

REFERENCES

1. Code of Federal Regulations, Title 30, Part 11, revised July 1, 1986.
2. Guyton AC. Textbook of medical physiology, 3rd ed, Philadelphia: W.B. Saunders Co., 1966, p. 578.
3. Clayton GD, Clayton FE, ed. Patty's industrial hygiene and toxicology, 3rd ed, Vol 1, New York: John Wiley & Sons, 1978.
4. A guide to industrial respiratory protection. Cincinnati: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, 1976; HEW (NIOSH) publication no. 76-189.
5. Goodman LS, Gilman A. The pharmacological basis of therapeutics. 3rd ed, New York: The Macmillan Co, 1968, p. 897.
6. Hyatt EC. Respirator protection factors. New Mexico: Los Alamos scientific laboratory of the University of California, informal report no. LA-6084-MS, 1976.
7. Myers WR, Peach MJ III, Allender J. Workplace protection factor measurements on powered air-purifying respirators at a secondary lead smelter--test protocol. Am Ind Hyg Assoc J 1984;45(4):236-41.
8. Myers WR, Peach MJ III, Cutright K, Iskander W. Workplace protection factor measurements on powered air-purifying respirators at a secondary lead smelter--results and discussion. Am Ind Hyg Assoc J 1984;45(10):681-88.
9. Myers WR, Peach MJ III. Performance measurements on a powered air-purifying respirator made during actual field use in a silica bagging operation. Ann Occup Hyg 1983;27(3):251-59.
10. Dixon SW, Nelson TJ. Workplace protection factors for negative pressure half-mask facepiece respirators. J Int Soc Respir Prot 1984;2(4):347-61.
11. Dixon SW, Nelson TJ, Wright JE. Program protection factor study on the 3M W316 AirhatTM. Presented at the American Industrial Hygiene Conference, May 22, 1984, Michigan. Detroit: E.I. du Pont de Nemours & Co.
12. Hinton JJ. Reliability of quantitative fit protection factors in assessing face-to-facepiece seals. [Unpublished thesis]. Houston, TX: University of Texas, Health Science Center, 1980.
13. Myers WR, Lenhart SW, Campbell D, Provost G. [Letter]. Am Ind Hyg Assoc J 1983;44(3):B25-26.

14. Myers WR, Peach MJ III, Cutright K, Iskander W. Field test of powered air-purifying respirators at a battery manufacturing facility. *J Int Soc Respir Prot* 1984;4(1):62-89.
15. Lenhart SW, Campbell DL. Assigned protection factors for two respirator types based upon workplace performance testing. *Ann Occup Hyg* 1984;28(2):173-82.
16. Linauskas SH, Kalos F. Study of efficiency and current use of respiratory protective devices. [Report prepared for the Atomic Energy Control Board. Ottawa, Canada]. Atomic Energy of Canada Limited, 1984.
17. Bentley RA, Bostock GJ, Longson DJ, Roff MW. Determination of the quantitative fit factors of various types of respiratory protective equipment. *J Int Soc Respir Prot* 1984;2(4):313-37.
18. Moore DE, Smith TJ. Measurement of protection factors of chemical cartridge, half-mask respirators under working conditions in a copper smelter. *Am Ind Hyg Assoc J* 1976;37(8):453-58.
19. Toney CR, Barnhart WL. Performance evaluation of respiratory protective equipment used in paint spraying operations, NIOSH Technical Information, HEW publication no. (NIOSH) 76-177, 1976.
20. Smith TJ, Ferrell WC, Varner MO, Putnam RD. Inhalation exposure of cadmium workers: effects of respirator usage. *Am Ind Hyg Assoc J* 1980;41:624-28.
21. Revoir WH. Respirators for protection against cotton dust. *Am Ind Hyg Assoc J* 1974;35(8):503-10.
22. American National Standards Institute, Inc. American national standard for respirator protection-respirator use-physical qualifications for personnel, ANSI Z88.6-1984. New York: ANSI, Inc., 1984, pp. 7-15.
23. Code of Federal Regulations, Title 29, Part 1910, Section 134(e)(5), revised July 1, 1986.
24. Harber P. Medical evaluation for respirator use. *J Occup Med* 1984;26(7):496-502.
25. Manning JE, Griggs TR. Heart rates in fire fighters using light and heavy breathing equipment: similar near-maximal exertion in response to multiple work load conditions. *J Occup Med* 1983;25(3):215-18.
26. Kilbom A. Physical work capacity of firemen. *Scand J Work Environ Health* 1980;6:48-57.
27. Weiner DA, Ryan TJ, McCabe CH, et al. Exercise stress testing: correlations among history of angina, ST-segment response and prevalence

- of coronary-artery disease in the coronary artery surgery study (CASS). *N Engl J Med* 1979;301(5):230-35.
28. Epstein SE. Limitations of electrocardiographic exercise testing [Editorial]. *N Engl J Med* 1979;301(5):264-65.
 29. Nicklin D, Balaban DJ. Exercise EKG in asymptomatic normotensive subjects [Letter to the editor]. *N Engl J Med* 1984;310(13):852.
 30. Giagnoni E, Secchi MB, Wu SC, et al. Prognostic value of exercise EKG testing in asymptomatic normotensive subjects. *N Engl J Med* 1983;309(18):1085-89.
 31. Folli G. Exercise EKG in asymptomatic normotensives subjects [Reply to letter to the editor]. *N Engl J Med* 1984;310(13):852-53.
 32. Kanner RE, Morris AH, ed. Clinical pulmonary function testing: a manual of uniform laboratory procedures for the intermountain area. 1st ed, Salt Lake City, Utah: Intermountain Thoracic Society, 1975.
 33. Amoores JE, Hautala E. Odor as an aid to chemical safety: odor thresholds compared with threshold limit values and volatilities for 214 industrial chemicals in air and water dilution. *J Appl Toxicol* 1983;3(6):272-90.
 34. Williams FT. Photometric measurement of respirator quantitative fit test protection factors and their interpretation, use and meaning, Dynatech Frontier Technical Note, 108-0008, 1978.
 35. Halperin WE, Ratcliffe JM, Frazier TM, Becker SP, Schulte PA. Medical screening in the workplace: proposed principles. *J Occup Med* 1986;28(8):547-52.
 36. Raven PB, Dodson AT, Davis TO. The physiological consequences of wearing industrial respirators: a review. *Am Ind Hyg Assoc J* 1979;40(6):517-34.
 37. James RH. Breathing resistance and dead space in respiratory protective devices. U.S. Department of Health, Education, and Welfare, National Institute for Occupational Safety and Health, Cincinnati, Ohio, October 1976.
 38. Gee JBL, Burton G, Vassallo C, Gregg J. Effects of external airway obstruction on work capacity and pulmonary gas exchange. *Am Rev Respir Dis* 1968;98:1003-12.
 39. Hodous TK, Petsonk L, Boyles C, Hankinson J, Amandus H. Effects of added resistance to breathing during exercise in obstructive lung disease. *Am Rev Respir Dis* 1983;128:943-48.

40. Raven PB, Jackson AW, Page K, et al. The physiological responses of mild pulmonary impaired subjects while using a "demand" respirator during rest and work. *Am Ind Hyg Assoc J* 1981;42(4):247-57.
41. Hodous TK, Boyles C, Hankinson J. Effects of industrial respirator wear during exercise in subjects with restrictive lung disease. *Am Ind Hyg Assoc J* 1986;47:176-80.
42. Altose MD, McCauley WC, Kelsen SG, Cherniack NS. Effects of hypercapnia and inspiratory flow-resistive loading on respiratory activity in chronic airways obstruction. *J Clin Invest* 1977;59:500-07.
43. Bentley RA, Griffin OG, Love RG, Muir DCF, Sweetland KF. Acceptable levels for breathing resistance of respiratory apparatus. *Arch Environ Health* 1973;27:273-80.
44. Love RG, Muir DCF, Sweetland KF, Bentley RA, Griffin OG. Acceptable levels for the breathing resistance of respiratory apparatus: results for men over the age of 45. *Br J Ind Med* 1977;34:126-29.
45. Deno NS, Kamon E, Kiser DM. Physiological responses to resistance breathing during short and prolonged exercise. *Am Ind Hyg Assoc J* 1981;42(8):616-23.
46. Raven PB, Davis TO, Shafer CL, Linnebur AC. Maximal stress test performance while wearing a self-contained breathing apparatus. *J Occup Med* 1977;19(12):802-06.
47. Craig FN, Blevins WV, Cummings G. Exhausting work limited by external resistance and inhalation of carbon dioxide. *J Appl Physiol* 1970;29(6):847-51.
48. Stemler FW, Craig FN. Effects of respiratory equipment on endurance in hard work. *J Appl Physiol* 1977;42:28-32.
49. Myhre LG, Holden RD, Baumgardner FW, Tucker D. Physiological limits of firefighters. Air Force School of Aerospace Medicine, Brooks AFB, TX, ESL-TR-79-06, 1979.
50. James R, Dukes-Dobos F, Smith R. Effects of respirators under heat/work conditions. *Am Ind Hyg Assoc J* 1984;45(6):399-404.
51. Hermansen L, Vokac Z, Lereim P. Respiratory and circulatory response to added air flow resistance during exercise. *Ergonomics* 1972;15(1):15-24.
52. Meyer E, Gurtner HP, Scherrer M. Physiological appraisal of a new respirator with positive pressure. *Pneumology* 1975;153:61-72.
53. Dahlback GO, Balldin UI. Physiological effects of pressure demand masks during heavy exercise. *Am Ind Hyg Assoc J* 1984;45(3):177-181.

54. Arborelius M, Dahlback GO, Data P-G. Cardiac output and gas exchange during heavy exercise with a positive pressure respiratory protective apparatus. *Scand J Work Environ Health* 1983;9:471-477.
55. Bjurstedt H, Rosenhamer G, Lindborg B, Hesser CM. Respiratory and circulatory responses to sustained positive-pressure breathing and exercise in man. *Acta Physiol Scand* 1979;105:204-14.
56. Black LF, Hyatt RE. Maximal respiratory pressures: normal values and relationship to age and sex. *Am Rev Respir Dis* 1969;99:696-702.
57. Bates DV, Macklem PT, Christie RV. Respiratory function in disease: an introduction to the integrated study of the lung, 2nd ed, Philadelphia: W.B. Saunders Co., 1971, p. 43.
58. Raven PB, Bradley O, Rohm-Young D, McClure FL, Skaggs B. Physiological response to "pressure-demand" respirator wear. *Am Ind Hyg Assoc J* 1982;43(10):773-81.
59. Harber P, Tamimie RJ, Bhattacharya A, Barber M. Physiologic effects of respirator dead space and resistance loading. *J Occup Med* 1982;24(9):681-84.
60. Petsonk EL, Hancock J, Boyles C. Physiologic effects of a self-contained self-rescuer. *Am Ind Hyg Assoc J* 1983;44(5):368-73.
61. Morgan WP. Psychological problems associated with the wearing of industrial respirators: a review. *Am Ind Hyg Assoc J* 1983;44(9):671-76.
62. Morgan WP. Psychological problems associated with the wear of industrial respirators. *J Int Soc Respir Prot* 1983;1:67-108.
63. Ronk R, White MK. Hydrogen sulfide and the probabilities of "inhalation" through a tympanic membrane defect. *J Occup Med* 1985;27(5):337-40.
64. Cantekin EI, Bluestone CD, Saez CA, Bern SA. Airflow through the eustachian tube. *Ann Otol* 1979;88:603-612.
65. daRoza RA, Weaver C. Is it safe to wear contact lenses with a full-facepiece respirator? Lawrence Livermore National Laboratory manuscript UCRL-53653, 1985, pp. 1-3.

IV. GLOSSARY

The following definitions of terms are provided to assist in the understanding and application of this decision logic.

ASSIGNED PROTECTION FACTOR (APF): See PROTECTION FACTOR.

BREAKTHROUGH: The penetration of challenge material(s) through a gas or a vapor air-purifying element. The quantity or extent of breakthrough during service life testing is often referred to as the percentage of the input concentration.

DISPOSABLE RESPIRATORS: A respirator that is discarded after the end of its recommended period of use, after excessive resistance or physical damage, or when odor breakthrough or other warning indicators render the respirator unsuitable for further use.

DUST: A solid, mechanically produced particle with a size ranging from submicroscopic to macroscopic.

EMERGENCY RESPIRATOR USE SITUATION: A situation that requires the use of respirators due to the unplanned generation of a hazardous atmosphere (often of unknown composition) caused by an accident, mechanical failure, or other means and that requires evacuation of personnel or immediate entry for rescue or corrective action.

ESCAPE GAS MASK: A gas mask that consists of a half-mask facepiece or mouthpiece, a canister, and associated connections and that is designed for use during escape only from hazardous atmospheres (see Subparagraph 5).

ESCAPE ONLY RESPIRATOR: Respiratory devices that are designed for use only during escape from hazardous atmospheres.

FILTERING FACEPIECE: A particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium. (See SINGLE-USE DUST or DUST and MIST RESPIRATORS and DISPOSABLE RESPIRATORS.)

FIT FACTOR: A quantitative measure of the fit of a specific respirator facepiece to a particular individual. (For further discussion of fit factors, refer to Appendix D.)

FUME: A solid condensation particulate, usually of a vaporized metal.

GAS: An aeriform fluid that is in a gaseous state at standard temperature and pressure.

IMMEDIATELY DANGEROUS TO LIFE OR HEALTH (IDLH): Acute respiratory exposure that poses an immediate threat of loss of life, immediate or

delayed irreversible adverse effects on health, or acute eye exposure that would prevent escape from a hazardous atmosphere.

MIST: A liquid condensation particle.

ORINASAL RESPIRATOR: A respirator that covers the nose and mouth and that generally consists of a quarter- or half-facepiece.

PLANNED or UNPLANNED ENTRY into an IDLH ENVIRONMENT, AN ENVIRONMENT OF UNKNOWN CONCENTRATION of HAZARDOUS CONTAMINANT, or an ENVIRONMENT of UNKNOWN COMPOSITION: A situation in which respiratory devices are recommended to provide adequate protection to workers entering an area where the contaminant concentration is above the IDLH or is unknown.

POTENTIAL OCCUPATIONAL CARCINOGEN: Any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory, or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance that is metabolized into one or more potential occupational carcinogens by mammals (29 CFR 1910.103, OSHA Cancer Policy).

PROTECTION FACTORS (See Appendix D):

ASSIGNED PROTECTION FACTOR (APF): The minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users.

SIMULATED WORKPLACE PROTECTION FACTOR (SWPF): A surrogate measure of the workplace protection provided by a respirator.

WORKPLACE PROTECTION FACTOR (WPF): A measure of the protection provided in the workplace by a properly functioning respirator when correctly worn and used.

RECOMMENDED EXPOSURE LIMIT (REL): An 8- or 10-hour time-weighted average (TWA) or ceiling (C) exposure concentration recommended by NIOSH that is based on an evaluation of the health effects data.

SERVICE LIFE: The length of time required for an air-purifying element to reach a specific effluent concentration. Service life is determined by the type of substance being removed, the concentration of the substance, the ambient temperature, the specific element being tested (cartridge or canister), the flow rate resistance, and the selected breakthrough value. The service life for a self-contained breathing apparatus (SCBA) is the period of time, as determined by the NIOSH certification tests, in which adequate breathing gas is supplied.

SINGLE-USE DUST or DUST AND MIST RESPIRATORS: Respirators approved for use against dusts or mists that may cause pneumoconiosis and fibrosis.

VAPOR: The gaseous state of a substance that is solid or liquid at temperatures and pressures normally encountered.

V. APPENDICES

APPENDIX A. NIOSH POLICY STATEMENT ON APPROVAL OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

NIOSH/MSHA TESTING AND CERTIFICATION OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Agency: National Institute for Occupational Safety and Health (NIOSH)

Action: Notice of Acceptance of Applications for Approval of Air-Purifying Respirators with End-of-Service-Life Indicators

Summary: 30 CFR 11; Sec. 11.150 states that NIOSH and MSHA may, after a review of the effects on wearers' health and safety, approve respirators for gases and vapors not specifically listed in that section. The current regulations also permit the use of "window indicators" for gas masks to warn the wearer when the canister will no longer remove a contaminant [11.102-5(c)(2)]. Although indicators are not mentioned in Subpart L, Chemical Cartridge Respirators, there is nothing in the regulations which explicitly prohibits their use. A NIOSH policy to allow end-of-service-life indicators (ESLI's) on air-purifying respirators for gases and vapors with adequate warning properties has already been established (Letter to All Respirator Manufacturers from Dr. Elliott Harris, June 18, 1975).

Use of ESLI's on chemical cartridge respirators for use against gases and vapors with poor warning properties could also be approved, because 30 CFR 11; Sec. 11.150; footnote 7 states:

"Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor)...." Thus, air-purifying respirators with ESLI's could be approved for substances such as acrylonitrile, because the OSHA acrylonitrile standard permits the use of chemical cartridge respirators.

Under the present regulations, NIOSH can also require "any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres" [30 CFR 11; Sec. 11.63 (c)]. NIOSH must notify the applicants in writing of these additional requirements [30 CFR 11; Sec. 11.63 (d)].

The purpose of this notification is to inform respirator manufacturers and users of the NIOSH requirements for approving air-purifying respirators with

either effective passive or active ESLI's for use against gases and vapors with adequate warning properties or for use against gases and vapors with inadequate warning properties whenever there is a regulatory standard already permitting the use of air-purifying respirators.

For additional information, contact: Chief, Certification Branch, 944 Chestnut Ridge Road, Morgantown, WV 26505, (304) 291-4331.

Supplemental Information

Because human senses are not foolproof in detecting gases and vapors and because many gases and vapors found in the workplace do not have adequate warning properties, NIOSH has been investigating alternate means of detection for respirator wearers. In 1976, NIOSH adopted its current policy which allows acceptance of applications for certification of air-purifying respirators, provided that the respirators are equipped with active ESLI's for use against gases and vapors with poor warning properties and are not specifically listed in 30 CFR 11.

An active ESLI is defined as an indicator that invokes an automatic and spontaneous warning signal (e.g., flashing lights, ringing bells, etc.). An active indicator does not require monitoring by the wearer although a passive indicator (normally color change indicator) does.

During the past several years, NIOSH has received notices of concern from respirator manufacturers, regulatory agencies, and general industry regarding the Institute's policy of accepting only active ESLI's for certification. At the October 1983 Mine Health Research Advisory Council (MHRAC) meeting, NIOSH presented a document briefing on "Consideration of Use of End-of-Service-Life Indicators in Respiratory Protective Devices," and requested that MHRAC provide recommendations to the Institute with regard to the appropriateness of the use of both active and passive ESLI's. MHRAC asked their Respirator Subcommittee to review the issue.

The Respirator Subcommittee held a public meeting in Washington, D.C., on December 19, 1983, to solicit comments from interested parties. The Subcommittee reviewed the comments and then reported back to the full committee at the February 2, 1984, MHRAC meeting. Based on the public comments, the Subcommittee also suggested a few additions or modifications be made to the NIOSH proposed evaluation criteria. NIOSH incorporated the recommendations. MHRAC also recommended that active and passive ESLI's are appropriate for use with respiratory protective devices provided that criteria are established for their certification and use to ensure that the user is not exposed to increased risk as a consequence of relying upon such ESLI's.

In order for NIOSH to determine the potential effects of ESLI's on user safety and health, NIOSH recommends that all applications for approval of gas and vapor respirators with ESLI's contain the following information:

CRITERIA FOR CERTIFICATION OF END-OF-SERVICE-LIFE INDICATORS

An applicant for certification of an ESLI for use against substances with poor warning properties must provide NIOSH with the following information:

1. Data demonstrating that the ESLI is a reliable indicator of sorbent depletion ($\leq 90\%$ of service life). These shall include a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are representative of actual workplace conditions where a given respirator will be used. A minimum of two contaminant levels must be utilized: the exposure limit (PEL, REL, TLV[®], etc.) and the exposure limit multiplied by the assigned protection factor for the respirator type.
2. Data on desorption of any impregnating agents used in the indicator, including a flow-temperature study at low and high temperatures and humidities which are representative of actual workplace conditions where a given respirator will be used. Data shall be sufficient to demonstrate safe levels of desorbed agents.
3. Data on the effects of industrial interferences which are commonly found in workplaces where a given respirator will be used. Data should be sufficient to show which interferences could impair the effectiveness of the indicator and the degree of impairment, and which substances will not affect the indicator.
4. Data on any reaction products produced in the reaction between the sorbent and the contaminant gases and vapors, including the concentrations and toxicities of such products.
5. Data which predict the storage life of the indicator. (Simulated aging tests will be acceptable).

In addition to the foregoing, all passive ESLI's shall meet the following criteria:

1. A passive ESLI shall be placed on the respirator so that the ESLI is visible to the wearer.
2. If the passive indicator utilizes color change, the change shall be such that it is detectable to people with physical impairments such as color blindness.
3. If the passive indicator utilizes color change, reference colors for the initial color of the indicator and the final (end point) color of the indicator shall be placed adjacent to the indicator.

All ESLI's shall meet the following criteria:

- 1. The ESLI shall not interfere with the effectiveness of the face seal.**
- 2. The ESLI shall not change the weight distribution of the respirator to the detriment of the facepiece fit.**
- 3. The ESLI shall not interfere with required lines of sight.**
- 4. Any ESLI that is permanently installed in the respirator facepiece shall be capable of withstanding cleaning and a drop from a height of 6 feet. Replaceable ESLI must be capable of being easily removed and shall also be capable of withstanding a drop from a height of 6 feet.**
- 5. A respirator with an ESLI shall still meet all other applicable requirements set forth in 30 CFR 11.**
- 6. If the ESLI uses any electrical components, they shall conform to the provisions of the National Electrical Code and be "intrinsically safe." Where permissibility is required, the respirator shall meet the requirements for permissibility and intrinsic safety set forth in 30 CFR 18, Subpart D. Also, the electrical system shall include an automatic warning mechanism that indicates a loss of power.**
- 7. Effects of industrial substances interferences which are commonly found where a given respirator will be used and which hinder ESLI performance, shall be identified. Substances which are commonly found where the respirator is to be used must be investigated. Data sufficient to indicate whether the performance of the respirator would be affected must be submitted to NIOSH. The user shall be made aware of use conditions that could cause false positive and negative ESLI responses.**
- 8. The ESLI shall not create any hazard to the wearer's health or safety.**
- 9. Consideration shall be given to the potential impact of common human physical impairments on the effectiveness of the ESLI.**

APPENDIX B. NIOSH POLICY STATEMENT ON USE OF SINGLE-USE AND DUST AND MIST RESPIRATORS FOR PROTECTION AGAINST ASBESTOS

June 21, 1984, OSHA Public Hearings

Under Title 30, Code of Federal Regulations, Part 11 (30 CFR 11), NIOSH is required to test and certify respirators within the categories specified therein when such devices are submitted to NIOSH by applicants. Currently, 30 CFR 11, Subpart K defines a number of dust, fume, and mist respirators which may be used for protection against certain hazardous particulate atmospheres. Among the respirators defined in Subpart K are single-use dust respirators designed as respiratory protection against pneumoconiosis-producing and fibrosis-producing dusts, or dusts and mists. Subpart K lists asbestos as one of the dusts against which the single-use dust respirator is designed to protect [Subpart K, Sec. 11.130(H)]. Although at the time of the promulgation of Subpart K, it may have been assumed appropriate to list asbestos as a fibrosis-producing particulate against which the single-use disposable respirator could be reasonably expected to provide adequate protection, NIOSH is no longer confident that such an assumption is reasonable because asbestos is also a potent carcinogen.

The current requirements as (specified in 30 CFR 11) for approval of a single-use dust respirator or dust and mist respirator do not include any tests with fibrous challenge aerosol. NIOSH is currently in the process of doing a comprehensive revision of 30 CFR 11 and intends to address the issue of appropriate respiratory protection for use against asbestos, and to require that any respirator for which such approval is sought be proven to provide effective protection against asbestos. NIOSH may change the regulations included in 30 CFR 11 only in accordance with procedures set forth in the Administrative Procedures Act. In the interim, NIOSH will continue to consider applications for approval of single-use and replaceable dust/mist respirators for use against asbestos only because of the legal requirement in the current approval regulations. However, NIOSH does not recommend the use of such respirators where exposures to asbestos may occur because such a recommendation would not be prudent based on the occupational health risk.

This policy position is contained in "The Statement of the National Institute for Occupational Safety and Health--The Public Hearings on Occupational Exposure to Asbestos."

APPENDIX C. ODOR WARNING: BACKGROUND INFORMATION

It is important to realize that 30 CFR 11 prohibits the use of MSHA/NIOSH approved air-purifying (organic vapor) respirators for protection against organic vapors with poor warning properties unless there is an OSHA standard that permits such use. Specifically, 30 CFR 11, Section 11.90(b), footnote 4 gives the standards for gas masks (canister devices), while 30 CFR 11, Section 11.150, footnote 7 gives the standards for chemical cartridge respirators. Thus the "organic vapor respirator" shall be approved only for organic vapors with adequate warning properties. In addition, the requirement for adequate warning properties also applies to all MSHA/NIOSH-approved air-purifying respirators for protection against organic gases and vapors.

A recent policy decision by NIOSH allows the use of respirators for protection against contaminants with poor warning properties, provided that certain conditions are met. These conditions are outlined in the policy statement in Appendix A. MSHA/NIOSH approval may be granted for a respirator designed for use against gases and vapors with poor warning properties if the respirator incorporates an effective end-of-service-life indicator (ESLI).

However, unless the respirator incorporates an ESLI, wearers of air-purifying chemical cartridge/canister respirators must rely on adequate warning properties to alert them to the breakthrough of the sorbent in the cartridge or canister. Amoores and Hautala [33] have noted:

The ability of members of the population to detect a given odor is strongly influenced by the innate variability of different persons' olfactory powers, their prior experience with that odor, and by the degree of attention they accord to the matter.

Amoores and Hautala [33] found that on the average, 95% of a population will have a personal odor threshold that lies within the range from about one-sixteenth to sixteen times the reported mean "odor threshold" for a substance. That is, about 2.5% of a population will be able to detect a substance's odor at concentrations less than one-sixteenth of the "odor threshold" for a substance. Correspondingly, about 2.5% of the individuals will need to be exposed to concentrations exceeding by a factor of 16 the "odor threshold" in order to perceive the odor. Thus for many substances the width of distribution of personal odor threshold is over two orders of magnitude of concentration. The "odor thresholds" reported in the literature generally are the median values for wide population distributions. Also, 50% of prospective respirator wearers can detect a substance's odor only at levels that must exceed the reported "odor threshold," and about 15% cannot detect the odor at levels that exceed the "odor threshold" by fourfold [33].

OSHA incorporated into the lead standard a new isoamyl acetate qualitative fit test protocol, developed by Du Pont, which requires odor threshold

screening [29 CFR 1910.1025, Appendix D (I)(A)]. Du Pont realized that a qualitative fit test depending on odor recognition would be ineffective if every individual were not first screened for the ability to detect the odor of isoamyl acetate at some minimum concentration. This is also true for detection of the odor of the gas or vapor used to alert the wearer of sorbent element (cartridge or canister) breakthrough. Thus NIOSH recommends screening tests for workers who wear air-purifying gas or vapor respirators to determine their ability to detect the odor below the exposure limit for that gas or vapor.

APPENDIX D. PROTECTION FACTOR: BACKGROUND INFORMATION

The U.S. Bureau of Mines referred to the term "Decontamination Factor" in their Approval Schedule 21B, first issued in 1965, and defined it to be "the ratio of the concentration of dust, fume, or mist present in the ambient atmosphere to the concentration of dust, fume, or mist within the facepiece while the respirator is being worn." The decontamination factor is now referred to as the respirator protection factor. The original definition and application given in schedule 21B has been somewhat generalized over the years.

The protection factor of a respirator is an expression of performance based on the ratio of two measured variables, C_1 and C_0 . The variable C_1 is defined only as the measured concentration of a contaminant inside the respirator facepiece cavity, and C_0 is defined only as the measured contaminant concentration outside the respirator facepiece. The relationship between these two variables can be expressed not only as the protection factor (C_0/C_1) but also as the penetration (C_1/C_0) or efficiency $[(C_0-C_1)/C_0]$.

The protection factor can be related to the penetration (p) and efficiency (E) as follows:

$$PF = C_0/C_1 = 1/p = 1/(1-E)$$

A further implicit condition on the PF function is that $C_1 \leq C_0$; therefore, the PF will always be greater than unity.

Protection factor assessments are made almost exclusively on man/respirator systems, while penetration and efficiency assessments are made only on component parts of the respirator system. It is important to recognize that on a man/respirator system, the measured variable C_1 becomes a complicated function of many individual sources of penetration (e.g., air-purifying element penetration, exhalation valve penetration, face seal penetration, and other inboard penetration) and those environmental conditions that would effect penetration. To deal with the multiple methods for determining and applying protection factors, a number of definitions have been proposed [13]. These definitions, described below in greater detail than in the Glossary, are as follows:

ASSIGNED PROTECTION FACTOR (APF): A special application of the general protection factor concept, APF is defined as a measure of the minimum anticipated workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to a percentage of properly fitted and trained users. The maximum specified use concentration for a respirator is generally determined by multiplying the exposure limit for the contaminant by the protection factor assigned to a specific class of respirators [13].

SIMULATED WORKPLACE PROTECTION FACTOR (SWPF): A surrogate measure of the workplace protection factor (WPF) of a respirator, SWPF differs from the WPF only in that it is measured in a laboratory simulation of a workplace setting rather than in the actual workplace. The definitions and restrictions of C_0 and C_1 are as described for the WPF. For laboratory protection factor testing to reliably estimate WPF's, a relationship must be demonstrated between the two tests. No such relationship has been identified in the literature. Until such a relationship can be shown to exist, the laboratory protection factor is of questionable use in determining or predicting the WPF [13].

WORKPLACE PROTECTION FACTOR (WPF): A measure of the actual protection provided in the workplace under the conditions of that workplace by a properly functioning respirator when correctly worn and used, WPF is defined as the ratio of the estimated contaminant concentration outside the respirator facepiece (C_0) to the contaminant concentration inside the respirator facepiece (C_1). The sampling restrictions placed on C_0 and C_1 are that both C_0 and C_1 should be TWA samples taken simultaneously while the respirator is being properly worn and used during normal work activities. In practice, the WPF would be determined by measuring the concentration inside and outside the facepiece during the activities of a normal workday [13].

FIT FACTOR: A special application of the protection factor ratio that represents a quantitative measure of the fit of a particular respirator facepiece to a particular individual, the fit factor is defined under the conditions of quantitative fit testing as the aerosol concentration in the test chamber (C_0) divided by the penetration that occurs through the respirator face seal interface (C_1) [34]. For C_1 to reflect only face seal leakage, high efficiency filters [greater than 99.97% efficient against $0.3 \mu\text{m}$ aerodynamic mass median diameter (AMMD) dioctylphthalate aerosol] are installed on the respirator. It is assumed that either no leakage or only a negligible amount of leakage into the facepiece occurs through the exhalation valve or any source other than the face seal. The fit factor is measured on a complete respirator worn by a test subject who follows a regimen of slow head movements, deep breathing, and talking; a polydispersed oil mist or sodium chloride aerosol is used that has an AMMD of approximately $0.6 \pm 0.1 \mu\text{m}$ (with a geometric standard deviation of approximately 2 to 2.4).

APPENDIX E. MEDICAL ASPECTS OF WEARING RESPIRATORS: BACKGROUND INFORMATION

In recommending medical evaluation criteria for respirator use, one should apply rigorous decision-making principles [35], using knowledge of screening test sensitivity, predictive value, etc. Unfortunately, many gaps in knowledge in this area exist. The problem is complicated by the large variety of respirators, their conditions of use, and individual differences in the physiologic and psychologic responses to them. For these reasons, the preceding guidelines (see Subparagraph 10) are to be considered as informed suggestions rather than established NIOSH policy recommendations. The following information is intended primarily to assist the physician in developing medical evaluation criteria for respirator use.

Health Effects of Wearing Respirators

Brief descriptions of the health effects associated with wearing respirators are summarized below. Interested readers are referred to recent reviews for more detailed analyses of the data [36,37].

Pulmonary: In general, the added inspiratory and expiratory resistances and dead space of most respirators cause an increased tidal volume and decreased respiratory rate and ventilation (including a small decrease in alveolar ventilation). These respirator effects have usually been small both among healthy individuals and, in limited studies, among individuals with impaired lung function [38-42]. This generalization is applicable to most respirators meeting Federal regulations when resistances (particularly expiratory resistance) are low [1,43,44]. While most studies report minimal physiologic effects during submaximal exercise, the resistances commonly lead to reduced endurance and reduced maximal exercise performance [45-49]. The dead space of a respirator (reflecting the amount of expired air that must be rebreathed before fresh air is obtained) tends to cause increased ventilation. At least one study has shown substantially increased ventilation with a full-face respirator, a type which can have a large effective dead space [50]. However, the net effect of a respirator's added resistances and dead space is usually a small decrease in ventilation [39,45,46-48,51].

The potential for adverse effects, particularly decreased cardiac output, from the positive pressure feature of some respirators has been reported [52]. However, several recent studies suggest that this is not a practical concern, at least not in healthy individuals [53-55].

Theoretically, the increased fluctuations in thoracic pressure while breathing with a respirator might constitute an increased risk to subjects with a history of spontaneous pneumothorax. Few data are available in this area. While an individual is using a negative pressure respirator with relatively high resistance during very heavy exercise, the usual maximal peak negative oral pressure during inhalation is about 15-17 cm of water [53]. Similarly, the usual maximal peak positive oral pressure

during exhalation is about 15-17 cm of water, which might occur with a respirator in a positive pressure mode, again during very heavy exercise [53]. By comparison, maximal positive pressures, such as those during a vigorous cough, can generate 200 cm of water pressure [56]. The normal maximal negative pleural pressure at full inspiration is -40 cm of water [57], and normal subjects can generate -80 to -160 cm of negative water pressure [56]. Thus while vigorous exercise with a respirator does alter pleural pressures, the risk of barotrauma would seem to be substantially less than that of the cough maneuver.

In some asthmatics, an asthmatic attack may be exacerbated or induced by a variety of factors including exercise, cold air, and stress, all of which may be associated with wearing a respirator. While most asthmatics who are able to control their condition should not have problems with respirators, a physician's judgment and a field trial may be needed in selected cases.

Cardiac: The added work of breathing from respirators is small and could not be detected in several studies [38,39]. A typical respirator might double the work of breathing from 3 to 6% of the oxygen consumption, but this is probably not of clinical significance [38]. In concordance with this view is the finding of several studies that at the same workloads heart rate does not change with the wearing of a respirator [39,54,58-60].

In contrast, the added cardiac stress due to the weight of a heavy respirator may be considerable. A self-contained breathing apparatus (SCBA), particularly one that uses compressed air cylinders, may weigh up to 35 pounds. Heavier respirators have been shown to reduce maximum external workloads by 20% and similarly increase heart rate at a given submaximal workload [46]. In addition, it should be appreciated that many uses of SCBA (e.g., for firefighting and hazardous waste site work) also necessitate the wearing of 10-25 pounds of protective clothing.

Raven et al. [40,58] found significantly higher systolic and/or diastolic blood pressures during exercise for persons wearing respirators (although increases were minimal, i.e., ≤ 10 mmHg systolic, 0-2 mmHg diastolic). Arborelius et al. [54] did not find significant differences for persons wearing respirators during exercise.

Body Temperature: Proper regulation of body temperature is primarily of concern with the closed circuit, self-contained breathing apparatus that produces oxygen via an exothermic chemical reaction. Inspired air within these respirators may reach 120°F (49°C), thus depriving the wearer of a minor cooling mechanism and causing discomfort. Obviously this can be more of a problem with heavy exercise and when ambient conditions and/or protective clothing further reduce the body's ability to lose heat. The increase in heart rate due to increasing temperature represents an additional cardiac stress.

Closed-circuit breathing units of any type have the potential for heat stress since warm expired gases (after exothermic carbon dioxide removal with or without oxygen addition) are rebreathed. Respirators with large dead space also have this potential problem, again because of partial rebreathing of warmed expired air [50].

Diminished Senses: Respirators may reduce visual fields, decrease voice clarity and loudness, and decrease hearing. Besides the potential for reduced productivity, these effects may result in reduced industrial safety. These factors may also contribute to a general feeling of stress [61].

Psychologic: This important topic is discussed in recent reviews by Morgan [61,62]. There is little doubt that virtually everyone suffers some discomfort when wearing a respirator. The large variability and the subjective nature of the psycho-physiologic aspects of wearing a respirator, however, make studies and specific recommendations difficult. Fit testing obviously serves an important additional function in providing a trial to determine if the wearer can psychologically tolerate the respirator. General experience indicates that the great majority of workers can tolerate respirators and that experience aids in this tolerance [62]. However, some individuals are likely to remain psychologically unfit for wearing respirators.

Local Irritation: Allergic skin reactions may occur occasionally from wearing a respirator, and skin occlusion may cause irritation or exacerbation of preexisting conditions such as pseudofolliculitis barbae. Facial discomfort from the pressure of the mask may occur, particularly when the fit is unsatisfactory.

In addition to the health effects associated with wearing respirators (described above) specific groups of respirator wearers may be affected by the following factors:

Perforated Tympanic Membrane: While inhalation of toxic materials through a perforated tympanic membrane (ear drum) is possible, recent evidence indicates that the airflow would be minimal and rarely if ever of clinical importance [63,64]. In highly toxic or unknown atmospheres, use of positive pressure respirators should ensure adequate protection [63].

Contact Lens: Contact lenses are generally not recommended for use with respirators, although little documented evidence exists to support this viewpoint [65]. Several possible reasons for this recommendation are noted below:

- a. Corneal irritation or abrasion might occur with the exposure. This would, of course, be a problem primarily with quarter- and half-face masks, especially with particulate exposures. However, exposures could occur with full-face respirators due to leaks or

inadvisable removal of the respirator for any reason. While corneal irritation or abrasion might also occur without contact lenses, their presence is known to substantially increase this risk.

b. The loss or misplacement of a contact lens by an individual wearing a respirator might prompt the wearer to remove the respirator, thereby resulting in exposure to the hazard as well as to the potential problems noted in "a." above.

c. The constant airflow of some respirators, such as powered air-purifying respirators (PAPR) or continuous flow air-line respirators, might irritate a contact lens wearer.