

Respiratory Protection Guidelines

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Respirators (respiratory personal protective devices) are an essential component of programs for protecting workers against inhaled toxins. They are occasionally used in other settings such as protecting patients against inhaled irritants and for protecting military personnel civilian populations against chemical, biologic, or nuclear warfare. In most instances, those using respirators will be normal, healthy persons. The use of respirators should not prevent the accomplishment of job tasks.

Respirators are used for protection against a wide variety of inhaled agents, including chemical, biologic, and radioactive materials. The ultimate target organ often is not the lung itself. Rather, the respiratory tract simply serves as an organ of uptake. Hence, the adequate respiratory protection program will prevent many forms of disease, not simply respiratory disease.

Although the fundamental concept of respiratory personal protection dates to Roman times (when pig bladders were used for protection against lead), there still is only limited consensus about many aspects of respiratory protection programs. This document will provide an overview of respiratory protection programs and specifically address medical aspects.

This document is intended to meet the following goals. (1) To summarize the components of a complete respiratory protection program. This should help physicians and others understand the scope of activity that is necessary for the establishment of a program of respiratory protection. (2) To provide guidance to clinicians in medically determining suitability for respiratory use. This is based on knowledge of how respirators work and their potential adverse effect on users. (3) To briefly describe the regulatory and public policy framework for respiratory use in the United States. (4) To define unresolved questions and needs for research data.

This statement does not include all the information necessary for establishing a respiratory protection program. Regulations change periodically. References to regulations are current as of the date of preparation of this document. Readers should carefully review updated regulations when specific programs are instituted. Selection of respiratory type requires full characterization of exposures. This usually requires industrial hygiene expertise.

This report leads to several conclusions.

1. Respiratory protection can be very effective in preventing illness. However, it must be properly applied, considering all aspects of a complete program. Physicians or other professionals should not undertake respiratory protection efforts without an adequate understanding of all the components involved. Respirators should not be used without adequate training, fit testing, and monitoring programs.
2. There are uncertainties about the degree of protection afforded respirators. In particular, the protection factor determined in a controlled laboratory setting often overestimates actual protection. Excessive leaks at the sealing surfaces of the respirator to the user's face, inadequate respirator performance, and non-compliance with proper utilization can make the actual workplace protection factor lower than the measured or assigned protection factor. The use of assigned protection factors or

personal quantitative fit test results obtained under optimal circumstances overestimates degree of protection obtainable.

3. At the current time, there is no medical test that can completely predict which user will encounter difficulty. Therefore, the practice of testing potential users prior to respirator use should be de-emphasized. Instead, there is a need for more detailed evaluations of the small number of users who report difficulty with use. Thus, postplacement rather than only **preplacement** testing is needed. Respirator users should be periodically re-assessed after actually using the device.
4. Medical certification for respirator use does not routinely require physical examinations or pulmonary function testing. Often, a well-designed questionnaire can serve as a screening tool to select subjects who require a more in-depth evaluation. The physician serving as medical supervisor must be responsible for the assessment of each case, not only for setting general policy. The physician should be knowledgeable about clinical diagnoses and about respirator effects and types. In selected situations such as high risk workers or use of heavy respirators (e.g., SCBA types) in thermal stress situations (such as use of impermeable protective clothing), testing of cardiopulmonary fitness may be warranted.
5. Respirators have potential adverse effect on many psychologic and physiologic processes. These range from anxiety to degradation of work performance and interference with communication. Musculoskeletal system loads may often be as significant as respiratory loading for many types of respirator applications.
6. There is considerable controversy about the proper role of respirators for protection against infectious agents and other bioaerosols. This document defines areas of controversy and suggests methods of obtaining data that would resolve the issue.

I. PROGRAMMATIC ASPECTS

Respirator use is not the method of choice for controlling exposures. Industrial hygiene controls, employing engineering and administrative strategies for worker protection, should be used prior to employing personal protective equipment (PPE) such as respirators in controlling a worker's exposure. When these other methods do not offer adequate worker protection from a hazard, a respirator can provide additional protection and mitigate the hazard.

The control of hazards should begin at the process, equipment, and plant design levels where effluents can be effectively controlled at the outset (i.e., the use of less toxic materials in the process, and adequate exhaust ventilation and filters to control the effluents). When it is not always practical to provide and maintain totally effective engineering controls, appropriate individual respiratory protection equipment should be used for respiratory protection as necessary (1). Administrative controls such as reassigning susceptible workers or enforcing policies limiting time spent by workers in exposure situations are also occasionally used.

The United States Occupational Safety and Health Administration (OSHA) promulgates regulations to address the use of respirators. OSHA's Code of Federal Regulation (CFR) 1910.134 states that when effective engineering controls are not feasible,

TABLE 1
REGULATORY REQUIREMENTS FOR THE SELECTION, USE,
AND MAINTENANCE OF RESPIRATORS

Occupational Safety and Health Act of 1970	Occupational Safety and Health Administration (OSHA), Department of Labor (DOL)	Title 29 CFR 1910
Title II of the Energy Reorganization Act of 1974	Nuclear Regulatory Commission (NRC)	Title 10 CFR Part 20
Federal Mine Safety and Health Act of 1977	Mine Safety and Health Administration (MSHA), Department of Labor (DOL) National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC), Department of Health and Human Services (DHHS)	Title 30 CFR Parts 11, 70 42 CFR Part 84 Subpart K
Toxic Substances Control Act	Environmental Protection Agency (EPA)	Title 10 CFR 750

* The Federal regulations cited above and guidelines issued in accordance with these regulations, with few exceptions, call for selection and use of respirators that have been certified by MSHA and NIOSH. Exceptions include MSHA's allowance of use of certain respirators previously approved by the Bureau of Mines (BOM), the OSHA acceptance of cylinder interchange, and "buddy breathing systems" for use by fire fighters in 29 CFR 1910.156, and the NRC acceptance of supplied-air suits tested by Los Alamos National Laboratory. Although respirators listed by Department of Agriculture (DOA) continue to be acceptable for protection against specified pesticides, the Department of the Interior (DOI)/(BOM) is the agency responsible for testing and approving pesticide respirators (from reference 4: NIOSH Guide to Industrial Respiratory Protection Publication No. 87-1 16, pg. 81).

or while they are being instituted, appropriate respirators shall be used. In addition to the general respirator regulations of 29 CFR 1910.134, regulations apply to many agent-specific regulatory standards (Tables 1-3).

The **employer** is responsible for implementing a respirator program and assuring that regulatory requirements are met. Respirators, any necessary medical examinations, etc., must be provided at no cost to the employee.

The Respiratory Protection Program

Respirators should not be used unless a complete program is in place. Physicians should seek assurance that the program is complete before indicating that a worker is medically fit for respirator use.

The Respiratory Protection Program should be administered by one person (e.g., industrial hygienist, occupational medicine physician, health physicist, safety engineer, or other health/safety

professional) in liaison with the company's medical department. In operations that do not have such an in-house occupational health professional, the respiratory program should be administered by a person fully trained in the administration and handling of respirators (i.e., use, maintenance, training, regulatory aspects) to supervise the program property.

Components of a Respiratory Protection Program

The comprehensive respiratory protection program should be practical and flexible enough so that employees in a potentially hazardous atmosphere will use the equipment properly and follow the rules appropriately. According to current regulations, it should include at least the components listed in Table 4 (see also references 2-4).

One of the most important aspects of administering a Respiratory Protection Program is the development of **written** Standard Operating Procedures. These should be regularly updated and periodically reviewed.

The selection of respirators should be based on the hazard to which the worker is exposed. Other factors include the work rate, size of area covered, mobility, and work requirements and conditions, as well as the limitations and characteristics of the available respirators. The NIOSH Respirator Decision Logic succinctly summarizes methods of selecting the appropriate respirator. In addition, the American National Standard Institute (ANSI) Practices for Respiratory Protection (**Z88.2-1969**, **Z88.2-1980**, **Z88.2-1992**) (5) provides useful guidance.

It is essential that there is a **formal training program so** that the user will be properly trained in the use and limitations of the respirator. All employees (including managers/supervisors) should be instructed by competent persons. The content of the training program should be adjusted, depending on circumstances. However, the following should be included in the training program regardless of the circumstances (OSHA 29 CFR 1910.134 and references 1 and 4).

An explanation/discussion of the engineering and administrative controls in use and why respirators are also needed.

An explanation of the nature of the respiratory hazard and

TABLE 2

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)
STANDARDS SPECIFIC SUBSTANCES REQUIRING
RESPIRATORY PROTECTION*

Standards	Substances
29 CFR 1910.1001 (g)	Asbestos
29 CFR 1910.1017	Vinyl chloride
29 CFR 1910.1028 (g)	Benzene
29 CFR 1910.1043	Cotton dust
29 CFR 1910.1048 (g)	Formaldehyde
29 CFR 1910.120 (5)	Hazardous waste
29 CFR 1910.1018	Inorganic arsenic
1910 CFR 1029	Coke oven emissions
29 CFR 1910.1044	1,2 dibromo-3-chloropropane
29 CFR 1910.1045	Acrylonitrile
29 CFR 1910.1047	Ethylene oxide
29 CFR 1910.10'38	BCME
29 CFR 1910.1025 (f)	Lead

* OSHA regulations governing the use of respirators in general industry may be found in 29 CFR 1910.134; in the construction industry, they are cited in 29 CFR 1926.103; and those for maritime industry are cited in 29 CFR 1915.152 and 1918.102. At the time of preparation of this document, OSHA has not yet formally promulgated its standard for tuberculosis control; this will have significant implications for health care and other industries.

TABLE 3
RESPIRATORY PROTECTION SOME OTHER STANDARDS AND GUIDELINES

Code of Federal Regulations (CFR)	Accident Prevention Signs and Tags
29 CFR 1910.145	Access to Employee Exposure and Medical Records
29 CFR 1910.20	Record-keeping Requirements
29 CFR 1904	Mine Safety and Health Administration
30 CFR I	Electric Motor-driven Mine Equipment and Accessories (Chapter 1, Subpart D)
30 CFR 18	NIOSH-certified Personal Protective Equipment
30 CFR 11	NIOSH-revised Respirator Certification Criteria
42 CFR 84 K	Department of Transportation (Shipping Container Specifications)
49 CFR 178	
American National Standards Institute (ANSI)	American National Standard for Respiratory Protection
ANSI 288.2-I 992	American National Standard for Respiratory Protection, Respirator Use, Physical Qualifications for Personnel
ANSI 288.6-1984	Practices for Respiratory Protection for the Fire Service
	Identification of Air-purifying Respirator Canisters and Cartridges
ANSI 288.5-I 981	
ANSI 288.7	Fire Department Occupational, Safety and Health Programs
ANSI and National Fire Protection Association (NFPA)	Open-circuit Self-contained Breathing Apparatus for Fire Fighters
ANSI/NFPA 1 SOD-1987	Respiratory Protective Equipment for Fire Fighters
ANSI/NFPA 1981-1987	Breathing Apparatus for the Fire Service, A Fire Officer's Guide
NFPA 198-1971	
NFPA FSP-29B-1975	National Institute for Occupational Safety and Health (NIOSH)
National Institute for Occupational Safety and Health (NIOSH)	NIOSH Respirator Decision Logic
NIOSH 87-108	A Guide to Industrial Respiratory Protection
NIOSH 87-116	NIOSH Pocket Guide to Chemical Hazards
NIOSH 90-1 17	Certified Equipment List
NIOSH	
Nuclear Regulatory Commission (NRC)	October 1976 Manual of Respiratory Protection against Airborne Radioactive Materials
NUREC 0041	

what happens when the respirator is not used properly. Instructions on when and where to use the respirator.

An explanation of why a particular type of respirator was selected.

An explanation/discussion of the functions, capabilities, and limitations of the respirator selected.

An opportunity to handle the respirator, and instructions on how to don the respirator and check its fit and operations.

Instructions in the proper wearing of respirators.

Instructions in respirator maintenance.

A discussion/instructions of how to recognize and handle hazardous emergency situations.

Regulations concerning the use of respirators.

As appropriate, explanations/instructions for special respirator use.

Every respirator wearer should receive *fitting instructions* and *practice on how the respirator should be worn*, how to adjust

it, and how to determine if its fits properly. Users should be instructed that most types of respirators require a tight facial seal and that these respirators should not be worn when conditions prevent a good face seal (i.e., facial hair/deformities, eyeglasses). The user must understand the importance of a proper facial fit.

A *respirator maintenance program* should be developed to ensure that the equipment continues to function effectively, and it should be adjusted to accommodate the type of plant, working conditions, and hazards involved. Elements/services that should be included in the maintenance programs are: (1) inspection for defects (including leaks); (2) cleaning and disinfecting; (3) Repair; (4) Storage.

Replacement or repairs should be done only by experienced persons with parts designed for the respirator. No attempt shall be made to replace components or to make adjustments or repairs beyond the manufacturer's recommendations. Replacement requirements for disposable respirators should be clearly delineated.

A specific plan for *storage of equipment* is necessary. Respirators should be stored in a convenient, clean, and sanitary location. The place selected must provide protection from environmental elements such as dust, sunlight, heat, extreme cold, excessive moisture, and damaging chemicals (OSHA 29 CFR 1910.134). In addition, respirators should be protected against mechanical damage.

All respirators should be *inspected* before and after each use and should be routinely inspected at least once a month. Proper inspection may identify defective respirators before they are used and prevent or mitigate a serious employee illness or death. Respirators used routinely should be inspected during cleaning, and worn or deteriorated parts should be replaced. Respirators not used routinely and those for emergency use (e.g., self-contained devices) should be maintained in sealed protective packages and be cleaned and inspected after each use.

As appropriate, *surveillance* of work area conditions and the degree of employee exposure or stress (combination of environmental conditions, work rate, and physiologic, and psychologic, burdens) should be maintained. Changes in work practices, operating conditions, and atmospheric conditions may influence

TABLE 4

COMPONENTS OF A MINIMALLY ACCEPTABLE PROGRAM*

- Written Standard Operating Procedures
- Selection of Respirators
- Training of Personnel
- Maintenance of Equipment
- Storage of Equipment
- Inspection of Equipment
- Exposure Monitoring/Surveillance
- Program Analysis/Evaluation
- Employee Medical Examination
- Use of Respirators (Approved/Certified)
- Cleaning and Disinfection of Respirators

* This table is based on the OSHA requirements of 29 CFR 1910.134.

the concentration of a hazardous substance in the work area. Monitoring the activities and the air contaminant concentration of contaminants should continue until it is assured that the contaminant exposure has not risen above the maximal protective capability of the respirators being used (3).

In addition, in confined spaces and/or in areas where communication is impaired and/or some other life- or health-threatening situation exists, precautions must be taken so that in the event of an accident, one person will be unaffected and have the proper rescue equipment to assist the others in the hazardous/emergency situation (3).

Periodic (at least annual) **program evaluation** should be completed and the written operating procedures modified as necessary to reflect the evaluation results. Respirator use is only one part of a worker protection program, and any evidence of overexposure should be followed to determine why inadequate protection existed, and actions should be taken immediately to remedy the situation.

Employees should not be assigned tasks requiring respirators unless it has been determined that they are physically able to perform the work and use the equipment. **Medical evaluation** is discussed later in this document. The respirator user's medical status should be reviewed periodically (e.g., annually). Respirator users should be included in medical surveillance programs as appropriate to detect effects of exposure.

Regulatory Aspects

Several U.S. agencies and standard-setting bodies regulate or propose professional standards for respirator use. The three principal agencies are the National Institute for Occupational Safety and Health (NIOSH) of the Department of Health and Human Services, Mine Safety and Health Administration (MSHA) of the Department of Labor, and the Occupational Safety and Health Administration (OSHA) of the Department of Labor. The Nuclear Regulatory Commission (NRC) has standards for respiratory protection against radioactive agents.

NIOSH has the responsibility for developing and promulgating certification tests and requirements for personal protective devices and industrial hazard-measuring instruments, certifying and testing these products, preparing a list of certified products, (6), and developing new test methods and requirements for respiratory protection products (1) (OSHA 42 CF 86). OSHA regulations governing the use of respirators in general industry may be found in CFR 29 1910.134. In addition, OSHA standards dealing with specific agents place specific requirements on respirator use.

The American National Standards Institute (ANSI) (5, 7, 8) and the National Fire Protection Association (NFPA) are voluntary organizations that propose standards for respirator design and use. Illustrative references to regulations and voluntary standards are shown in Tables 1-3.

Physician's Role

Physicians and other clinical professionals play significant roles in respiratory protection programs. The roles of physician in a respiratory protection program include the following.

1. **Assess information provided by the employer about exposures.** The employer should document in writing all relevant aspects of potential hazardous exposures and specific job duties. This should contain recommendations of a consulting certified industrial hygienist (CIH) when available. There may be occasions where it will be appropriate for this material to contain environmental and other monitoring data. It is not the primary responsibility of the physician whose sole role is that of medical certifier for respirator use to identify the need for respiratory protection or identify the appropriate type of respiratory protection. These are the responsibilities

of the employer. However, the medical certifier should endeavor to assure that this has been accomplished.

2. **Perform or review medical evaluations.** Medical evaluation for the ability to use respirators is required. Although a physical examination is traditionally performed, other methods may be appropriate; this is discussed subsequently. The physician must be in direct "supervision" of the program. The definition of "supervision" includes the organization of the medical aspects for consultation about specific workers and specific situations, as well as regular review of the work of paramedical personnel and/or questionnaires.
3. **Identify workers requiring medical certification.** In conjunction with the employer, the physician must determine who needs to be certified for respiratory protection. In addition to the obvious potentially exposed workers, one must also consider workers in training and nonworkers such as outside inspectors, contractors, visitors, and others.
4. **Use good medical judgment and knowledge.** The physician must use personal knowledge judgment about underlying acute and/or chronic diseases, particularly those related to the heart and lungs. The physician should be aware of the adverse effects of respiratory protection. These are discussed later in this document.
5. **Maintain ethical principles.** The physician should be aware of ethical concerns, particularly those relating to what medical information about the worker can be revealed to the employer. Generally, the physician should only communicate to the employer the worker's fitness for respirator use. Specific reasons for failure to achieve fitness for respirator use are generally confidential and should not be provided to the employer, e.g., the ethics statement of the American College of Occupational and Environmental Medicine (ACOEM) and the Americans with Disabilities Act (ADA) provide guidelines for information release).
6. **Evaluate medical problems.** Because the respiratory certification examination may be the only time that the worker comes into contact with a medical professional, appropriate further evaluation and referral for detected medical problems should be done.
7. **Relate to the overall medical surveillance program.** Although the respiratory protection program is a separate function from medical surveillance, in practice, information obtained as a part of the respiratory certification program often will be used as part of an overall surveillance program. Therefore, the data should be obtained, recorded, and stored in such a way as to be usable, not only for the ongoing respiratory protection program in that overall deteriorates in respiratory function, epidemiologically significant complaints, and/or sentinel events may be the initial clue for the physician to evaluate the effectiveness of the respiratory protection program.
8. **Periodically evaluate program.** There should be an ongoing analysis and reevaluation of the respiratory protection program, through both informal and formal audit procedures. Again, this may be combined with the epidemiologic evaluation of data from a wider surveillance program.
9. **Other roles.** Physicians with particular training and experience in occupational medicine may accept broader responsibilities such as assessing exposures and attendant risks.

Use in Nonoccupational Settings

Although respirators are used primarily in the occupational setting, they may occasionally be employed elsewhere. Even though there may be no regulatory mandate, physicians should assure that proper selection, training, and maintenance will be performed. Therefore, physicians should carefully counsel patients using respirators about their limitations and the need for proper use.

The hazards leading to some nonoccupational uses are comparable with occupational use. For example, respiratory protection is needed for some hobbies such as stained glass making (lead exposure), some pottery work (silica exposure), and the spray painting. Furthermore, in agricultural settings, family members may need respiratory protection. Choice of respirators requires specific expertise. Some physicians may wish to provide such advice.

Many hobbies (e.g., workshop) generate large amounts of dust, usually of large particle size. If the dust is relatively inert, the hobbyist may utilize a single-use dust respirator or a single-use dust-mist mask if low concentrations of mist (e.g., nonisocyanate spray paint) are present. A full respiratory protection program is not needed when used only for nuisance control purposes in a nonoccupational setting. Some respirators sold for general use are not approved by NIOSH and are not appropriate for occupational settings.

Respirators are also used in military operations for protection against possible chemical, biologic, and nuclear (CBN) attack. The military services have developed extensive internal programs for active-duty personnel. However, protection may also be offered to civilian populations when a threat exists. There is inadequate experience with such efforts, which would require respirator use by children, the aged, and persons with cardiorespiratory disease. Perhaps the most extensive recent civilian use was during the recent Gulf War when the Israeli general population used respiratory protection. Although there have been no formal reports, there did not appear to have been major adverse effects.

Respirators have also been suggested for use by patients. In mildly oxygen-deficient atmospheres (e.g., commercial aircraft cabins during flight), supplemental oxygen may be employed by patients with COPD. Respirators have also been suggested for use by asthmatics. Respirators for patients' use should be employed only when the hazard level is well understood. It is essential to counsel patients about the limitations of the protection provided.

Physicians should not "prescribe" respirator use by patients without full understanding of the hazard and the protective efficacy of the respirator. Furthermore, if an employer allows a worker to use a physician-prescribed or self-purchased respirator at work, the U.S. employer is obligated to have a complete respirator program, including training, maintenance, and audit. Therefore, the suggestion to use a respirator at work, even if based upon one patient's unique clinical features, must be coordinated with the work-site employer.

II. RESPIRATOR SELECTION

The appropriate use of respirators requires understanding of inhalation exposures. Respirable hazards are associated with the cutting oils employed in manufacturing, aeroallergens released in agriculture, laser plumes generated in the operating room, and drug-resistant mycobacteria. For many chemical substances and physical agents, choosing a level of personal respiratory protection can be aided by available reference values—the threshold limit values (TLV) issued by the ACGIH (American Conference of Government Industrial Hygienists) or the permissible exposure limits (PEL) issued by OSHA. NIOSH provides Recommended Exposure Limits (RELs) for many agents. For many airborne infectious agents, the concept of a reference level is difficult since, in principle, a single inhaled infectious agent can replicate in the host, and the sources of infectious aerosols are often mobile and unsuspected.

Respiratory protection program planning must be based on the assessment of the likelihood of disease, which depends both on the dose received and on the susceptibility of the person exposed. Susceptibility may be influenced by both inherent charac-

teristics of the exposed person and by interactions with other environmental agents.

Exposure is determined by the concentration of the agent in inhaled air and the duration of inhalation of the contaminated air. The same cumulative exposure may thus be achieved by various combinations of concentration and duration; however, from a biologic perspective, short-term peaks of exposure may have different effects from longer and sustained exposures that yield the same cumulative exposure. **Dose** refers to the quantity of the environmental agent delivered to target and uptake sites in the lung; dose may be considered at a range of levels from gross anatomic regions to target sites at the molecular level. Dose and exposure are not necessarily equivalent for inhaled particles and gases. At a particular exposure, the dose may differ with the levels of ventilation, the partitioning of breathing between oral and nasal routes, and the physical interactions among the contaminants in the inhaled air. **Retention** describes the portion of the inhaled material that is not exhaled.

Thus, respirator use decisions should not be based upon rote reliance on promulgated governmental standards (e.g., PELs), which typically consider only air levels (exposures) rather than dose or susceptibility. Rather, air levels per se can only be considered a first approximation of the level of protection needed. The following section discusses other factors affecting risk and the need for respiratory protection from a mechanistic perspective

Mechanisms of Deposition and Uptake

The respiratory tract is divided into three major regions: the upper respiratory tract, including the nose, mouth, nasopharynx, oropharynx, epiglottis, and larynx; the tracheobronchial region of the lower respiratory tract, including the conducting airways from the trachea through the terminal bronchioles; and the pulmonary region, including the respiratory bronchioles, alveolar ducts, alveolar sacs, and alveoli.

The upper respiratory tract is important for two reasons. First, it is a potential site of injury. Second, the uptake efficiency of the upper respiratory tract for various inhaled agents affects the dosimetry of inhaled agents to the lower respiratory tract zones. The nose often possesses different uptake efficiencies for toxic agents than does the mouth. During quiet breathing most persons (termed normal augmenters) breathe through their nose, though some people (referred to as mouth breathers), breathe oronasally even at rest. When work loads generate minute ventilation greater than 35 L/min, normal augmenters shift to **pronasal** breathing. During oronasal breathing, approximately 45 to 60% of inspired flow is through the oral pathway (9, 10).

The uptake of **gases** is a function of the reactivity and solubility (aqueous and lipid) of the gas, the breathing pattern, and the mode of breathing (nasal or oronasal). A highly soluble gas such as SO₂ is absorbed very rapidly in the liquid lining of the respiratory tract. During nasal breathing a low concentration of SO₂ is almost entirely removed by the nose and nasopharynx. The mouth is a less efficient absorber of SO₂, thus allowing SO₂ to penetrate into the tracheobronchial region, where it is rapidly absorbed in the larger airways and does not penetrate into the deep lung. Ozone, on the other hand, is not soluble but is very reactive. Consequently, it easily penetrates beyond the upper respiratory tract (11) and reacts very rapidly with the liquid lining of the lung in the gas diffusion region of the lung, leading to virtually 100% uptake efficiency in the pulmonary region (12). Some gases such as various volatile organic compounds can be absorbed by the blood and distributed to other systemic organs such as the liver where they may be metabolized.

Increased minute ventilation, which might occur in work situations, generally will lead to greater doses (product of minute ventilation and concentration) of inhaled substances. The **physicochemical** properties of a specific substance, however, determine

how the delivered dose is affected by increased minute ventilation associated with increased work levels. For example, for compounds such as ozone that react strongly with lung tissue and fluid, increasing minute ventilation can shift the regional dose of the substance to more peripheral structures of the lung (e.g., from small airways to terminal and respiratory bronchioles), thereby potentially placing the lung at greater risk than a comparable exposed dose at rest.

Different principles apply to spherical particles and fibers (13). Spherical, nonhygroscopic particles deposit in the respiratory tract by three principal mechanisms: inertial impaction, gravitational sedimentation, and **Brownian** diffusion. Inertial impaction occurs when particles entrained in air flowing through a tube slip across velocity streamlines. Such a situation occurs when streamlines change direction, for example, at a bend in an airway or at an airway bifurcation. Deposition occurs when the slipping particles collide with an airway wall. Gravitational sedimentation occurs when a particle settles out of an air stream because of the force of gravity. The probability of deposition depends on the particle aerodynamic diameter. The probability of deposition by inertial impaction increases with residence time. For particle diameters greater than 0.5 μm , sedimentation and impaction are the primary deposition mechanisms. In the upper and the tracheo-bronchial regions, impaction is the primary mechanism, with deposition probability increasing as inspiratory flow increases. In the pulmonary region, gravitational sedimentation is the principal mechanism of particle deposition, with deposition probability increasing with increasing residence time (i.e., decreasing flow). For particles less than 0.5 μm in diameter, impaction and sedimentation are less important, and **Brownian** diffusion becomes a dominant mechanism. Deposition by diffusion depends on particle diameter: smaller particles diffuse more rapidly. Diffusion probability is also increased with increasing residence time. As particles decrease in size (< 0.01 μm) they begin to behave more and more like a highly reactive gas. They diffuse relatively rapidly toward the airway walls, and after deposition do not come back out into the air stream.

Deposition of small particles (< 0.5 μm) can be enhanced by electrostatic forces. Surface charges on particles can induce image charges on airway surfaces, resulting in coulomb attraction of the particles to the airways. This mechanism could be important in occupational settings where mechanical processes responsible for aerosol generation can cause a large charge build-up on particles.

Other considerations affect the deposition of hygroscopic particles. Because of the warm moist environment of the respiratory tract, hygroscopic particles can change their size. Ferron and colleagues (14) studied the minimum particle size for deposition in the respiratory tract shifts from 0.5 μm (for a nonhygroscopic aerosol) down to 0.2 μm . Another effect is an increase in total deposition of an initially dry hygroscopic aerosol compared with a nonhygroscopic aerosol for particle sizes > 0.2 μm . For a 1-urn dry **NaCl** aerosol, total deposition is 80% compared with 20% for the same sized nonhygroscopic aerosol.

Fibers present a more complex picture of deposition. Lippman (15) has extensively reviewed asbestos fiber deposition characteristics. In addition to the mechanisms discussed above for deposition of spherical particles, fibers can also deposit by interception. In the discussion above it was assumed that an aerosol particle deposits when its center of mass intersects an airway wall. Because fibers have a greater geometrical extent in their long dimension, the end of a fiber may come in contact with an airway wall without the center of mass being near the airway wall. Clearly, the longer the fiber, the higher the probability of deposition by interception. Furthermore, deposition by interception is enhanced by **nonsymmetrical** fibers or fiber agglomerates. Symmetrical fibers (i.e., **cylindrical** fibers) tend to align with the flow axis, thus

presenting the smallest dimension capable of intercepting an airway wall. A nonsymmetrical fiber, on the other hand, may not be aligned with the flow axis and therefore present a larger dimension for interception, with a resultant higher deposition probability. Secondary flows generated at airway bifurcations also tend to enhance deposition by disrupting the alignment of fibers with the flow axis. As with spherical particles, fibers can have significant surface charges that can lead to deposition by **electrostatic** image forces. Asbestos fibers may have enough surface charge because of mechanical fiber processing that deposition can be affected (16).

Bioaerosols are pollutants that result from microorganisms and other biologic sources. To be of biologic importance as a pollutant, materials must be either volatile or be of a sufficiently small size that they can become an aerosol. Bioaerosols exhibit complex behavior, including diffusion and coagulation with one another to form larger particles. The behavior is dependent on a variety of forces, including **Brownian** motion, thermal, electrical, molecular, gravitational, and acoustic forces. Regardless of their makeup, however, bioaerosols are believed to behave like other airborne particles with similar aerodynamic properties.

Many bioaerosols are not stable in size, rapidly dehydrating in relatively dry atmospheres to much smaller particles, sometimes coalescing with other particles when concentrated, or growing in size under humid conditions. Very large particles settle rapidly onto surfaces, or impact on surfaces because of their inertia. Although particles 10 to 50 μm in diameter can remain airborne long enough to be inhaled, they are entirely filtered by the upper respiratory tract, causing symptoms when the upper respiratory tract is vulnerable. Particles in the range of 1 to 5 μm have a negligible settling tendency, allowing wide airborne transmission, and a sizable fraction to penetrate the upper respiratory defenses, potentially causing lower respiratory illnesses such as hypersensitivity pneumonitis or tuberculosis.

Bioaerosols may be infectious or noninfectious. For those containing infectious organisms, characterization may be either by physical characteristics (e.g., particle counts) or by biologic measures of infectivity. A higher level of protection is needed for a more virulent organism or for an agent for which the infective dose is small.

In **summary**, the use of respirators should be based upon understanding of factors affecting risk and hence the need for protection. Concentration, duration of exposure, particle/gas physical characteristics, and ventilatory pattern all affect the actual dose.

Selection of Respirator

If respirator use is needed, the proper one should be chosen on the basis of the nature of the hazard, the duration of exposure, and characteristics of the user. Selection of respirators should proceed sequentially as shown in Table 5.

There are several major classes of respirators. They may be categorized in several ways.

1. Method of Providing Air with Reduced Contaminant Levels.
 - (1) **Air-purifying Respirators** remove much of the **toxicant** from the inhaled air by filtration, adsorption, or absorption. The air may be drawn through the **filter/sorbent** in two ways: **negative-pressure respirator** (the user sucks air through it) and **powered air-purifying respirator** (PAPR) (a fan unit blows air through it). (2) **Atmosphere-supplying respirators** (provides air from an independent source rather than purifying ambient air). There are two types: **self-contained breathing apparatus** (SCBA) supplies air from a source, e.g., a tank carried by the user and generally worn on the back and **airline respirator** (the air is supplied via a hose from a source at a distance).

TABLE 5
RESPIRATOR SELECTION

-
1. Assess exposure
 - Agent, effect
 - Levels
 - Duration and frequency
 2. Determine if there are control measures that are preferable to respirator use
 3. Determine level of protection needed based upon exposure levels and reference values
 4. Identify any special circumstances (e.g., poor warning property of agent, IDLH atmosphere)
 5. Choose acceptable respirator types that can provide an adequate protection factor
 6. Assure that a full respiratory protection program is in place
 7. Consider personal characteristics of users.
-

2. Facial Connection and Mask Size. (1) *Tight fitting*: Nearly all respirators require a tight seal between the mask and the user's face. Mask types are characterized as *quarter*, *half*, or *full* depending on the portion of the face that is covered. The mask type (size) is the major determinant of the leakage that occurs at the mask's facial seal surface and the protection factor afforded by the respirator. Full face masks are most protective. (2) *Loose fitting*: Respirators of this type do not require a tight facial seal but rather depend on airflow to limit inhalation of toxic agents. Helmet hoods, commonly used in sandblasting, are examples of this type. (3) *Mouthpiece only*: A small number of respirators used for very brief periods for emergency escape require that the user employ a mouthpiece.
3. Pressure Mode. Most devices are negative-pressure devices in which the pressure within the face piece becomes negative relative to the atmosphere during inhalation. Some atmosphere-supplying respirators may be used in the positive pressure mode, which seeks to maintain a positive pressure throughout the respiratory cycle to reduce the possibility of any facial seal leak leading to inhalation of toxic material. Powered air-purifying respirators (**PAPRs**) are air-purifying respirators that may provide some additional protection because a fan unit rather than negative pressure generated by the user provides airflow into the mask.

Selecting a respirator requires detailed information on the toxic agents involved, legal requirements of governmental agencies, the degree of risk, frequency of exposure, and personal factors (4). Although these considerations do not alter the underlying principles of filtration efficiency and face seal required for personal respiratory protection, they may greatly alter the overall benefit of a respirator program. The NIOSH Respirator Decision Logic manual (17) provides general guidance in a systematic manner.

There are special considerations when a respirator is to be used in an immediately dangerous to life and health (IDLH) atmosphere. Very high levels of protection must be afforded. An IDLH exposure situation is defined as one that poses "an immediate threat to life or health or conditions that pose an immediate threat of severe exposure to contaminants such as radioactive materials, which are likely to have adverse cumulative or delayed effects on health!" (18). It thus may include situations with exposure to high concentrations of immediately toxic materials (e.g., cyanides), carcinogens, very hypoxic atmospheres, or agents leading to incoordination and disorientation. When the situation is IDLH because of extremely toxic materials (rather than a hypoxic environment), this generally requires an atmosphere-supplying respirator operated in a positive-pressure mode. An auxiliary air supply is generally made available to allow escape if the primary air supply fails (e.g., a user of an airline posi-

tive-pressure respirator should also have a small **airtank** immediately available for use if the airline hose fails).

Typically, in a situation immediately dangerous to life or health because of oxygen deficiency, a positive-pressure self-contained breathing apparatus (SCBA) or a combination positive-pressure supplied-air respirator and auxiliary self-contained air supply may be used. A full face mask is requisite when the situation is IDLH because of toxic materials. When used for escape only from an IDLH atmosphere any positive-pressure SCBA or a combination positive-pressure supplied air respirator with escape SCBA (smaller air supply) may be used.

The warning properties of the exposure agent must also be considered, particularly for use of cartridge and **cannister** respirators. Some agents can be detected by smell or irritation, whereas others cannot. If saturation of the sorbent occurs with **subsequent** breakthrough of the agent, the user may be significantly exposed if the agent has poor warning properties. Thus, a higher degree of protection is generally required for exposure agents with poor warning properties.

Degree of Protection Afforded by Respirator

The degree of "protection" offered by a respirator depends on two factors: (1) the efficiency of the collection device in removing the contaminant from the outside air, and (2) the efficiency of the respirator in preventing leaks through the face piece (through the seal to the face and through other respirator elements such as valves). For most respirators, the more important influence on the protection offered by a respirator is its ability to prevent face piece leaks (the "fit" of a respirator).

In the past, differences in respirator "protection" have been addressed with the use of a "protection factor" (PF), which reflects a respirator's ability to reduce the contaminant concentration for the wearer. The "protection factor" has been defined as the ratio of the contaminant concentration outside the respirator to the contaminant concentration inside the face piece. Thus, a protection factor of 10 means that the concentration inside the mask is one-tenth that outside. To determine the maximum concentration at which a particular class of respirators may be worn, the protection factor is multiplied by the appropriate occupational exposure limit (e.g., TLV, PEL, or REL).

There are a variety of protection factors that differ in the manner in which protection is derived. For the purposes of this document, the most important of these are the "fit factor" (FF) and the "assigned protection factor" (APF). The fit factor represents a specific person's protection derived from a fit test (described further on in this document). There are qualitative fit factors and quantitative fit factors derived from qualitative and quantitative fit tests, respectively.

An "assigned protection factor" is defined by the American National Standards Institute (ANSI) as "the expected workplace level" of respiratory protection that would be provided by a properly functioning respirator or class of respirators to properly fitted and trained users." (ANSI 288.2, 1992) (19). In other words, an assigned protection factor represents the protection *expected* for a particular type of respirator when it is worn by workers, who have been fitted and trained in its use. The APF may be derived from studies of respirators worn in workplace situations or in laboratories; from "professional judgment" is used if data are lacking about a particular respirator's performance. Today it is generally accepted that workplace studies of "protection" provide the most representative data for determination of an assigned protection factor.

The actual values of respirator **APFs** are controversial for several reasons. Studies have shown that little correlation exists between "protection factors" measured in a laboratory setting (fit factors) and protection factors measured in workplace settings, usually referred to as workplace protection factors (WPF). The

reasons for this lack of correlation are not clear, but they are probably related to the differences in how fit factors and **WPFs** are measured. The latter usually involves 8-h measurements of inside and outside face-piece concentrations, whereas the former is derived from very short measurements (on the order of minutes) taken while the wearer performs specific "exercises." In addition, **APF** values are controversial because the data from which they are derived often show considerable interindividual and **intraindividual** variability.

There are several reference sources about **APFs**. In 1995, NIOSH used the standard protection factors and assigned them to new classes of respirators as defined in a proposed criteria document (60 CFN 30338).

The 1992 ANSI 288.2 standard, considered by many to be the most up to date, sets **APF** values for the various respirator classes. These **APFs** were determined by reference to data from workplace protection factor (**WPF**) studies only. There are other **APF** values (OSHA and NIOSH, for example); many are based on older data. In the case of OSHA, each of the substance-specific standards (e.g., cotton dust, asbestos, benzene, etc.) contains a description of respiratory protection requirements based on certain **APF** values. There is considerable variability in the actual **APF** values used in each of these standards, so the specific OSHA standard should be consulted if exposure is to one of these substances. For exposure to other materials one must use "professional judgment," which usually means the use of tables developed by ANSI or NIOSH. It is important to note that the committee that produced the latest ANSI standard recognizes that even its **APF** values may not be the "best" ones possible. In an Annex to the ANSI standard it is noted that research is still needed on the method of assigning a protection factor to a respirator class and that more data are needed for selecting **APF** values.

Qualitative and Quantitative Fit Testing

Fit testing measures the fit for a specific worker. After selecting a respirator (wearers should be given a choice of several sizes from several manufacturers), donning it for at least 10 min (to assure its comfort), and performing fit checks (as described in the manufacturer's instructions), qualitative (or quantitative) fit testing should then be performed. During these tests a set of exercises is performed, which may include (for tight-fitting face pieces) actions such as breathing normally, breathing deeply, turning head from side to side, moving head up and down, talking (generally using standardized statements), breathing normally.

There are qualitative or quantitative fit-test procedures. Qualitative fit tests use test agents that elicit a response from the wearer (i.e., taste, smell, or irritation). If the wearer detects the agent during the test, the respirator does not fit properly.

For qualitative fit tests, two protocols have been suggested by ANSI, one using isoamyl acetate (using respirators equipped with organic vapor cartridges) and the other using saccharin mist (using respirators equipped with filters). In the near future, **Bitrex** may replace saccharin for qualitative fit testing. For detailed descriptions of these protocols see the AIHA Manual (20). A third protocol has been suggested by NIOSH using irritant smoke for testing **HEPA** respirators; such tests should be carried out in an appropriate hood system or in a negative pressure room.

Quantitative fit tests measure mass or number concentrations of the test agent inside and outside a respirator while it is worn. Older systems employed a generated aerosol of sodium chloride or oil mist (dioctyl phthalate), whereas newer systems measure concentrations of ambient aerosols. Particulate and gas and vapor air-purifying respirators (previously certified under 30 CFR 11) are tested with **HEPA** filters in place to assure that the measurement reflects the "fit" of the respirator rather than the behavior developed; until then it is recommended that the protocols

described in the AIHA respiratory protection manual be followed (20).

In view of the variability of protection factor data, it is general practice to use a "cutoff," which is 10 times greater than the **APF** for the respirator when performing quantitative fit testing for an individual respirator wearer in order to assure adequate protection. Qualitative fit tests have only been validated for use in determining fit factors up to 100, which means they can only be used for **APFs** ≤ 10 . Thus, a qualitative fit test may only be used to evaluate the protection of disposable (**HEPA**) and quarter- or half-face-piece elastomeric face-piece-negative pressure respirators.

For any respirator with **APF** greater than 10, a quantitative fit test must be used to determine if the respirator fits properly. Positive-pressure respirators (types designed to maintain the pressure within the mask at a positive pressure to the outside in order to minimize inward leaks) are generally tested in the **negative-pressure** mode using a fit factor of 100 (corresponding to an **APF** of 10). This is considered the worst case situation for such respirators (i.e., when the positive-pressure mode fails and the wearer must fall back on using the respirator in its negative-pressure mode).

Disposable respirators are considered acceptable by OSHA except in asbestos-exposure situations. In the cotton dust standard OSHA gives disposable respirators a protection factor of 5, based on data developed for disposable dust/mist respirators ANSI has assigned a protection factor of 10 to disposable respirators, based on data developed using disposable **HEPA** filters, which should be more representative of the face-piece fit of the respirator. There are at present no fully validated protocols for qualitative fit tests of disposable dust/mist respirators. For quantitative fit testing a Large Particle Quantitative Fit Test has been developed that employs a large diameter (2 to 2.5 μm) oil as a challenge aerosol. This particle size should undergo little or no penetration through dust/mist filters but should experience leakage through a respirator face-piece seal.

Although tight-fitting face pieces can experience leakage at any point around the face piece, some points are more vulnerable to leakage than are others. Negative-pressure air-purifying, half-face-piece respirators are most likely to leak around the nose and under the chin. Full-face-piece respirators are most likely to leak under the chin. The latter respirator class carries an **APF** 10 times higher than the former, largely because it is easier to fit a face piece to the forehead than around the nose.

Worker Acceptance

Some respirators are considered more "acceptable" than others by workers. Disposable respirators are the most acceptable to workers, probably because they place so little stress on the wearer and do not require maintenance, **cleaning**, or storage. When greater protection is required, however, one must consider that tight-fitting faces pieces quickly become very uncomfortable as heat and humidity build up in the face piece. Powered air-purifying respirators are often considerably more comfortable because and constantly blowing air helps cool the face. These respirators are becoming more widely used because of their greater acceptance by workers.

Airline respirators are generally well accepted by workers, but they have the significant disadvantage of tying the worker to an air hose. Depending upon the type of work being performed, this can become a serious problem. A self-contained breathing apparatus has the advantage of freeing the worker from an air hose, but the physiologic demands of such protection are considerable. The issue of worker acceptance should be considered in tandem with the work requirements as well as the other types of personal protection required. Full-body suits add much additional stress when the work is strenuous or the environmental

conditions create severe temperature of humidity situations within the suit.

The degree to which use of a respirator interferes with work performance should be considered. For example, respirators may interfere with mobility, ability to communicate, or use of tools such as stethoscopes.

Role of Respirators in Exposure Control for Bioaerosols

The hierarchy of controls for occupational hazards applies as well to bioaerosol exposures, except perhaps for the substitution of less hazardous materials. Although respirator use may play a significant role, it is generally not the primary means of controlling exposure. Respirators can be more effective when the source of exposure may be clearly and consistently identified (eg., animal handling facility, bronchoscopy on patients with suspected tuberculosis) than when the source is poorly identified (eg., patients with unsuspected tuberculosis in general medical settings).

Sources of bioaerosols can sometimes be identified and eliminated, as by treatment of an infectious case of tuberculosis or the removal of a source of **fungal** spores in a building's ventilation system. Administrative interventions can be used effectively; for example, limit access of staff to animal quarters to avoid hypersensitivity reactions to animal proteins. When necessary, environmental control measures can be effective in reducing exposure when sources cannot be entirely eliminated. Isolation, dilution, and removal through ventilation and filtration are the standard engineering approaches to controlling airborne hazards, including many bioaerosols. For a variety of infectious agents it is also possible to accelerate inactivation through ultraviolet irradiation in rooms and ventilation ducts. For high risk exposures where no control measures achieve satisfactory protection, personal respiratory protection may be indicated. However, to the extent that exposure to infectious diseases may be unpredictable, from unsuspected source cases for example, even personal respirators will not necessarily provide complete protection however good their filtration properties and face fit. The use of respirators in nontraditional settings such as health care institutions also requires the acceptance of wearers, patients, and bystanders.

The powered air-purifying respirator (PAPR) with a **HEPA** filter probably affords the best protection from a tuberculosis exposure; but at several hundred dollars per unit, it is not economically feasible for all uses. It may also be less acceptable (hood ensemble and power pack) than a particulate respirator. PAPR with **HEPA** is a prudent choice, especially when performing high hazard procedures such as bronchoscopy on a patient with known or suspected tuberculosis.

The new **N95** classification defines the minimal acceptable performance characteristics for particulate respirators. This redefinition will make provision of respiratory protection more economically feasible.

Although disposable respirators used by health care personnel need not be discarded after each patient, they should be replaced periodically, when deformed to prevent adequate fit, if soiled or splashed with body fluids, known **formite** transmission, or in other circumstances that may be defined by local infection control committees.

If used with other controls as intended, respirators can be practical from the perspective of patients, personnel, and administrators without compromising worker safety. To the extent that diagnosis, treatment, administrative controls, and effective environmental precautions substantially reduce the relatively low risk of transmission from known and suspected cases of tuberculosis, respirators may add only marginally to worker protection in many settings. The cost effectiveness of individual interventions to prevent tuberculosis infections should be assessed for institutions at different levels of risk in the context of other risk and safety expenditures. A range of respirator options should

be available. For extremely high risk situations, for example, performing bronchoscopies or autopsies on patients with suspected multiple-drug-resistant (MDR) tuberculosis or other potentially fatal infections, positive-pressure respirators (air line or powered air-purifying respirators) may be warranted.

III. WORKER MEDICAL ASSESSMENT

Respirator Effects

Designed to protect the worker from airborne hazards, respirators themselves create a number of potentially adverse effects that should be understood by physicians involved in their use. These physiologic and psychologic effects have been reviewed by several investigators (21-27), and they are summarized here.

Physiologic Aspects

Increases in resistance to breathing, dead space, and physical load can all come about from the wearing of a respirator. The increased resistance to inspiratory and expiratory flow that a respirator imposes can cause an increase in tidal volume, a decrease in breathing frequency, and a decrease in minute ventilation, with a concomitant decrease in alveolar ventilation (28-30). In respirators certified by NIOSH (31) these effects have been shown to be small and generally well tolerated in both healthy individuals and in persons with impaired lung function (31-38). The increased dead space of a respirator tends to increase minute ventilation because of the rebreathing of expired air that occurs. This added stress, although variable depending on the type of respirator and the individual, is usually not limiting (26, 39, 40).

During submaximal exercise the effects on work performance from wearing most respirators seem to be small. When submaximal work load was held constant, several studies showed that heart rate did not appear to be affected by a respirator (32, 36, 37, 40-42). However, increased resistances and dead space can lead to decreased (by approximately 10%) maximal work performance (30, 43-46). Heavy self-contained breathing apparatus (which can weigh as much as 40 pounds) can increase the work load of an individual and decrease, therefore, the maximal external work load by 20% or more (43).

Some studies have suggested a potential for adverse respirator effects such as decreased cardiac output from the **positive**-pressure feature of some respirators. These effects, however, do not seem to be of practical concern, at least in healthy persons (41, 47, 48).

Psychological and Psychophysical Aspects

Worker compliance with wearing required respirators has been studied based on direct observation of the amount of time of appropriate use. These studies show that acceptability to workers is a significant factor limiting the ability of respirators to provide protection against inhalation hazards (49). It is for this reason that industrial hygienists generally consider passive protective measures (such as enclosure and ventilation) preferable to the use of these devices.

In the workplace, the discomfort of the device is probably the factor most frequently limiting effective respirator uses. Respirators fitting tightly over the face cause a build-up of moist warm air inside the mask. In a warm environment, this enclosure also slows convection of heat away from the face, the normal cooling process of evaporation from the skin. The wearer's sensory discomfort rises in proportion to the temperature within the mask (50, 51). Even disposable paper respirators lacking exhalation valves can lead to an unacceptable build-up of facial heat.

The discomfort of facial heat may add to the discomfort inherent in wearing other forms of protective equipment such as the ultraviolet light-filtering face masks used by welders or the

vapor-barrier suits frequently used to protect the skin against -exposure during hazardous waste cleanup. The discomfort of respirators' elastic head straps in attaining a sufficiently tight facial seal, pressure on the face, the perception of inspiratory resistance, the feeling of being enclosed, and effects on vision and (in the case of powered and air-supplying respirators, on hearing) may all contribute to a functional inability to keep the respirator on for more than a brief period of time in some persons. This inability is at times associated with panic attacks or claustrophobia.

Impairment of sensory function, quite apart from discomfort, can also be an important factor limiting the ability to use a respirator in specific jobs. In some cases, knowledge of the physical environment and demands of the job is necessary to make a decision about the safety of a particular respirator. Full face respirators with transparent face masks may limit peripheral vision in a way that increases risk for injury in an environment with moving hazards or heavy equipment (52). Other jobs, particularly in construction and heavy industry, rely on speech and hearing either to accomplish the task or to maintain safety; the noise of certain respirators with motors or continuous airflow may limit their use, or their use by some workers in these situations.

Medical Evaluation and Criteria for Medical Certification for Respirator Use

The necessary medical evaluation and criteria for safe use of respiratory protective devices have not been precisely determined. Therefore, clinical judgment must be applied to specific circumstances. However, general guidelines are provided here to assist the certifying physician. As noted in earlier, governmental regulations in the United States often require that a physician must supervise the medical evaluation process, but they generally do not specifically mandate a physical examination.

Although respirators do place additional stresses on the user, with certain exceptions noted below, these stresses are not likely to result in unacceptable risk for persons otherwise medically qualified to perform the work. If the work to be done while wearing the respirator is significantly more strenuous or **anxiety-provoking** than the other components of the worker's job; the medical evaluation must consider the worker's fitness for this activity overall, not just for the ability to tolerate the respirator. Therefore, identification of the essential requirements of work and potential physical, chemical, and biologic **stressors** performed during respirator use is necessary.

Other than inquiring about past tolerance of respirators, no good method of predicting which persons will be unable to tolerate a respirator is currently available. This is one of many reasons why a practical trial of the respirator in the workplace may be necessary before determining that a newly hired or assigned worker can use a respiratory safely and effectively. Although not associated with a particular pathophysiologic diagnosis, true inability to tolerate a particular kind of device may legitimately lead to the need to substitute an alternate and better-tolerated means of protection. However, tolerance to the discomfort caused by all respirators can develop with experience.

Medical certification of individual users should occur in three tiers: (1) primary pre-use certification evaluation, (2) **postcertification** evaluation routinely provided to all users, and (3) careful evaluation of users identified for having potential problems with use.

In addition to evaluating individual users, the evaluating physician should endeavor to assure that there is an **adequate overall respiratory protection program** as described above.

Precertification Evaluation

A screening questionnaire often can provide information on symptoms and known medical conditions that may necessitate

restrictions on respirator use or require further evaluation. Any previous difficulty using respiratory protective devices or worker concerns about the proposed use should be identified and evaluated. Questions about breathlessness with activity, including current work tasks, are relevant. For respirator use in environments immediately dangerous to life (IDLH) and health or for emergency and rescue operations where even brief removal may be hazardous, questions on cough, phlegm, and asthma or episodic wheezing are appropriate. Information concerning known cardiovascular impairment and symptoms suggestive of ischemic heart disease such as exertional chest pain should be obtained for all users.

More detailed questioning is appropriate for use of **SCBAs** and when strenuous exertion or heat stress are part of the proposed working conditions. Identification of musculoskeletal impairments is relevant for SCBA use and for work requiring specific agility, including rescue operations. Queries regarding visual and auditory impairments are needed if these senses are critical for the job and may be diminished by respirator use. However, visual impairment requiring glasses or contact lenses is not an absolute contraindication to respirator use with full face-piece masks. A previous history of or concern about claustrophobia should be elicited, especially for work conditions immediately dangerous to life and health (IDLH). Questions about specific chronic conditions such as diabetes or seizure disorders may also be appropriate for work in IDLH environments. Finally, a question about general health may reveal chronic conditions relevant to specific work situations.

Clinical judgment is needed to determine if a physical examination is necessary. In general it is needed only when information from the questionnaire suggests the presence of a condition for which evaluation will be enhanced by a direct examination. Measurement of blood pressure and pulse is useful as a basic health screen especially for workers with jobs requiring moderate or greater exertion, but this can be done by a qualified individual other than the certifying physician and reported on the questionnaire.

A perforated tympanic membrane is no longer considered a contraindication to work in most environments requiring respiratory protection, so an otoscopic examination is usually not necessary. A direct physical examination may be needed to **evaluate** specific functional impairments such as a limited range of motion of the arms for a worker required to don a respirator for emergency situations. Also, workers required to wear SCBA equipment with strenuous exertion should have a clinical examination if older than 45 yr of age or if any abnormality is detected by the screening questionnaire.

Pulmonary function testing has not been demonstrated to provide sensitive or specific indicators for respirator tolerance or safety. Nevertheless, measurement of ventilatory function by spirometry may often be useful for estimating the worker's overall fitness for the overall physical demands of the work requiring respirator use. For use of **SCBAs** with strenuous exertion, **spirometry** should be considered for those older than 45 yr of age and for any worker reporting respiratory symptoms or abnormalities on the questionnaire. For other situations, spirometry should be strongly considered for those older than 55 yr of age or for any worker reporting respiratory symptoms with the level of exertion required by the work proposed. The level of ventilatory function that ensures safe use of any respirator or for any conditions of work cannot be stated with certainty. However, in the absence of other factors limiting the worker's overall ability to tolerate demands of the job and the respiratory protective equipment, FEV₁ of 60% or greater of the predicted value suggests that a trial of respirator use is allowable. For light duty work using low resistance respirators, even lower levels of function may not be disqualifying, but a more thorough clinical evaluation should be done.

Other laboratory tests of respiratory function are unlikely to provide information that is critical to the ability to predict safe use of a respirator, but clinical judgment must be applied to individual cases. Measurements of maximal oxygen consumption is helpful in assessing overall fitness for strenuous exertion, but it is usually unnecessary for making a determination of whether a trial of respirator use under the proposed work conditions is allowable. If a worker has demonstrated the ability to tolerate the exercise level required on the job without the respirator, formal exercise testing other than to assess the possibility of cardiovascular abnormalities, primarily ischemic heart disease, is generally not of benefit.

Exercise testing for cardiovascular fitness may be necessary for use of **SCBAs**, especially if the work requires strenuous exertion, heat stress will be present, or a clinical indication of a cardiovascular abnormality is present. The use of respirators in conjunction with water-impermeable protective clothing can impose significant thermal stress. Such situations occur in the hazardous waste, nuclear, and other industries. It may also be advisable in the first two situations for workers older than 45 yr of age regardless of clinical status. Resting **ECGs** may be useful if clinically indicated, but by themselves are not predictive of risk from respirator use during exertion.

Other tests may be indicated in special circumstances. Hearing and vision testing should be performed on potential rescue team members if these senses are critical to safety or job performance.

The degree of risk to health resultant from the additional physiologic loads imposed by respirators can be estimated only in general terms. Tolerance may be more dependent on comfort and psychological factors than physiologic changes with important medical consequences. The decision of whether a worker can be authorized for a trial of respirator use must be based on a clinical estimate of the likelihood of an unacceptable medical conse-

quence. In the absence of clear contraindications, it is usually medically reasonable to authorize a trial of use if adequate provisions are made for detecting and evaluating any difficulties the worker may experience. If serious consequences could result from intolerance during a trial period, use of the respirator in simulated rather than actual working conditions may be necessary to determine if a trial in actual conditions should be allowed.

Postcertification Follow-up

Two types of postcertification follow-up are needed: (1) routine follow-up for all users, and (2) detailed assessment of users reporting potential difficulty.

Because fully accurate prediction of tolerance of respirators is not possible, the certifying physician must ensure that a qualified person is overseeing the respiratory protection program and that administrative measures are in place to ensure detection and further evaluation of any difficulties experienced by workers using respirators. Workers should be specifically queried about difficulties after a reasonable trial period and provisions made for reevaluation by the physician if significant difficulties are experienced.

Guidelines for the frequency of periodic reevaluation have been published by several researchers and groups. For younger workers without significant medical problems, reevaluation each 2 yr may be adequate. For older workers or for use of SCBA, yearly reevaluation of users of respirators may be appropriate. Reevaluation for use of air-purifying respirators in non-IDLH conditions may require only an update of the screening questionnaire with further examination if significant changes in symptoms or medical conditions are noted.

Physician Responsibility

The medical evaluation program must be directly supervised by a physician with knowledge of respirator types, effects of respi-

TABLE 6
ELEMENTS OF MEDICAL ASSESSMENT

Pre-use Certification Questionnaire	All users	Physician review Elements include: prior use and tolerance breathlessness asthma cough and sputum (especially if brief mask removal is hazardous) chest pain claustrophobia musculoskeletal symptoms (particularly if heavy device must be used) heat tolerance
Medical examination	Recommended for SCBA users and older workers; optional for others	
Spirometry	Optional	
Exercise testing	Recommended for workers in thermal stress situations with high exertion levels	Must include assessment of cardiac response
Physical agility testing	If needed for job and affected by respirator use (e.g., airline, SCBA)	
Psychologic testing	Not recommended	
Routine Postcertification Assessment Questionnaire	Routinely done	Within 2 mo after initial use; biannually thereafter. Must have a clear plan for follow up of "positive" responses
Medical examination	Recommended for SCBA users and older workers; optional for others	
Spirometry	When clinically indicated	
Evaluation of Users Reporting Difficulty		
Medical examination	Mandatory (must be individualized)	Examiner must understand respirators and workplace exposure factors
Psychologic evaluation	When indicated	
Work-site assessment	Often needed to assess use conditions	

rator use and clinical conditions that may affect work ability and risk. The physician must be responsible for the evaluation of each individual user, not merely serving to establish general policies. General guidelines for medical assessment are shown in Table 6. However, an appropriate program should be developed for each setting, recognizing its specific risks.

IV. RESEARCH NEEDS

Although much is known about respiratory protection, there are major unanswered questions of great import to health protection in occupational and nonoccupational settings.

Exposure characterization is a critical step in selecting appropriate respiratory protection methods. Improved characterization of particle size distribution is needed. Although long-term (e.g., 8-h) average exposure measures are convenient, improved methodology for characterization of short-term exertions is critically needed. Measures of exposure for infectious, toxic, and antigenic bioaerosols need to be improved. (4, 53-58).

Respirator performance must also be studied systematically. Degradation of performance (e.g., because of sorbent saturation) or changes in physiologic effects (e.g., by filter loading) over time needs to be assessed. Appropriate measures of respirator efficiency for a wide array of exposures must be developed. In particular, assessment of protective efficacy against bioaerosols is currently inadequate; methods other than reliance upon particular size per se are needed.

Empiric studies of protection under real life conditions, rather than laboratory settings, must be conducted. Such studies must consider heretofore poorly addressed factors such as compliance, effect on work performance, and cost-benefit analysis as well as the more traditional factors such as face seal leakage. In addition, properly performed studies of methods to improve proper utilization are needed.

Clinically oriented research is needed to assess the use of respirators by persons with particular medical conditions, ranging from respiratory disorders to Axis II psychologic disorders. Studies conducted in healthy volunteers may not be applicable to all users.

Systematic studies of persons who report experiencing adverse tolerance should be conducted. Consensus Conference or other methods should be employed to focus attention on the "secondary" evaluations, considering persons reporting difficulty. Although several review articles address "primary" assessments, the ATS Committee has concluded that no method relying on "primary" evaluation of all users is likely to be adequately predictive of adverse outcomes of respirator use; rather, there is a need for developing methods for detailed assessment of subjects after a period of "trial use." Cohort or public health "sentinel event" studies to identify adverse events should be conducted. Routine systematic surveillance for respirator program failures serve both research and direct public health practice needs. Failures include equipment failures, "user failures" (i.e., adverse impact of use), and occurrence of excess disease (e.g., tuberculosis or lead toxicity) that could have been prevented by respirator use.

Technical improvements in online sensors for breakthrough and leakage would provide valuable methodology to assure protection. Development of end-of-service-life indicators would be of benefit.

Studies of respirator use in nonoccupational settings are also needed. Gradually increasing use in such settings may occur. Catastrophic events, (biologic or chemical warfare, major chemical leaks, or natural events such as earthquakes and volcanoes) also may suddenly mandate widespread use.

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