50 dust-mist respirator filters from each production lot of filters obtained from the respirator manufacturers. The results of the initial aerosol particle penetration tests are given in Table X. . . .

Thus a total of ten of the fifteen production lots of dust-mist respirator filters tested allowed initial NaCl aerosol penetrations such that 99% of these production lots permitted penetrations less than 5%. It must be remembered that none of the respirator manufacturers who supplied the dust-mist respirator filters had developed these filters to meet any initial aerosol particle penetration requirement involving the 0.6 μm MMAD [about 0.15 μm CMD] NaCl aerosol particle, but instead, these respirator manufacturers had developed the filters to meet the previously mentioned silica dust particle and silica dust penetration criteria . . . It is thought that the test results in Table X show that the respirator manufacturers have the capability of producing dust-mist respirator filters whereby 99% of the filters in a production lot would permit NaCl aerosol particle penetrations less than 5.0%.[312]

NIOSH recognizes that an APF of 2 for some non-powered, DM-filter halfmasks may effectively eliminate these filters as a practical choice for respirator purchasers and users. Since an APF of 1 represents a totally ineffective respirator (zero protection), restricting DM-filter-mask usage to the narrow APF range of 1 to 2 may substantially reduce the use of all DM filters. However, in the absence of specific and reliable information as to which particular DM and DFM filters and use conditions will result in hazardous leakage and which will not, NIOSH concludes that an APF decrease from 10 to 2 for non-powered, DM-filter halfmasks is fully warranted. This is because of the hazardous filter leakage exhibited by some of these filter types in four research studies.

However, reducing the class APF from 10 to 2 for all non-powered, DM-filter halfmasks will prevent purchasers and users from benefiting from the superior efficacy available from most masks in this class. A single APF of 2 for all DFM-filter halfmasks eliminates a major incentive to respirator manufacturers to market their medium-to-high-efficacy filter halfmasks. Halfmask manufacturers with superior DM filters are in effect "held hostage" to the APF of 2 generated by poorer performing filters of a few manufacturers. This results in a few DM-filter manufacturers controlling the APF for this class as stated in 1975 by the 3M Company.[313]

Similarly, NIOSH recognizes that an APF of 6 for non-powered, DFM-filter halfmasks may significantly diminish the selection and use of these filters in many workplaces. Reducing DFM-filter halfmask usage to a restricted APF range of 1 to 6

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[312]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, Progress Report, #LA–5805–PR (December 1974), pp. 32–33.

[313]3M Company: Comments—Standards Completion Project, Ketone Hearings, Inflationary Impact. Comments submitted to OSHA Docket SCP–1, St. Paul, Minnesota (December 1, 1975), p. 7

will eliminate some current uses of these filters where APFs of 6 to 10 are required. However, NIOSH concludes that an APF decrease from 10 to 6 for non-powered, DFM-filter halfmasks is fully warranted due to the hazardous filter leakage exhibited in four research studies by some of these filter types.

The only reasonably safe way that all NIOSH-certified DM filters on non-powered halfmasks could be used at an APF of 10 would be to perform contaminant-size monitoring in the environments where the filters will be used. This would enable purchasers and users to identify those environments with contaminant sizes that could result in hazardous DM-filter leakage. However, as previously discussed in this evaluation, less than 30% of employers perform exposure-level monitoring before assigning respirators to their employees despite federal regulatory requirements to do so. Thus it is highly doubtful that employers would do the necessary contaminant-size monitoring if it were required in addition to exposure-level monitoring. Hence NIOSH concludes that size-monitoring requirements as a condition for use of DM-filters would not adequately assure protection of employees from hazardous DM-filter leakage.

Table P—Input Variable Values and Intermediate Values for APFs Recommended for DM- and DFM-Filter Masks Certified Under 30 CFR Part 11.

Respirator Type	*APF* for HEPA-filter mask (considers only face-seal leakage)	L_{filter} from Figures IV and V	Computed *APF* for filter mask (Eqn 17)	Recommended APF
Non-powered, quarter or half-mask with DM filter(s)	10	0.50	1.82	2
Non-powered, fullface mask with DM filter(s)	50	0.50	1.96	2
Non-powered, quarter or half-mask with DFM filter(s)	10	0.06	6.49	6
Non-powered, fullface mask with DFM filter(s)	50	0.06	12.7	13
Powered, quarter or halfmask with DM filter(s)	50	0.50	1.96	2
Powered, fullface mask with DM filter(s)	50	0.50	1.96	2
Powered, loose-fitting helmet or hood with DM filter(s)	25	0.50	1.92	2
Powered, quarter or halfmask with DFM filter(s)	50	0.06	12.7	13
Powered, fullface mask with DFM filter(s)	50	0.06	12.7	13
Powered, loose-fitting helmet or hood with DFM filter(s)	25	0.06	10.2	10

16—Evaluation of the ANSI 1991 APF-determination strategy.

NIOSH evaluated a second APF-determination strategy that was recently used by the ANSI Subcommittee Z88.2 (Practices for Respiratory Protection) to develop APFs for the ANSI Z88.2-1991 *American National Standard Practices for Respiratory Protection.*[314,315] The ANSI-proposed 1991 APFs have been presented earlier as Table D in this evaluation. As noted earlier in this evaluation,[316] this ANSI nonregulatory standard has been submitted to the ANSI Board of Standards Review for their approval.

The ANSI Subcommittee's APF-determination strategy was based on the general knowledge that NIOSH-certified DM and DFM filters provide adequate protection for "larger" contaminant sizes. This strategy must assume that a contaminant-size criterion can be established above which purchasers and users can be assured that hazardous filter leakage will not occur through any NIOSH-certified DM or DFM filter during use according to a manufacturer's instructions. Additionally, to benefit from this strategy *an employer must conduct initial and periodic contaminant-size monitoring in addition to the initial and routine exposure-level monitoring required in an adequate respirator-use program.*

The following decision sequence outlines the steps required for filter-mask selection under the 1991 ANSI Z88.2 strategy for determining APFs for masks certified under 30 CFR Part 11. Note that this is a *simplified* explanation, since other important considerations are involved such as, but not limited to:

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[314]Da Roza, R. A. and P. R. Steinmeyer: The New ANSI Z88.2, *Respiratory Protection Newsletter* 6(5):1–7 (September/October 1990).

[315]ANSI Z88 Committee on Respiratory Protection: *American National Standard Practices for Respiratory Protection, ANSI Z88.2–1991,* submitted by Z88 Secretariat for ANSI approval, Livermore, California (March 6, 1991), Table 1, pp. 19–22.

[316]Refer to material presented in this evaluation under *Nonregulatory APF Values Used During the 1970s and 1980s.*

- Is the contaminant a dust, fume, or mist?

- Is the applicable exposure control limit less than 0.05 milligrams per cubic meter or does it equal or exceed 0.05 milligrams per cubic meter?

- Is the contaminant concentration less than its IDLH concentration? Other selection considerations of a *respirator decision logic* also must be complied with.

Step #1—START: Given that a particulate-filter respirator is appropriate for the given contaminant, work environment, and prospective user, go to Step #2.

Step #2—DETERMINE: Is the contaminant size known? That is, has at least initial monitoring for contaminant-size distribution(s) been performed? If NO, go to Step #3. If YES, go to Step #6.

Step #3—DECIDE: Is it feasible and desirable to conduct an initial monitoring program for contaminant-size distributions? If NO, go to Step #4. If YES, go to Step #5.

Step #4—ACTION: Use *only* a HEPA filter at an APF = 10 for a non-powered halfmask; APF = 25 for powered air-purifying mask with loose-fitting hood or helmet facepiece; or APF = 50 for non-powered fullface mask or powered mask with half-mask or fullface facepiece. Periodically conduct routine exposure-level monitoring.

Step #5—ACTION: Conduct initial and periodic contaminant-size monitoring in addition to the initial and routine exposure-level monitoring required in an adequate respirator-use program. Then go to Step #6.

Step #6—DECIDE: Is contaminant size ≥ adequate-filter-protection criterion? If NO, go to Step #4. If YES, go to Step #7.

Step #7—ACTION: As appropriate, use a NIOSH-certified DM- or DFM- filter mask at an APF = 10 for a non-powered halfmask; APF = 25 for powered air-purifying mask with loose-fitting hood or helmet facepiece; or APF = 50 for non-powered fullface mask or powered mask with halfmask or fullface facepiece. Periodically return to Step #5 and conduct periodic contaminant-size monitoring in addition to routine exposure-level monitoring.

NIOSH has concluded that it is undesirable and unreasonable to require the conduct of initial and periodic contaminant-size monitoring to determine if the contaminant size exceeds some adequate-filter-protection criterion in order to assign an APF to NIOSH-certified DM and DFM filters (i.e., APF = 10). There are several reasons supporting this decision.

As noted earlier in this evaluation, since so few employers currently perform exposure-level monitoring required by OSHA regulations, it is highly doubtful that they

would perform additional contaminant-size monitoring even if it were to be required.[317] Next, the technical expertise necessary to measure contaminant size distributions and interpret the results is not generally available to employers. Because of reasons number two and three, it is likely that the ANSI proposal would compromise the health and safety of respirator users. Lastly, there are two serious technical deficiencies in the *adequate-filter-protection criterion* for contaminant size of 2 μm MMAD required in the 1991 ANSI standard. These technical deficiencies could compromise the health and safety of respirator users.

The ANSI standard contains the following requirements regarding filter selection in order to use the standard's APF values:

> If the contaminant is an aerosol, with an unknown particle size or less than 2 μm (MMAD), a high efficiency filter shall be used. If the contaminant is a fume, use a [DFM] filter approved for fumes or a high efficiency [HEPA] filter. If the contaminant is an aerosol, with a particle size greater than 2 μm (MMAD), any filter type (dust, fumes, mist, or high efficiency) may be used.[318]

The first technical deficiency with this requirement is that it creates the incorrect perception for respirator purchasers and users that any contaminant with one half its total mass contained in sizes *less than 2 μm* (i.e., less than its MMAD) will be incapable of hazardous leakage through a NIOSH-certified DM or DFM filter. A contaminant size distribution with an MMAD of 2 μm would have a CMD of about 0.2 to 1 μm, depending on the variability (geometric standard deviation) of the size and mass distributions. That is, half of the particles would be smaller than 0.2 to 1 μm diameter, which is the size range of hazardous leakage through DM and DFM filters as shown in Figures VI through XIII of this evaluation.

More importantly, Figures XVI and XVII indicate that at least three NIOSH-certified DM filters will exhibit user PFs less than 10 for particle sizes up to 4 μm diameter. Thus inadequate DM-filter protection can be unknowingly provided to users if the contaminant size distribution has an appreciable portion of its mass in particles with count diameters up to 4 μm (and possibly larger sizes).

However, an ANSI-type MMAD criterion should be *substantially larger* than the 2 μm MMAD given in the ANSI 1991 standard. For example, if one were to decide that no more than 16% of an inhaled contaminant's mass should be in particle sizes less than 4 μm, and the geometric standard deviation (GSD) for the cumulative count

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[317]Refer to discussion presented in this evaluation under *Evaluation of a Possible Hazard to Respirator Wearers Due to Contaminant Leakage Through DM and DFM Filters.*

[318]Ibid., p. 19–20.

and cumulative mass distributions were about 2.5 to 3.0, then the required minimum MMAD would be equal to 4 μm times the GSD, which is *at least* a 10 μm and 12 μm minimum MMAD respectively. If one desired even less than 16% of an inhaled contaminant's mass in less than 4 μm-sized particles, then even larger minimum MMADs would be required, depending on the count and mass GSDs.[319]

Based on Figures XVI and XVII, the ANSI criteria should be revised so that most of a contaminant's mass (e.g., 95%) resides in particles with diameters above *at least* 4 μm. The ANSI MMAD criteria value of 2 μm is *substantially too low*. Additionally, an MMAD criteria *is inappropriate* because 50% of a contaminant's mass resides in particle sizes less than the MMAD.

However, note that selection of 4 μm for a non-MMAD acceptable-size criterion would leave no margin of safety to account for the fact that the data presented in Figures XVI and XVII are neither based on a representative sample of all NIOSH-certified DM filters nor are the plotted data necessarily from the worst-performing filters certified under 30 CFR Part 11. It must be recognized that Figures XVI and XVII are based on filter-leakage data reported from a restricted number of manufacturers, a limited number of different filter lots from each filter make and model, and limited sample sizes tested by each research team. Thus it is highly probable that other NIOSH-certified DM-filters are available that exhibit *worse protection* than indicated by Figures XVI and XVII at contaminant sizes *above 4 μm*. Any APF-determination strategy similar to that used by the ANSI Subcommittee must take the preceding considerations into account.

The second technical deficiency in the ANSI requirement quoted above is that it incorrectly assumes that a NIOSH-certified DFM-filter will provide adequate protection against any fume regardless of its size. Fumes are generally less than 1 μm diameter in size[320] and DFM filters, as with DM filters, exhibit their highest hazardous leakage in the size range of about 0.1 to 0.4 μm particle diameter. As discussed earlier in this evaluation, NIOSH has concluded that DFM filters exhibit a characteristic leakage of 6% at medium work rates.[321] For this reason NIOSH concluded these filters should be limited to an APF of 6 (Table P of this evaluation), not the 10 permitted in the ANSI standard. Any APF-determination strategy similar to that used by the ANSI Subcommittee should not permit the use of DFM filters at an APF of 10 against fumes of unknown particle size. If an APF of 10 is needed for a non-

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[319]Hinds, W. C.: *Aerosol Technology*, John Wiley & Sons, New York (1982), pp. 87–95.

[320]Ibid., p. 6.

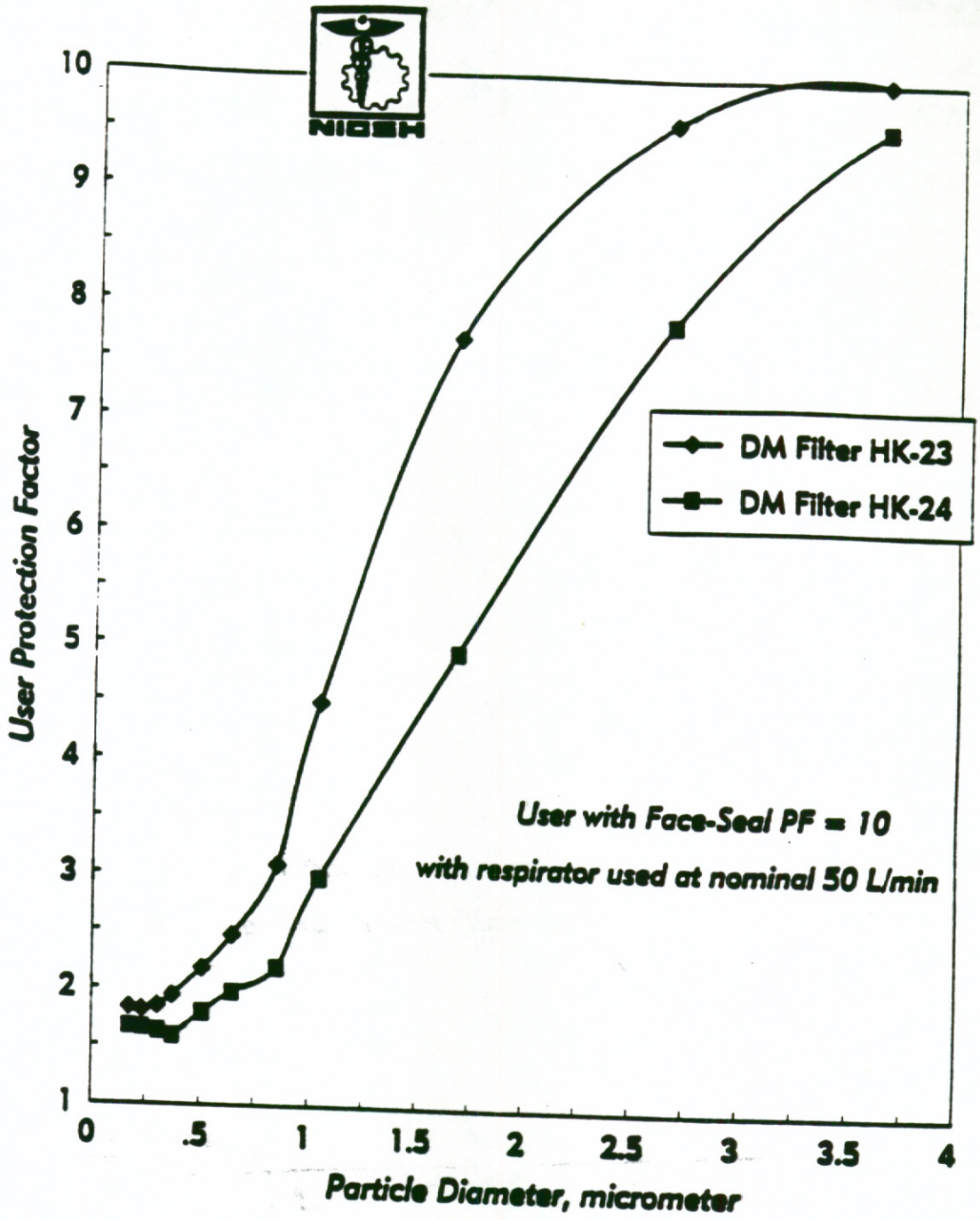
[321]Refer to discussion presented in this evaluation under *Computation of APF Values for DM- and DFM-Filter Masks Recommended in Table P.*

powered halfmask, only HEPA filters should be used against unknown particle sizes for an ANSI-type APF strategy.

Additionally under the ANSI proposal, not only will *more wearers* have to use HEPA filters, but those *more expensive filters* will have to be *replaced more frequently*. To obtain the excellent protection that HEPA filters provide, filter-design tradeoffs have resulted in poor filter-loading capacities. That is, compared to DM or DFM filters, HEPA filters will more quickly reach the point of unacceptable breathing resistance for the user (i.e., they will clog faster).

Table Q—Summary Evaluation of ANSI Z88.2–1991 Approach to APFs for Filter Respirators.

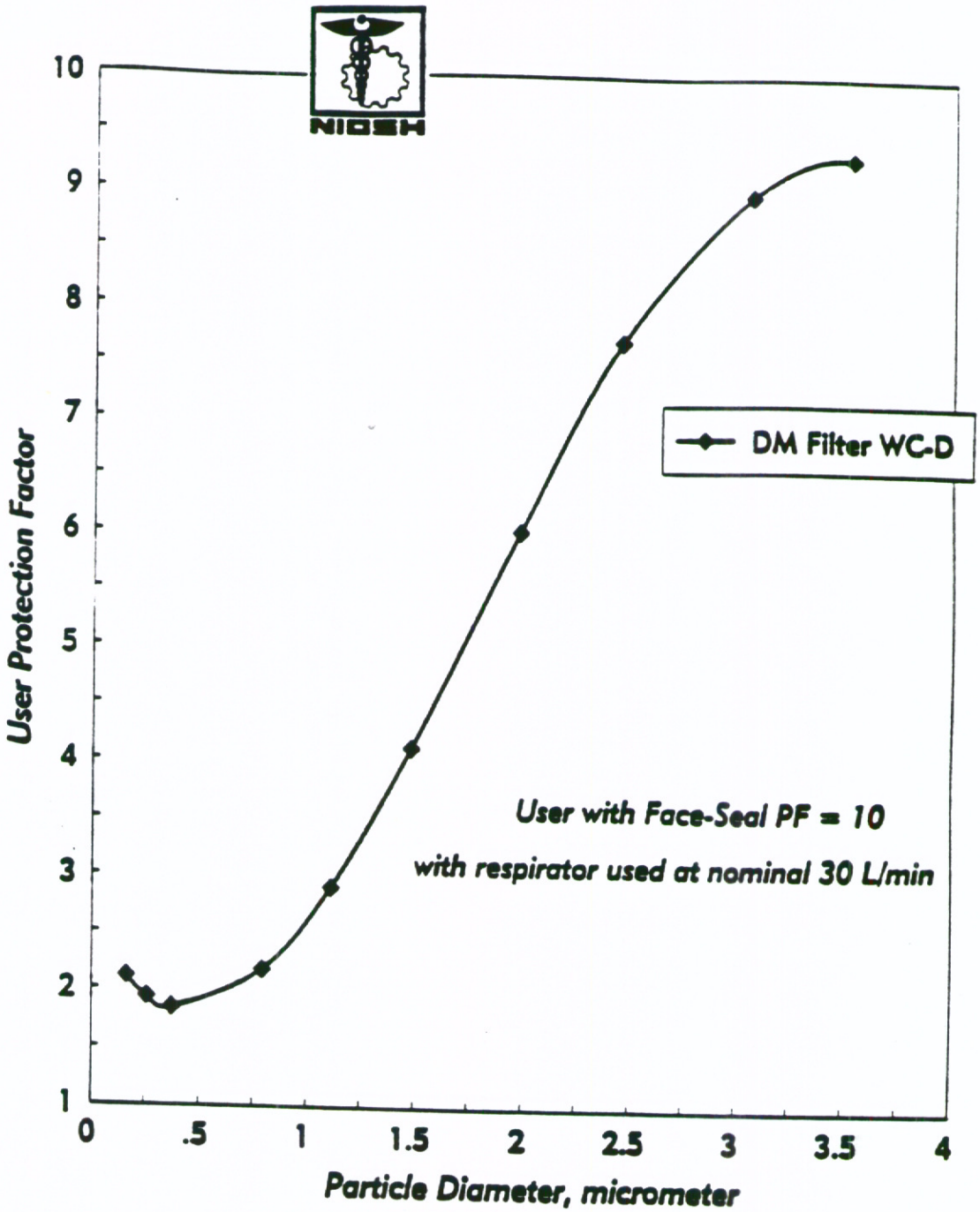
ANSI Z88.2–1991 APFs for Filter Respirators
ADVANTAGES 1—APFs of 10 for DM and DFM filters for non-powered, halfmask facepieces. 2—No increase in costs to purchasers where the easier-to-wear and less-expensive DM and DFM filters can be worn (e.g., PFs ≤ 10).
DISADVANTAGES 1—Purchasers will have to buy the much more expensive HEPA filters, if contaminant-size monitoring is not performed by employer. 2—HEPA filters increase the wearing burden on users and increases costs to purchasers. 3—An adequately-protective size criterion must be determined. 4—May inadequately protect users. If errors are made in the contaminant-size monitoring program and a contaminant is actually smaller than reported, then DM- and DFM-filter mask users could be put as risk of receiving hazardous exposures. 5—Use of HEPA filters can be uncomfortable for wearers since they have a higher breathing resistance. Also, they may need to be replaced more frequently than DM or DFM filters since they may clog more frequently. 6—Because workplace contaminant-size distributions substantially vary within days, between days, and between operations, OSHA will have difficulty determining whether a workplace was in compliance with an APF for DM and DFM filters that was a function of compliance with a contaminant-size criterion.



	.173	.232	.306	.372	.509	.643	.849	1.04	1.66	2.67	3.65
DM Filter HK-23	1.83	1.81	1.85	1.94	2.18	2.47	3.09	4.59	7.71	9.62	10.0
DM Filter HK-24	1.67	1.66	1.63	1.59	1.80	1.98	2.20	2.96	4.96	7.67	9.59

CDC
CENTERS FOR DISEASE CONTROL

Figure XVI—Effect of Particle Size on User Protection Factors for a Face-Seal PF of 10 at a Characteristic 50 L/min for DM Filters *HK-23* and *HK-24* Certified Under 30 CFR Part 11.



CDC
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	.164	.259	.374	.792	1.11	1.48	1.98	2.45	3.05	3.52
DM Filter WC-D	2.11	1.93	1.84	2.18	2.91	4.13	6.03	7.71	8.97	9.3

Figure XVII—Effect of Particle Size on User Protection Factors for a Face-Seal PF of 10 at a Characteristic 50 L/min for DM Filter *WC–D* Certified Under 30 CFR Part 11.