NATIONAL INDUSTRIAL SAND ASSOCIATION

To the Reader

The *Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry* will be kept current by revising its content as technical advances are made and the knowledge regarding the health effects of silica exposure progresses. When revisions are made, you will be mailed pages for insertion into the manual, and you will be asked to remove the outdated pages. Revised pages will be dated with the month and year of the revision. NISA reserves the right to cease publication and revision of this manual, in which case you will be notified. To receive revised pages, please complete the information below, and mail the bottom portion of this page to:

National Industrial Sand Association
2011 Pennsylvania Avenue, NW, Suite 301
Washington, DC 20006

Phone: (202) 457-0200
Fax: (202) 457-0287

Name _____

Company _____

Address _____

_____

_____

Phone _____

Fax _____

Email _____

OCCUPATIONAL HEALTH PROGRAM FOR EXPOSURE TO CRYSTALLINE SILICA IN THE INDUSTRIAL SAND INDUSTRY

SECOND EDITION, APRIL 2010

NATIONAL INDUSTRIAL SAND ASSOCIATION

2011 PENNSYLVANIA AVENUE, NW, SUITE 301
WASHINGTON, DC 20006

National Industrial Sand Association
2011 Pennsylvania Avenue, NW, Suite 301
Washington, DC 20006
Telephone: (202) 457-0200
Email: info@sand.org
Website: www.sand.org

This edition is a major revision of the "Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry," First Edition, Copyright © 1997 by the National Industrial Sand Association, Inc.

IMPORTANT INFORMATION—READ THIS FIRST

This manual is not intended to satisfy or to be a substitute for the safety and health requirements of federal, state, or local regulatory agencies. Appropriate regulations and laws should be consulted and followed. The program described in this manual has been developed to meet the specific needs and challenges of the industrial sand industry for surveillance of exposure to crystalline silica. It is not intended to be an occupational health program (OHP) for exposure to crystalline silica in other industries, since parts of this program may not be well suited to other industries and elements of an appropriate program specifically aimed at another industry may not be included in this program.

The scope of this program is purposely limited to surveillance of exposure to respirable crystalline silica. It does not address the corrective measures, such as engineering and administrative controls, that are necessary when exposures approach or exceed acceptable limits. The National Industrial Sand Association (NISA) has prepared for its member companies other information sources on control measures applicable to the industrial sand industry, which supplement this manual. In addition to the assessment of crystalline exposure and medical assessment of silicosis covered in this manual, the other elements of the NISA Silicosis Prevention Program include: commitment of the member company to the program and the goal of eliminating silicosis, control of exposures through engineering and administrative measures or the use of personal protective equipment, involvement of workers in the prevention aspects of the program, and implementing a smoking cessation program as part of an inclusive respiratory program to prevent smoking-related lung diseases. More importantly, the environmental and medical programs described in this manual must not be considered total programs. Other stresses

such as noise, heat, radiation, non-silica-bearing dusts, chemical contaminants, and other site-specific conditions, although obvious elements of a total occupational health program, are beyond the intended coverage of this program.

CONTENTS

PREFACE

This manual provides guidelines by which National Industrial Sand Association (NISA) member companies can monitor occupational exposures and associated respiratory health effects of crystalline silica exposure.

The program consists of the following basic components:

- Job placement health evaluations for respiratory status.
- Periodic respiratory health evaluations.
- Workplace dust exposure monitoring.
- Integration of exposure and medical findings.

This manual provides guidelines by which NISA member companies can engage in monitoring of silica exposures and medical surveillance of their employees both to control exposure to respirable crystalline silica and to provide a data base for future epidemiological studies. The guidance included in this manual reflects the recommendations of health research organizations such as the American Thoracic Society (ATS) and the National Institute for Occupational Safety and Health (NIOSH) and regulatory agencies such as the Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA). This guidance is provided to assist member companies in designing a program to meet the elements of assessment of silica exposure and medical assessment of silicosis of the NISA Silicosis Prevention Program. However, each company is ultimately responsible for tailoring its program to meet its individual needs. Competent physicians, industrial hygienists, and other professionals should be consulted as needed for advice on implementing a program that meets these guidelines.

We are indebted to Jonathan B. Borak, MD, DABT, Yale University School of Medicine, New Haven, CT; Daniel A. Henry, MD, FACR, Virginia Commonwealth University School of Medicine, Richmond, VA; and John Howard, MD, MPH, JD, LLM, and Frank Hearl, PE, NIOSH, CDC, Washington, DC, for their review and valuable contributions to the preparation of this manual.

OCCUPATIONAL HEALTH PROGRAM FOR EXPOSURE TO CRYSTALLINE SILICA IN THE INDUSTRIAL SAND INDUSTRY

SECTION 1—INTRODUCTION

Industrial sand is used in a wide variety of manufacturing and industrial processes. It is an indispensible ingredient in glass — it becomes walls and windows of buildings, mirrors, light bulbs, eyeglasses, and even windows for spacecraft. It is used as a proppant in the hydraulic fracturing process by the oil and gas industry to restore or increase oil and gas production. It is a raw material for many whiteware ceramics such as earthenware, stoneware, and porcelain. Industrial sand is a raw material for the production of Portland cement and is extensively used for water filtration.

The resistance of industrial sand to heat makes it a necessity to ferrous and nonferrous foundries and to steel mills, which use it as a surface lining in conveying, casting, and molding molten metals. Ground silica is an ingredient in fiberglass and paints. Nearly all industries in the U.S. and abroad use silica sand in some way, and for most of the industrial sand used, there are no known suitable substitutes.

The exposure to airborne respirable crystalline silica remains a significant occupational hazard encountered by the industrial sand workforce. The primary health risk is from the inhalation of respirable crystalline silica dust, which may result in the occupational lung disease silicosis. Respirable crystalline silica from occupational sources has been designated as a carcinogen by the International Agency for Research on Cancer (IARC). Other evidence has linked exposure to respirable crystalline silica with the increased incidence of several autoimmune disorders, diseases affecting the kidneys, tuberculosis, and other non-malignant

respiratory diseases. The recognition, evaluation, and control of exposures to respirable crystalline silica have long been of concern to the occupational health profession and to NISA.

The primary purpose and intent of this manual is to provide mechanisms by which individual NISA member companies can properly and systematically monitor the environmental aspects of dust exposures at their operations and the respiratory health status of employees. Ultimately, this manual serves as a guide for adequately protecting the workforce from the effects of respirable crystalline silica. The material presented in this manual is organized into separate sections in a logical sequence providing the rationale for and the various interrelated required components to be considered in developing an ongoing occupational health program. The manual consists of three major sections—health effects of exposure to crystalline silica, dust surveys, and medical surveillance—which are summarized below.

Health Effects of Exposure to Crystalline Silica

The section of the manual on "Health Effects of Exposure to Crystalline Silica" contains a general review of the human respiratory system, how silica is deposited in the body, and how the body deals with the silica particles followed by a basic review of the health impacts associated with exposure to respirable crystalline silica. An introduction to the concepts associated with medical health surveillance and the ability to use this information in epidemiological studies is then covered. The section wraps up with a discussion of occupational exposure limits for respirable crystalline silica.

Workplace Dust Surveys

The section titled "Workplace Dust Surveys" consists of recommendations for collecting and analyzing air samples to evaluate exposures of workers to respirable crystalline silica. The procedures are presented in a language and format intended to be used by a safety officer,

laboratory technician, quality control analyst, or any person within a company who has responsibility for the industrial hygiene program. This section includes procedures for conducting sampling using 10-millimeter Dorr-Oliver cyclones for personal and area sampling as well as the utilization of direct reading instruments.

Medical Surveillance

The section titled "Medical Surveillance" presents criteria for a medical surveillance program designed for the early detection of pulmonary disease. Much of this section relates to a respiratory medical surveillance program and prescribes both baseline and periodic medical surveillance of the workforce. Procedures by which the medical information is to be obtained are described in detail. The section is intended for health professionals since the health surveillance program must be the responsibility of those trained in evaluating and interpreting data related to exposure to respirable crystalline silica. However, any member company employee or employees who have responsibility for the safety and health program should have a working knowledge of the elements of the medical surveillance program.

The data collected using the criteria presented in this section will be the basis for maintaining surveillance of employees' responses to exposures to respirable crystalline silica and for future epidemiological studies.

Summary

This manual is the basis for an OHP for dust exposure and medical assessments to respirable crystalline silica for NISA member companies. The contents of this manual offer a means of protecting workers' health from exposure to respirable crystalline silica and provide a source of data for epidemiological studies of the industry.

SECTION 2—HEALTH EFFECTS OF EXPOSURE TO CRYSTALLINE SILICA

THE HUMAN RESPIRATORY SYSTEM

Only a small portion of the dusts that are breathed in and enter the lungs are deposited and remain there; the rest leave the lungs when a person exhales. Some dust particles that remain behind are later removed by lung clearance mechanisms. However, the deposited dust particles that remain behind may be capable of causing local injury to the lung. Understanding how dust particles get into and are deposited in the lung, and how some remain and others are removed, requires information about the human respiratory system. The following discussion provides some introductory material on this subject.

Description of the Respiratory Tract

The lungs provide a means of exchanging oxygen needed by the body's cells as well as a means of removing carbon dioxide, a waste product produced as cells use oxygen. This process is referred to as gas exchange. As shown in Figure 2-1, air entering through the nose or mouth passes immediately into the pharynx and then into the larynx, or voice box. From this point, the air enters the trachea, or windpipe (the beginning structure of the lung), which then divides into the right and left bronchi. The bronchi divide into successively smaller branches called bronchioles. As these air passages progress further into the lungs, the total cross-sectional area increases, resulting in a slowing down of the air. The trachea, bronchi, and larger bronchioles are lined with a mucus membrane and cells that are covered with cilia. The cilia, minute hairlike structures, constantly lash back and forth in the mucus, which moistens the airway walls. This process is called mucociliary action (See Figure 2-2).

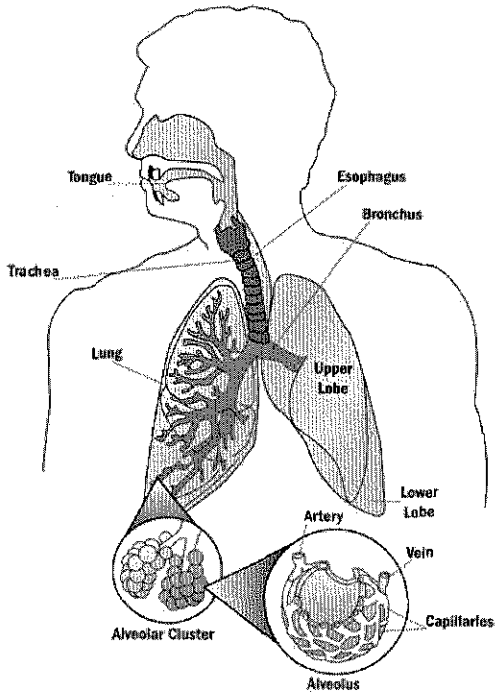


FIGURE 2-1—HUMAN RESPIRATORY SYSTEM

Beyond the terminal bronchioles are alveolar (air) sacs whose walls make up extremely small air-filled cavities called alveoli that are only 150–400 micrometers in diameter (400 micrometers is 0.015 inches). The walls of the alveoli contain pulmonary capillaries (extremely small blood vessels) within which the oxygen and carbon dioxide gas exchange (transfer) takes place.

There are approximately 300 million alveoli in the lung, along with 14 million alveolar ducts. The total surface of these 300 million alveoli and 14 million alveolar ducts is approximately 90 square yards, which is roughly the size of a tennis court. The surface area depends on individual factors such as age, sex, body structure, and state of health.

Because of the delicate and complicated structure of the thin walls that separate the alveolar air spaces from the bloodstream (capillaries), the lungs are in a weak position to resist injury from airborne dust particles that become deposited in the alveoli. Fortunately, the larger

airborne particles are deposited in the twisting air passages through which the air must pass and are quickly removed by ciliary clearance that takes place along these airways. In a small percentage of cases, however, these defenses are overrun by smaller particles, which are deposited in the alveoli, where harmful reactions may occur. When these natural defenses are overrun by small crystalline silica particles, silicosis can develop.

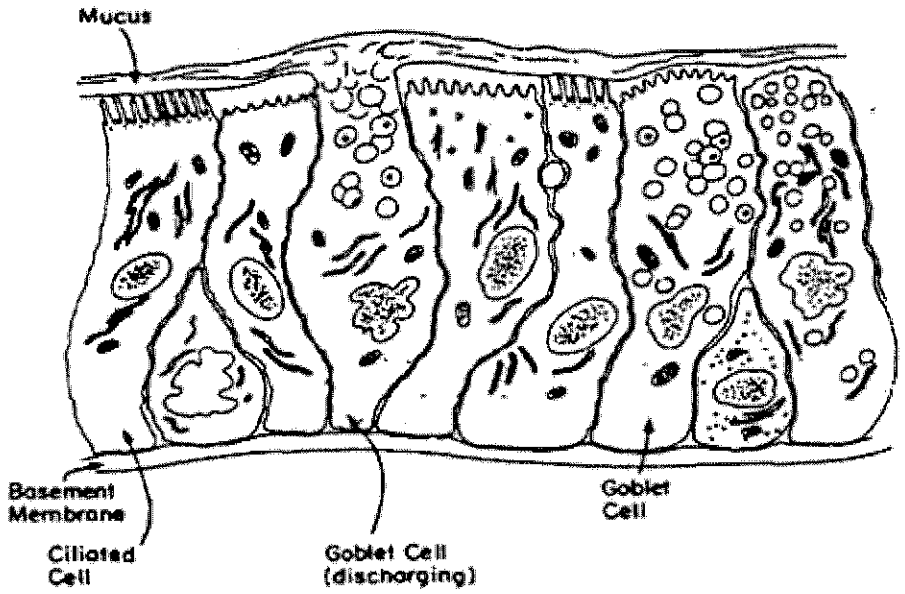


FIGURE 2-2—MUCOCILIARY ESCALATOR

Influence of Particle Size on Deposition

Small dust particles capable of entering the lungs and being deposited there are influenced by three primary means:

1. Inertial impaction.
2. Gravitational settling (sedimentation).
3. Diffusion (Brownian motion).

These three mechanisms and examples of how the branching of airways influences deposition are shown in Figure 2-3. Inertial impaction occurs when inhaled particles being carried along in

an airway are unable to change direction and travel around the turns where airways branch and divide. The forward motion, or momentum, of the particle carries it on its initial path so that it collides with the airway wall and comes to rest. With gravitational settling or sedimentation, as the airways branch and become smaller and smaller, the dust particles slow because the total cross sectional area of the airways is increasing. As the dust particles slow, they settle out because of the influence of gravity and come to rest on the airway walls or surfaces of the alveoli. An example of gravitational settling can be seen when a shaft of light enters a darkened room and small dust particles are seen floating and falling through air. The third mechanism of deposition in the lungs is diffusion, or Brownian motion. All airborne particles move randomly as a result of being constantly bombarded by gas molecules in the air. Particles less than 0.5 micrometer in diameter, especially those less than 0.1 micrometer in diameter, have such a small volume and mass that they have significant Brownian motion. A micrometer is extremely small (1 micrometer is equal to 1/39,000th of an inch). For comparison, a human hair

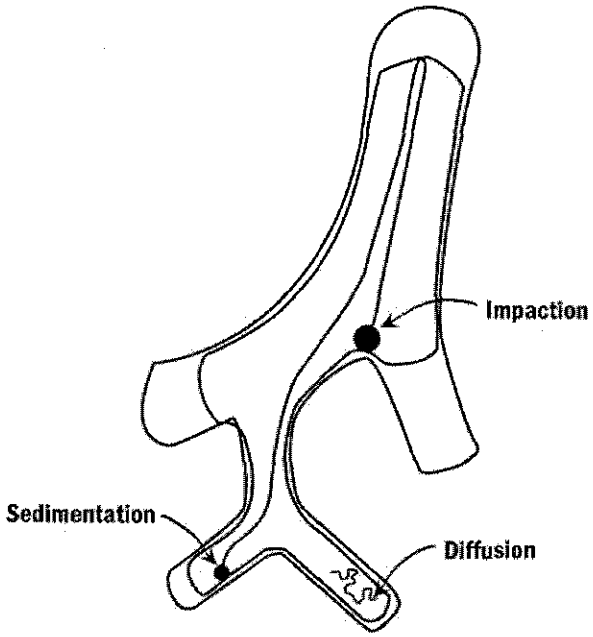


FIGURE 2-3—PRINCIPAL MECHANISMS OF DUST DEPOSITION IN THE LUNG

is approximately 90 micrometers in diameter. The movement of these very small particles is completely random, and if a particle is in close proximity to the alveolar wall, it is likely to be deposited due to impacts with the gas molecules in this fashion.

As the dust particles become smaller and smaller, the first two mechanisms, impaction and sedimentation, become less effective since the smaller particles are able to change direction in the airways and avoid colliding with the airway wall. Similarly, as particles become smaller, they are less likely to settle out and instead continue to be moved along by air currents in the airways. It is only the smallest of dust particles (below one micrometer) that are captured by the diffusion process. The velocity in the airways also affects where dust particles will be deposited. The higher the velocity in an airway, the more effective inertial impaction will be in removing particles since they are less able to change direction. The opposite is true for both gravitational settling and diffusion. The slower the velocity, the more the particles will be able to settle out, and the more likely they are to come into contact with an airway wall through random Brownian motion. Based on these physical laws and the knowledge of airflow patterns during the respiratory cycle, one can make the following predictions: The coarsest particles found in industrial dust exposures (10 micrometers and larger in diameter) will be deposited largely by impaction in the nasal chamber, owing to relatively high air velocities in this entrance structure. To a lesser extent (and with decreasing effect), inertial deposition will also take place at points of branching as the dust-laden air descends through the passageways of the upper respiratory tract. Although the rate of gravitational settling is greatest for the coarsest particles, the probability of removal by this mechanism increases with depth of penetration into the respiratory structure owing to two facts—the decreasing distance of fall to the fixed surface of the increasingly smaller airways, and the longer time available for settlement as the air velocity decreases. The

alveolar spaces provide ideal settling chambers because of their minute size and the nearly still air conditions that prevail. Removal by diffusion is significant only for particles that are less than one micrometer and is especially favored in the tiny alveoli.

The importance of the mechanisms that affect where dust particles are deposited in the lungs is medically important. To be capable of causing silicosis, silica dust particles must reach the alveolar region and be retained there for long periods of time. Not all of the dust that penetrates to the alveolar region is retained. Some of the dust is exhaled without deposition, and some is quickly removed from the lung by the protective mechanisms discussed below.

Fate of Deposited Dust

Within the alveoli are specialized cells called macrophages that are released in large groups when stimulated by foreign bodies such as dust or bacteria. The macrophages surround and engulf the dust particles deposited in the lung. Some of the dust-laden macrophages, which are able to move freely within the air spaces of the lung and alveoli, are removed from the lung via two different pathways:

1. Mucociliary escalator. The macrophages that have engulfed dust particles move from the alveolar region to the bronchioles, which, as discussed above, are lined with a mucus film and special hair cells that sweep back and forth. The dust-laden macrophages and other large dust particles that are deposited in the upper respiratory system are swept along on the mucus layer until they reach the mouth where they are either swallowed or spat out. Since the digestive system is much more capable of coping with foreign particulate matter than is the respiratory system, the swallowed particles seldom do any harm. Most of the dust deposited in the alveolar spaces is removed in this manner.

2. Lymphatic system. Dust-laden macrophage cells may pass through the alveolar walls of the lungs into the lymphatic system, which starts as a network of fine vessels that drains the tissue spaces of lymph. These lymph vessels come together to form larger and larger vessels that eventually discharge the lymph into the bloodstream (see Figure 2-4). At the various branching points (bifurcations) of the trachea and the bronchi, the lymph passes through glands (called lymph nodes), one of whose functions is to filter foreign bodies. Hence, a great deal of particulate matter is deposited by the macrophages at the lymph nodes, where fibrosis of healthy tissue often starts. Other dust-laden cells may be deposited and remain on the alveolar walls where, again, fibrosis can be initiated.

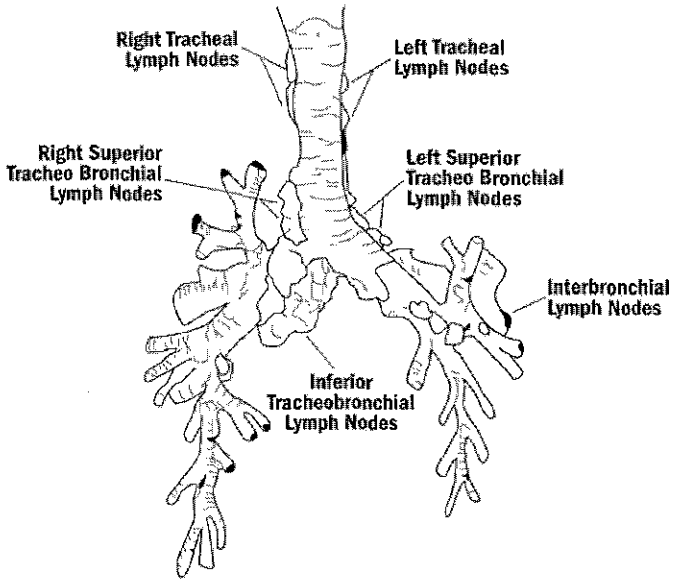


FIGURE 2-4 — POSITION OF LYMPH NODES IN THE RESPIRATORY SYSTEM

PNEUMOCONIOSIS

In general, the human respiratory system's reaction to any inhaled particle (dust, pollen, bacteria, etc.) depends directly on the size, form, concentration, and chemical composition of the particle. At least seven types of reactions are possible—irritation of the nose and throat, allergic

reaction, metal fume fever, pneumoconiosis, systemic reaction, radioactive damage, and carcinogenic damage. Of these, pneumoconiosis is the primary concern with silica-containing dusts. The issue of silica and lung cancer will be discussed later in this section.

The term pneumoconiosis means "dust in the lungs" and is defined in medical terms as the accumulation of dust in the lungs and the tissue reactions to its presence.[1] The inhalation of many types of dust, over a long period and at excessive concentrations over the permissible exposure limit (PEL), can result in scar tissue forming in the lungs, referred to as pulmonary fibrosis. The general term for this type of reaction to dust is pneumoconiosis; similar medical conditions take their names from the type of dust involved. The condition is termed silicosis for silica exposure, asbestosis for asbestos exposure, coal worker's pneumoconiosis for coal dust exposure, and so forth. The fibrosis or scarring that takes place in the lung from silica exposure is similar to a cut on the skin that in healing produces a scar. The pulmonary fibrosis is permanent; once the scarring forms, it will not go back to being healthy tissue.

SILICOSIS

Three types of silicosis can be produced when dusts containing crystalline silica are retained in the lung: chronic silicosis, accelerated silicosis, and acute silicosis.

Chronic Silicosis

Chronic silicosis is the most common type of silicosis. It results in scarring (pulmonary fibrosis) in the lungs and occurs after many years, usually 10–30, of breathing too much respirable crystalline silica.[2] Chronic silicosis is further divided into two different types, simple silicosis and complicated silicosis.

Simple silicosis is the term used to describe the mildest and earliest form of chronic silicosis. Workers with simple silicosis usually feel normal and have no physical symptoms. The

fibrosis in simple silicosis occurs mainly in the top most portion of the lungs (upper lung zones) and appears on the chest X-ray as small (1-10 millimeters), well-defined, rounded scarring (nodular lesions). If the fibrosis progresses, these nodular lesions can increase in number and size and be distributed within the lung zones.

Complicated silicosis results when these small lesions increase in size and grow together (coalesce) into larger lesions, appearing on a chest X-ray to be greater than $4/10^{th}$ of an inch (1 centimeter). A worker with complicated silicosis will have symptoms ranging from minimal complaints, such as a chronic cough with mucus production, to serious shortness of breath and rapidly occurring respiratory failure. The breathlessness is related to a loss in the ability of the lung to expand, which reduces the amount of air the lung can contain (lung volume). The condition can become worse and be disabling or even fatal.

Accelerated Silicosis

Accelerated silicosis results from breathing in very high concentrations of crystalline silica over a relatively short period (5-10 years), whereas chronic silicosis may take as many as 10-30 years to develop.[2] Although accelerated silicosis develops in a pattern similar to that of simple silicosis, with rounded scarring (nodular lesions) in the upper portion of the lungs, the time from first silica exposure to the beginning of disease and the worsening to complicated disease are much faster than with chronic complicated silicosis. This type of the disease is life threatening, and death may occur, as a result of insufficient levels of oxygen in the blood, in as little as 10 years.

Acute Silicosis

Acute silicosis is the most destructive and serious type of silicosis and develops from breathing in extremely high concentrations of crystalline silica over a period ranging from as

little as a few weeks to 5 years.[2,3,4] Acute silicosis differs from the other two types of silicosis in that the rounded scarring (nodular pattern) is absent. Instead, the chest X-ray's appearance is more similar to that of pneumonia (a hazy white image called "diffuse ground glass pattern" by doctors), resulting from the air spaces (alveoli) filled with a thick mucus (fluids and cells). Symptoms of acute silicosis include cough, weight loss, and fatigue and may progress rapidly to respiratory failure over a period of several months. Death can occur after a few months from lack of oxygen in the bloodstream. Acute silicosis has been reported among workers who engage in sandblasting and drilling through silica-containing rock; in the early 1980s, the condition occurred in some ground silica workers. In these situations, exposures have been uncontrolled, and measured silica levels have been found to be 10 to 30 times the MSHA PEL.

TUBERCULOSIS AND OTHER INFECTIONS

As silicosis progresses, it may be complicated by mycobacterial or fungal infections.[4] The most common of these infections is tuberculosis (TB). TB occurs when the alveolar macrophages are overwhelmed by silica dust and are unable to kill the infectious tuberculin bacteria (*mycobacterium tuberculosis*). Other mycobacterial infections include *mycobacterium kansasii* and *mycobacterium avium-intracellulare*. Fungal infections associated with silicosis include *cryptococcus* and *nocardia asteroids*. The New Jersey Department of Health recommends that tuberculin tests be administered to persons with silicosis as well as to those without silicosis who have at least 25 years of exposure to silica[5]

SILICA AND LUNG CANCER

Whether crystalline silica exposure is related to lung cancer in humans has been strongly debated among scientists.[4] In 1996, the IARC reviewed the published studies of cancer in laboratory animal experiments and in studies of workers exposed to respirable crystalline silica

and concluded there was "sufficient evidence in humans for the carcinogenicity (associated with cancer) of inhaled crystalline silica in the form of quartz or cristobalite (two different types of crystalline silica) from occupational sources.[6] IARC is part of the World Health Organization and is responsible for coordinating and conducting research on the causes of cancer and how cancers develop, and for developing strategies for controlling cancer. In the same year, the American Thoracic Society (ATS) adopted an official statement describing the adverse health effects of exposure to crystalline silica, including lung cancer.[7] The ATS is a professional society of physicians and scientists that study and treat lung diseases. The ATS found the following:

1. The available data support the conclusion that silicosis produces increased risk for lung cancer.
2. However, less information is available for the lung cancer risk among silicotics who never smoked and workers who were exposed to silica but did not have silicosis.
3. Whether silica exposure is associated with lung cancer in the absence of silicosis is less clear.

NIOSH is a U.S. government organization responsible for conducting occupational health and safety research and recommending measures to OSHA and MSHA to prevent occupational illness and injury. NIOSH has reviewed the studies considered by IARC and ATS, and NIOSH agrees with the conclusions of IARC and the ATS.[4,6,7] NIOSH recommends that crystalline silica be considered a potential occupational carcinogen.[8] NIOSH believes further research is needed to determine whether non-smoking workers exposed to increasing levels of silica dust are at increased risk for lung cancer and to determine why lung cancer risks appear to be higher in workers with silicosis. To reduce the risk of developing lung cancer, workers who smoke should make an effort to quit; all workers should take measures to prevent breathing in silica dust.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic obstructive pulmonary disease (COPD) is a slowly progressing disease of the airways characterized by a gradual loss of lung function.[9] COPD is a term used to describe two related lung diseases: chronic bronchitis and emphysema.[10] Chronic bronchitis is inflammation and may result in eventual scarring of the bronchi (airway tubes). Emphysema is enlargement and destruction of the alveoli within the lungs. Many persons with COPD have both of these conditions. Persons with COPD have difficulty breathing because they develop smaller air passageways and have partially destroyed alveoli. The air passageways also become clogged with mucus. Smoking cigarettes is the most important risk factor and cause of COPD. About 80 to 90 percent of COPD cases are caused by smoking, and a smoker is 10 times more likely than a nonsmoker to die of COPD. The best way prevent or keep COPD from getting worse is to quit smoking.[11] Breathing in excessive amounts of dust, fumes, smoke, gases, vapors, or mist at work over a long period may also cause COPD.[9,12] COPD caused by breathing dusts is not limited to dusts containing silica. As discussed above, it is generally accepted that occupational dust exposures, including dusts containing silica, are a cause of chronic bronchitis. Studies of South African and Australian gold miners and U.S. coal miners have found a relationship, independent of smoking, between exposure to mine dusts and chronic bronchitis.[4] U.S. studies of molybdenum miners, uranium miners, and taconite miners have not found a relationship, independent of smoking, between dust exposures and bronchitis.[4]

It has been known for many years that miners exposed to coal dust have an increased prevalence of emphysema, but its prevalence among non-coal-exposed workers is not as clear.[1,4] Studies of emphysema in workers exposed to dusts, including dusts containing silica, show conflicting results, and it is not clear whether silica exposure is associated with emphysema in all

exposed workers or mainly in silica-exposed workers who smoke.[4] NIOSH reviewed five studies, one that indicating a relationship with emphysema independent of smoking and two others that found no relationship between emphysema and years of mining.[13,14,15] The fourth study found that workers who smoked and were exposed to high dust were more likely to have emphysema, but the results among non-smokers were not interpretable since only four of 1553 miners were non-smokers.[16] The fifth study of 242 non-smoking miners did not find a relationship between the severity of emphysema and lung function measurements, years of gold mining, cumulative dust exposure, or severity of silicosis.[17]

AUTOIMMUNE DISEASES

There have been a number of medical reports describing autoimmune diseases among workers exposed to silica. The most frequently reported autoimmune diseases related to silica exposure have been scleroderma, systemic lupus erythematous (lupus), and rheumatoid arthritis. There are more than 80 types of autoimmune diseases, and some have similar symptoms.[18,19,20,21,22,23] The immune system protects the body from disease and infection. With autoimmune disease, one's own immune system mistakenly attacks healthy cells in the body. Though little is known about the specific causes of autoimmune diseases, medical experts have determined there is a genetic component as well as an environmental agent that triggers the autoimmune process. For unknown reasons, about 75 percent of autoimmune diseases occur in women, most frequently during the childbearing years. It has been difficult to conduct acceptable studies of some autoimmune diseases (for example, scleroderma and lupus) in silica-exposed workers because the disease is rare and because there are not a sufficient number of workers exposed.[24,25] NIOSH concluded that further clinical and immunologic studies are needed to

characterize the relationship between occupational exposure to crystalline silica and autoimmune diseases.[4]

KIDNEY DISEASE

Kidneys filter waste from the blood and remove it from the body as urine. Kidneys also release hormones that regulate blood pressure and stimulate the bone marrow to make red blood cells. When damaged, the kidneys cannot remove the waste as efficiently, and chronic kidney disease (CKD) can develop. Almost 20 million people in the U.S. have some type of CKD. Common causes and risk factors of CKD are high blood pressure, diabetes, heart disease, and a family history of kidney failure. Without proper treatment, CKD can lead to kidney failure requiring kidney dialysis or transplant. The factors relating to silica exposure and CKD are not well understood.[4] Silica may directly affect the kidney, thus causing injury, or kidney failure may be the result of an autoimmune injury similar to scleroderma, lupus, or rheumatoid arthritis.

Seven studies have found associations between occupational exposure to silica dust and kidney diseases such as end-stage renal disease, glomerulonephritis, chronic renal disease, and systemic vasculitis.[26,27,28,29,30,31,32] However, only four studies analyze whether the workers with higher exposure have more kidney disease.[27,30,31,32] One of found no increase in end stage renal disease overall, but did find an increase for one specific type of kidney disease (glomerulornephritis).[27] The Steenland et al. study found a relationship between increased silica exposure and end stage renal disease.[30] The deKlerk study found no relationship between end stage renal disease and silica, and it also failed to find an increase of end stage renal disease in workers with silicosis (evidence of heaviest exposure).[31] In a study of 2,670 industrial sand workers, researchers did not find any deaths from kidney disease related to increased levels of silica exposure.[32] There are two other studies that failed to find an increase of CKD in silica-

exposed workers. One study found an increase of renal failure among 583 workers diagnosed with silicosis, but renal failure was not related to the number of years exposed to silica or to the stage of silicosis by chest X-ray results.[33] Surprisingly, when this study was repeated and more workers diagnosed with silicosis were included (1328 workers), no increase in kidney failure was found.[34] Overall the studies of silica and associated kidney disease are not reliable enough to conclude that silica exposure causes kidney disease, although it might be the case. It is possible that this casual link may be answered if and when more reliable studies are conducted in the future.

OCCUPATIONAL MEDICAL SURVEILLANCE

The medical surveillance program, discussed in detail in Section 4, is structured to collect information to be used for three primary purposes: baseline evaluations, periodic health status evaluations, and epidemiological surveys.

Baseline Evaluations

The baseline evaluation has many advantages, two of the more important being (1) to assess whether the employee is physically capable of performing essential job functions safely, and (2) to develop baseline information on the individual for use in assessing future changes. The evaluation can also sometimes detect non-occupationally related conditions.

Periodic Health Status Evaluations

Periodic evaluations should be made for early detection of occupational illness and for identifying jobs and operations that pose a hazard and require further evaluation. When abnormalities are detected, whether or not they are occupationally related, they should be disclosed to the employee with appropriate medical follow-up, as recommended by a physician.

Epidemiological Surveys

It is important to collect medical data in a consistent and systematic manner that can be used to detect whether higher than normal cases of occupationally related diseases are occurring and to determine whether the incidence is correlated with occupational exposure or other factors. Epidemiological surveys depend on large numbers of employees to detect, or discount, adverse health effects, necessitating collective, uniform databases for smaller industries such as the industrial sand industry.

OCCUPATIONAL EXPOSURE LIMITS

MSHA adopted an exposure limit for crystalline silica in surface metal and nonmetal mines from the 1973 Threshold Limit Values (TLVs®) established by the American Conference of Governmental Industrial Hygienists (ACGIH).[35] OSHA adopted a PEL for crystalline silica as quartz in general industry that pertains to the regulation of industrial sand in manufacturing operations from the 1968 TLVs®.[36] TLVs® refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. As it turns out, although the sources for the adopted respirable quartz PELs are slightly different for OSHA and MSHA, the corresponding formulas and consequently the PELs are the same.

TLVs® for substances that produce chronic effects, such as crystalline silica, are based on a time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek. The MSHA exposure limit for respirable dust that contains quartz, expressed in milligrams per cubic meter, is determined from the following formula:

$$Quartz(\mathrm{Respirable}) = \frac{10}{\%\,Quartz + 2}$$

Below are examples of the calculation of the exposure limit for a respirable dust containing different percentages of respirable quartz.

Example 1

The following example shows how to calculate the exposure limit for respirable dust containing 10 percent quartz:

$$PEL = \frac{10}{10 + 2}$$

$$= \frac{10}{12}$$

$$= 0.83 mg/m^3$$

Example 2

The following example shows how to calculate the exposure limit for respirable dust containing 70 percent quartz:

$$PEL = \frac{10}{70 + 2}$$

$$= \frac{10}{72}$$

$$= 0.14 mg/m^3$$

The ACGIH Threshold Value Committee determined that cristobalite, one of the three major crystalline forms of crystalline silica, demonstrated a more severe response than quartz in animal studies and produced a diffuse rather than a nodular fibrosis. Therefore, ACGIH recommended a lower threshold value for cristobalite. The MSHA exposure limit for respirable

cristobalite is one half the value for quartz. The exposure limit for respirable dust containing cristobalite is determined from the following formula:

$$PEL = \left(\frac{10}{\%Cristobalite + 2} \right)(0.5)$$

NIOSH was authorized under the 1970 Occupational Safety Act. One of its responsibilities under the Act was to conduct research and recommend workplace standards for OSHA. Later, this NIOSH responsibility was added for MSHA under the 1977 Mine Safety and Health Act. In 1974, NIOSH established a recommended exposure limit of 0.05 mg/m^3 as a 10-hour TWA for respirable crystalline silica to prevent the risk of silicosis from occupational exposure.[37] In 1989, NIOSH identified crystalline silica as a potential occupational carcinogen.[8]

In 2005, the ACGIH revised its current crystalline silica exposure limit by adopting a TLV of 0.025 mg/m^3 for all three common forms of crystalline silica (quartz, cristobalite, and tridymite).[38] Table 2-1 outlines the MSHA and OSHA federal legal standards for silica exposure and the guidelines of NIOSH and the ACGIH regarding occupational silica exposure. Hazard communication standards in the U.S. and other countries often require that legally enforceable and other recommended occupational exposure limits be transmitted by various means to end users. Appendix A contains a listing of the current occupational silica standards and guidelines for various countries at the time of the preparation of this manual.

Reference	Substance	Guideline or Limit (mg/m3)
MSHA	Respirable dust containing quartz in underground surface metal and nonmetal mines	PEL = 10 ÷ % quartz + 2 (8-hr TWA)
OSHA	Respirable dust containing silica, quartz	PEL = 10 ÷ % quartz + 2 (8-hr TWA)
	Respirable dust containing silica, cristobalite	PEL = half of value calculated from the formula for quartz (8-hr TWA)
	Respirable dust containing silica, tridymite	PEL = half of value calculated from the formula for quartz (8hr TWA)
NIOSH	Respirable crystalline silica	REL = 0.05 (for up to a 10-hr workday during a 40-hr workweek)
ACGIH	Respirable crystalline silica:	
	α-Quartz	TLV = 0.025 (8-hr TWA)
	Cristobalite	TLV = 0.025 (8-hr TWA)

TABLE 2-1—U.S. GUIDELINES AND LIMITS FOR OCCUPATIONAL EXPOSURE TO CRYSTALLINE SILICA AND RESPIRABLE DUST CONTAINING CRYSTALLINE SILICA

SECTION 3—WORKPLACE DUST SURVEYS

PURPOSE

The primary purpose of dust sampling recommended in this manual is to characterize the environment in the breathing zone of individual workers to evaluate their work exposure. Breathing zone samples are collected within a few inches of the worker's nose to determine the amount of respirable dust the worker inhales during the workday. Worker dust exposure assessments can be used for comparison with occupational exposure limits and as a measure of dose in epidemiological studies; other reasons include evaluating the effectiveness of engineering controls, changes in dust levels as a result of process changes, and the adequacy of personal protective devices such as respirators.

In some situations *area sampling* is conducted by placing samplers at strategic locations in the workplace to measure concentrations of dust in the general workplace air. For the purposes of this program, area sampling may be appropriate to document dust levels in work areas thought to be relatively dust free, such as offices, laboratories, and lunchrooms. Area sampling can also be used to evaluate dust sources and the effectiveness of engineering controls, work practices, and administrative controls.

In other situations, personal data real-time aerosol monitor (PDR) sampling is conducted by affixing the instrument to an individual or by placing instruments at strategic locations in the workplace. The PDR provides instantaneous quantification of airborne respirable dust levels within the workplace; this information can be used to confirm attempted improvements in dust control or, conversely, to identify improvement opportunities.

The goal of this section of the OHP is to collect sufficient personal breathing zone samples from all employees exposed to industrial sand so that cumulative individual exposure

assessments can be made. The order of preference for interpreting personal exposures based on air sampling is as follows:

1. Employee's personal breathing zone sample.
2. Estimates of exposure based on averaging measured exposures of workers engaged in similar activities or similar exposure groups.
3. Estimates of exposure based on general area sampling accompanied with appropriate time–motion studies.

RESPIRABLE DUST SAMPLING

The level of airborne dust present at any given work site depends on several factors: the type of task being performed and how that task is being performed; the physical (wet or dry) state of the material being handled, the size of the particulates, and the nature and location of the work site, (for example, an enclosed or open space).

The airborne dust to which the industrial sand worker is exposed is generally considered to be in one of two classes:

1. Respirable particulates that are small enough to be inhaled into the lung (generally less than 10 micrometers in diameter).
2. Non-respirable particles that are too large to be respirable and generally do not enter the deep lung region.

FIGURE 3-1—RESPIRABLE DUST SAMPLING SETUP

Respirable dust sampling is performed using a sampling train consisting of (1) a cyclone separator and filter assembly, (2) a sampling pump, and (3) tubing to connect the cyclone and pump (Figure 3-1). The cyclone assembly is a two-stage sampler that separates the larger particles in the dust and allows the smaller particles to pass through the cyclone, where they are collected on a filter for analysis (Figure 3-2). The fraction of dust collected on the filter represents the dust that is capable of penetrating into and being retained in the lung (respirable dust).

Respirable Sampling Equipment

1. *Size-selective device.* Respirable dust samples are collected using a two-stage, 10-millimeter nylon cyclone size-selective sampler that meets ACGIH criteria.

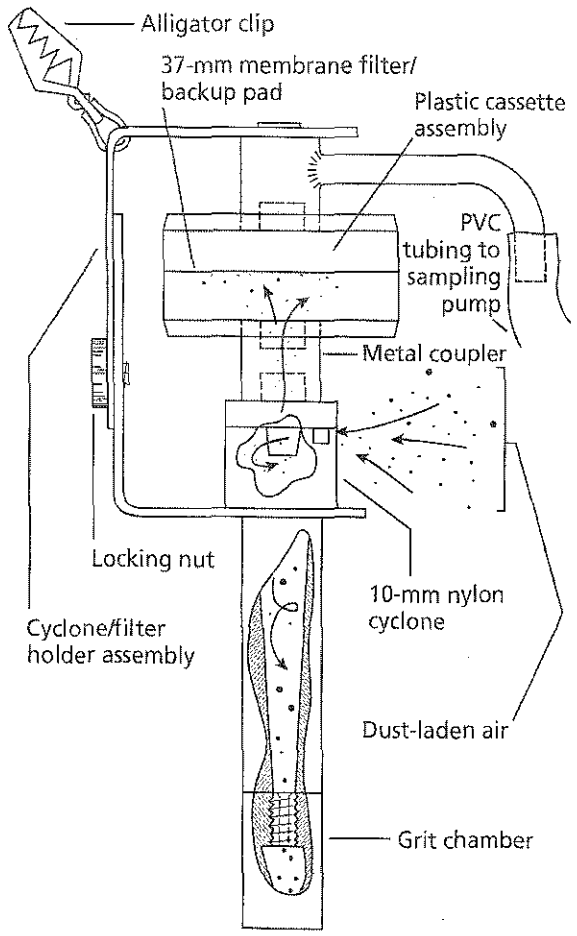


FIGURE 3-2—10-MILLIMETER CYCLONE (1.7L DORR — OLIVER) WITH FILTER

2. *Filters and filter holders.* The cyclone assembly is connected to a two-piece 37-millimeter cassette containing a collecting medium that consists of a 37-millimeter, low-ashing polyvinyl chloride (PVC) filter with a 5.0-micrometer pore size. Duplicate filters or blanks are subjected to identical handling but do not have air drawn through them and are submitted with sampled filters to serve as controls. For each day of sampling, one blank filter or a number equal to approximately 10 percent of the total number of filters submitted for analysis, whichever is greater, should be sent to the laboratory.
3. *Backup pads.* A backup pad is used to support the PVC filter inside the cassette.

4. *Personal sampling pumps.* A portable battery-operated pump that will draw 1.7 liters of air per minute for at least 8 hours is used as a vacuum source. Sampling pumps equipped with flow-compensating features automatically maintain the desired flow rate as dust loading on the filter increases. These pumps are recommended because of their inherent accuracy.

Calibration of Sampling Train

Since the accuracy of a dust sample is no greater than the accuracy of the volume of air measured, proper calibration of the sampling pump is essential for correct interpretation of the pump's indicated flow rate. The performance or ability of the 1.7 L Dorr-Oliver cyclone to separate the respirable fraction of the dust, smaller than 10 microns, from the non-respirable fraction, is reliant upon a flow rate of 1.7 liters per minute (lpm). Flow rates less than 1.7 lpm will allow particles exceeding 10 microns to be collected, causing an over-reporting situation. Conversely, flow rates exceeding 1.7 lpm can cause under-reporting. Any error in the assumed airflow rate through the collecting filter will result in a corresponding error in the final calculation of the dust concentration. Therefore, descriptions of two calibration techniques used for pumps in connection with this dust monitoring program are provided below. Both techniques utilize the "bubble meter" method as the primary standard.

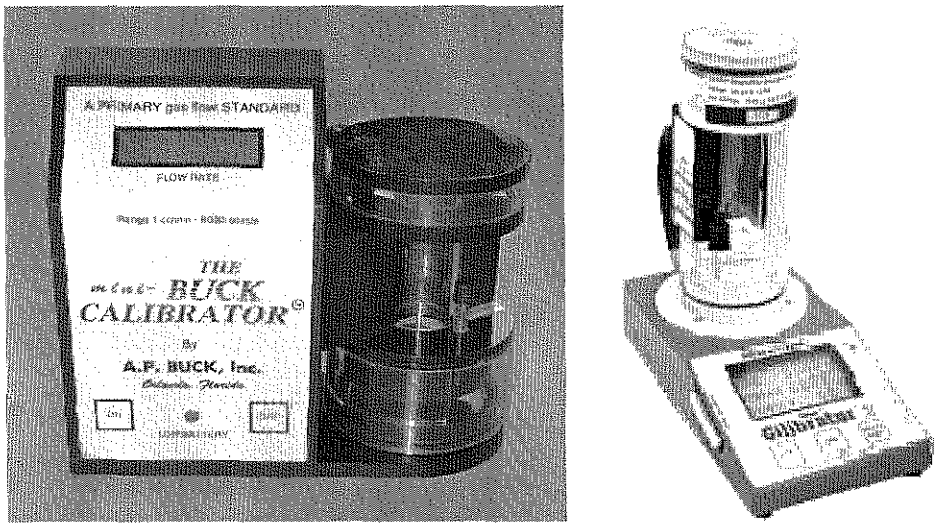
The most widely used technique is the electronic digital readout calibration device because of its speed and ease of use. These devices require recalibration by the manufacturer from time to time to ensure their accuracy.

The secondary procedure is based on the use of a glass burette. While it is accurate, simple, relatively inexpensive, and scientifically accepted as a primary standard, this method is considerably slower, requires preparation time, and involves conversion factors in determining flow rates.

ELECTRONIC FLOW APPARATUS AND CALIBRATION METHOD

Apparatus

1. An electronic flow calibrator. These calibration instruments are highly accurate electronic bubble flow-meters that provide instantaneous airflow readings and cumulative averaging of multiple measurements. They measure the flow rate of gases and present the results as volume per unit of time, e.g., liters per minute (Figure 3-3).
2. A jar or other container with an opening large enough to admit the sampling head (cyclone assembly) and an airtight lid fitted with two tubing connectors. (Note that jars are commercially available for this purpose.)
3. A sampling head (10-millimeter nylon cyclone assembly with an assembled 37-millimeter cassette and a 5-micrometer pore size, 37-millimeter-diameter PVC filter, and backup pad; see Figure 3.2).
4. A battery-powered portable sampling pump capable of producing a flow of 1.7 lpm with the sampling head in place.
5. Connecting tubing (flexible PVC with an outside diameter of 3/8 inch and an inside diameter of 1/4 inch).
6. A soap solution or equivalent (for example, kids' bubble solution).



Courtesy of A. P. Buck, Inc. and Sensidyne, LP

FIGURE 3-3—ELECTRONIC FLOW CALIBRATORS

Procedure

1. Assemble the apparatus as shown in Figure 3-4. Follow the manufacturer's instructions carefully; the steps listed below are usually outlined in the instructions.
2. Visually inspect the PVC tubing and connections for kinks, obstructions, cuts, etc.
3. Wet the inside of the electronic flow cell with the supplied soap solution by pushing on the button several times.
4. Turn on the pump and adjust the pump to a flow rate of 1.7 lpm.
5. Press the button on the electronic calibrator, which in turn will automatically release a bubble and measure the time it takes to traverse the detection zone. The accompanying readout or printer will display or print out the calibration flow rate reading in liters per minute.
6. Repeat Step 5 until two consecutive readings are obtained that are within five percent of each other and within ± five percent of 1.7 lpm.
7. If necessary, adjust the pump while it is still running, using the manufacturer's recommended procedures.

8. Repeat the procedure for all the pumps to be used for sampling and record entries in the calibration log.

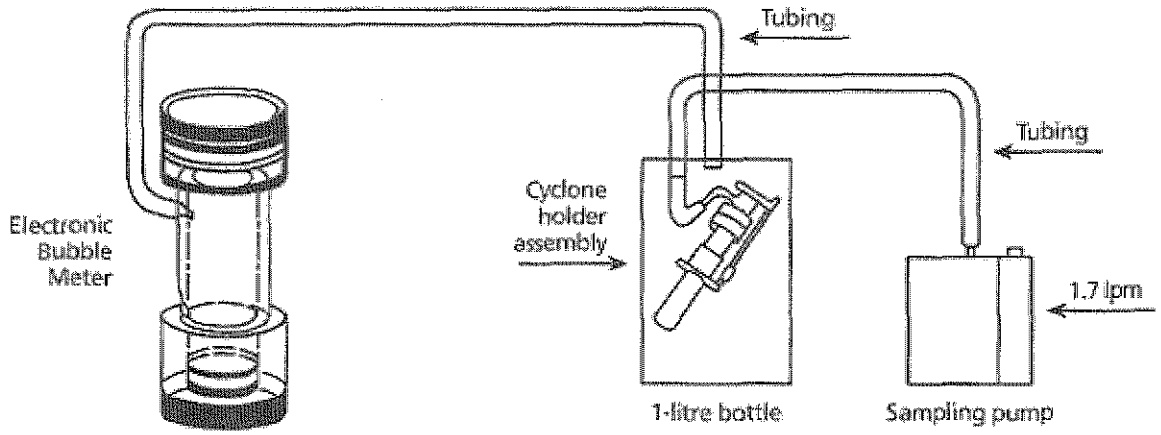


FIGURE 3-4—CALIBRATION OF CYCLONE RESPIRABLE DUST SAMPLER USING AN ELECTRONIC FLOW CALIBRATOR

Burette Apparatus and Calibration Method (Manual)

Apparatus

1. A 1-liter burette for use as a soap-bubble meter.
2. A jar or other container with an opening large enough to admit the sampling head (cyclone assembly) and an airtight lid fitted with two tubing connectors. (Note that jars are commercially available for this purpose.)
3. A sampling head (10-millimeter nylon cyclone assembly with an assembled 37-millimeter cassette and a 5-micrometer pore size, 37-millimeter diameter PVC filter, and backup pad; see Figure 3-2).
4. A battery-powered portable sampling pump capable of producing a flow of 1.7 lpm with the sampling head in place.

5. Connecting tubing (flexible PVC with an outside diameter of 3/8 inch and an inside diameter of 1/4 inch).
6. A timing device (for example, a stopwatch or electronic timer).
7. A support (a rectangular base with rod).
8. Two burette clamps.
9. A beaker or dish capable of fitting over the large opening of the burette.
10. A soap solution or equivalent (for example, kids' bubble solution).

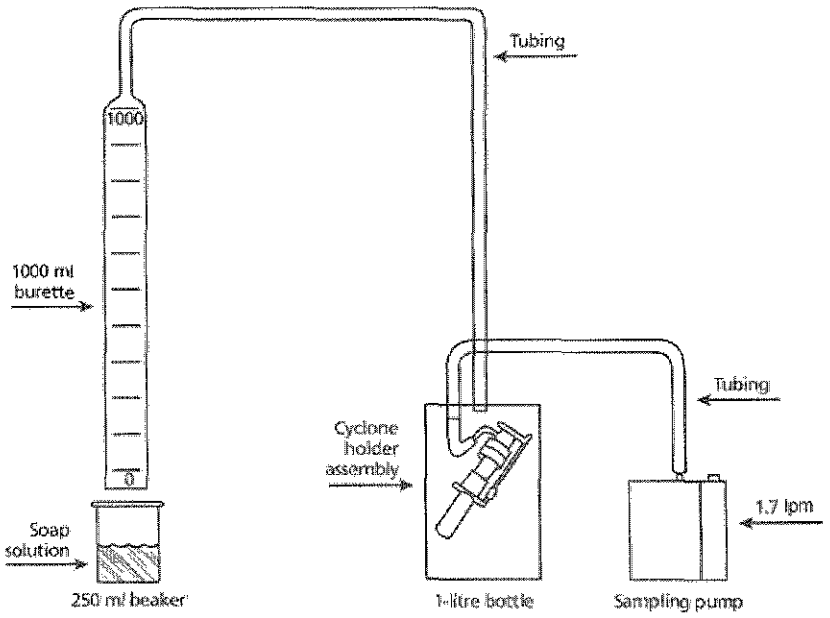


FIGURE 3-5—CALIBRATION OF CYCLONE RESPIRABLE DUST SAMPLER USING A BUBBLE METER

Procedure

1. Assemble the apparatus as shown in Figure 3-5.
2. Calibrate the sampler as follows:
   a. Record the name of the person doing the calibration, date, temperature, barometric pressure, and pump serial number (see Appendix B, Form B-1, for examples of calibration log entries).

b. Calculate the time, at the existing temperature and barometric pressure conditions, for the bubble to traverse the 1000-milliliter distance within the burette at a rate equivalent to 1.7 lpm. The following formula can be used to determine the bubble traverse time. The temperature (in degrees Celsius) and the barometric pressure (in inches of mercury) are available through local weather reporting systems and National Weather Service radio broadcasts. Conversion factors are listed below.

$$T_{bt} = \left(\frac{351.51}{273.16 + C}\right)P_b$$

Where:

T_{bt} = bubble traverse time, in seconds.

C = temperature, in degrees Celsius.

P_b = barometric pressure, in inches of mercury (Hg).

The following example illustrates how to calculate bubble traverse time for a temperature of 85°F (29.44°C) and a barometric pressure of 30.10 inches of mercury:

$$T_{bt} = \left(\frac{351.51}{273.16 + 29.44}\right)(30.10)$$
$$= 34.96$$

In this example, at a temperature of 85°F (29.44°C) and a barometric pressure of 30.10 inches of mercury, when a bubble traverses the burette in 34.96 seconds, the corresponding pump flowrate will be 1.7 lpm.

The formula for bubble traverse time at standard atmospheric pressure (25°C and 760 mm Hg) was derived from the formula for basic flow rate:

$$F_r = \left(\frac{V_m}{T_s}\right)\left(\frac{P_b}{K}\right)\left(\frac{298}{760}\right)(60)$$

Where:

F_r = flow rate, in liters per minute.

V_m = measured volume, in liters.

T_s = time, in seconds.

P_b = barometric pressure, in millimeters of mercury.

K = temperature, in kelvins (see "Conversion Factors" below).

c. Switch the sampling pump on and set its flowmeter to 1.7 lpm.

d. Start the timer as the bubble passes the lower (0-milliliter) mark on the burette; stop the timer as the bubble passes the upper (1000-milliliter) mark. Check the pump flowmeter setting. If it has not changed (that is, it remains 1.7 lpm), record the flowmeter setting and the timer indication to the nearest 0.1 second. Make at least three such measurements at each flow setting.

e. Readjust the sampling pump's flowmeter to achieve the calculated bubble traverse time (Step b) and repeat Step d. Repeat this process until the calculated bubble traverse time is achieved. Record and/or mark the sampling pump's rotameter, if so equipped, or airflow reading at which the calculated bubble traverse time was achieved, since this represents the actual flow rate of 1.7 lpm. For constant flow pumps, it may be necessary to refer to the manufacturer's recommended procedure for adjusting flow.

Conversion Factors

Temperature, in kelvins

= Temperature, in degrees Celsius, plus (+) 273

Pressure, in millimeters of mercury

= Pressure, in inches of mercury, times (x) 25.4

Calibration Log

An accurate record of the calibration data must be maintained. A running log of the calibrations performed on each sampling unit should be kept as part of the dust survey records. The NIOSH *Manual of Analytical Methods* recommends that sampling pumps be calibrated with each use and that this calibration be performed with the sampling device in line. It also recommends that calibration records be maintained for each unit. Forms and examples of a calibration log are found in Appendix B.

Because the accuracy of dust sampling results is only as good as the precision of the instruments used, extreme care should be exercised in performing all calibration procedures. The following list summarizes the philosophy of air sampler calibration:

1. Use care, and pay attention to detail.
2. Ensure that all sampling and calibration connections are as short and free from constrictions and resistance as is possible.
3. Exercise care in reading scales and timers and in making adjustments.
4. Obtain enough data to provide confidence in the calibration measurements.
5. Maintain complete, permanent records.
6. When calibration results differ from previously recorded results, determine the cause before accepting the new data or repeating the procedure.

Sampling Procedures

This subsection provides detailed, step-by-step procedures for collecting samples of airborne respirable dust from the breathing zone of workers and from general work areas. The information obtained from such samples will be entered into occupational exposure records and will be used to make exposure characterizations of individual workers.

Personal Sampling Procedure

To measure the amount of airborne dust to which a worker is exposed, prepare and calibrate a personal sampling pump and sampling apparatus, as discussed above. The sampling head (cyclone assembly) must be located in the worker's breathing zone by attaching the cyclone assembly to the upper lapel, collar, or another point on the worker's clothing in an area bordered by the right and left shoulders, upper chest, and forehead (see Figure 3-6).

Samples of airborne respirable silica from workers' breathing zones are collected as follows:

1. Prepare and calibrate the sampling pump in accordance with the procedures discussed above.
2. Select the worker to be sampled, and inform the worker about the sampling process:
    a. Inform the worker that the pump should not interfere with normal work procedures.
    b. Instruct the worker not to cover the inlet of the cyclone, not to tamper with the cassette, not to remove the sampler for any reason, and to keep the orientation of the sampler head (cyclone assembly) in a vertical position.
    c. Emphasize the need for the worker to continue to work in a routine manner and to report any unusual occurrences during the sampling period.
    d. Tell the worker what you are doing, what the sampling device does, and the reason for the sampling (to evaluate exposure to respirable silica dust).

e. Inform the worker when and where the sampler will be removed and how to contact you if a problem arises during sampling.

3. Assemble the sampling train as shown in Figure 3-2:

   a. Confirm that the cassette is numbered with a sample identification code. The sample number is to be noted on Form B-2, "Respirable-Dust/Silica Sampling Data Sheet" (see Appendix B). If the cassette is not numbered, assign it a unique identification number that can be used to identify the sample at a later time.

   b. Remove the blue and red plugs from the cassette and place them in a plastic bag or other clean, convenient location.

   c. Assemble the cassette and cyclone as shown in Figure 3-2:

      (i) Make sure the backup pad or metal screen is on top of (that is, on the pump side of) the assembly. The dust-laden air is drawn into the cyclone and up through the filter.

      (ii) Make sure that all fittings are tight and that the cassette is secured to the lapel holder. (Note: O-ring seals may need replacing due to aging if the seal with the grommet of the cassette is not tight).

      (iii) Make sure the cyclone is properly attached and the fitting into the bottom of the cassette is tight.

   d. Insert the metal coupler on the end of the tubing into the outlet of the cassette and attach the other end of the tubing to the pump inlet.

4. Attach the sampling train to the worker as shown in Figure 3-1:

   a. Attach the pump to the worker's belt, preferably in the back. It is advisable to have some adjustable belts available for this purpose.

      (i) Position the pump so it does not interfere with the worker's activities.

      (ii) Position the pump so the exhaust port is not covered or obstructed.

b. Attach the sampling train to the lapel or collar of the worker's clothing in the breathing zone. Attach the sampling train so the cyclone's grit chamber is on the bottom of the assembly and the filter side of the cassette is facing down. Be certain the inlet orifice of the cyclone is facing away from the body of the worker and is not covered by articles of clothing.

c. Clip, pin, or tape the tubing to the worker's clothing to reduce the possibility of its interfering with the worker's tasks.

5. Prepare at least one blank filter or a number equal to approximately 10 percent of the total number of samples submitted for analysis, whichever is greater, for each day of sampling. The blank filter is used to determine the amount of weight change on the filter due to outgassing from the cassette assembly. The amount of outgassing from the cassette assembly is related to temperature fluctuation in the environment.

   a. Do not remove the pre-sealed shrink band or the small plugs from the cassette. Mark the shrink seal band with "BLANK" for easy identification.

   b. Subject the blank or control filters to the same time, temperature, and handling conditions as the exposed filters; that is, take the blank filters to the location being sampled, or allow the individual to possess/retain the filter cassette during the test, and treat the blanks the same as the exposed filters when in the office or laboratory.

6. Collect the sample:

   a. Turn on the pump; adjust the flow rate to a setting corresponding to 1.7 lpm, as determined during the calibration procedure; and record on the sampling form the time, the pump and filter numbers, and the worker's location.

   b. Observe the pump's operation for a short time and adjust it as necessary to maintain a calibrated flow rate of 1.7 lpm.

c. Check the pump's flow rate and sampling train as frequently as is practical, for example, at the end of the first half-hour of sampling and every two hours thereafter to ensure the pump is operating properly, the filter is not becoming overloaded, and tubing and connections are not leaking or kinked, as well as to ensure the proper flow rate.

Note: If a buildup of dust on the filter is apparent (that is, if the filter becomes overloaded), the cassette should be replaced. If the pump motor is racing or running at a higher speed than when the test was started, the filter may have excessive buildup and should be an indicator to change filters.

d. Record all pertinent information on the sampling data sheet:

(i) For pumps lacking constant flow capability, record pump and sampling-train checks, any adjustments to the pump, the suspected reason for adjustments, and the degree of adjustment (for example, "up 1/2 ball" or "down 1/4 ball") for pumps with rotameters.

(ii) If the cassette is changed because of overloading, record the new filter number and the start time.

(iii) Record the controls in use, provide a general description of the types of controls, and state whether or not they seem adequate.

(iv) Record potential sources of exposure, provide a general description of these sources, state whether it is a routine or occasional source, and suggest possible additional controls.

(v) Record the worker's activity and equipment operating in the area throughout the sampling period (see Appendix B, Form B-3).

e. Collect a full-shift sample. If the filter shows large visible deposits and the pump cannot maintain a flow rate of 1.7 lpm, two or more consecutive samples may need to be collected.

7. Be at the location specified for sampler removal before the end of the shift.

8. Collect the sampling train from the worker:
    a. Before removing the device from the worker, turn off the pump and immediately record the pump-off time.
    b. Remove the sampling apparatus. For respirable dust sampling, carefully remove the cyclone/filter assembly, *making sure to keep the cyclone upright.* This ensures accurate measurements because it keeps the larger particles in the grit chamber from falling back through the cyclone onto the filter.
    c. Remove the cassette from the sampling train and reinsert the plugs in the cassette.
    d. Place the blank filters with the exposed filters for later packaging and shipment to the laboratory.
9. When sampling is completed, the filter must remain in the cassette. Do not tamper with the pre-sealed shrink band. Package the exposed and blank cassettes securely in a container that will maintain the integrity of the samples, and arrange for the samples to be transferred to the laboratory for analysis. Include copies of the sampling forms and any other data needed by the laboratory for calculating and reporting results.
10. Handle all equipment and supplies associated with the dust monitoring program with extreme care. This is particularly true of the filters, since they can easily be contaminated. To avoid problems such as fugitive dust, fluctuating humidity, and temperature gradients, a specially designated room or area should be used for handling and storing supplies and for calibrating equipment.

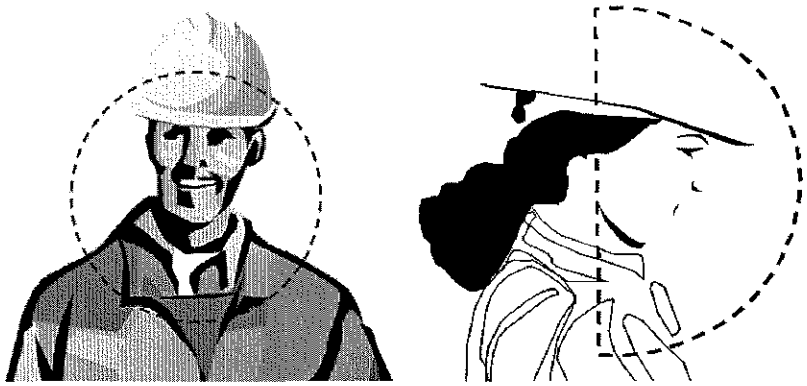


FIGURE 3-6—PERSONAL BREATHING ZONE

General Workroom or Process-Area Sampling Procedure

For the reasons listed below, air sampling in general work areas may be a necessary part of the ongoing dust monitoring program. This can be done with the same equipment used for personal sampling.

1. For some job activities, it may be impractical to use personal sampling equipment on the worker. In such cases, a reasonable estimate of time-weighted exposure can be made on the basis of results from general area sampling and appropriate time–motion analyses.
2. When a personal sample indicates exposure to an excessive concentration of respirable silica dust, without the use of a real-time aerosol monitoring device, there is no direct way of determining which of the worker's several job activities contributed most significantly to his or her total exposure. Strategic general area sampling during specific jobs can be used to define relative exposure potentials and thus allow appropriate, selective, corrective action to be implemented.
3. General area sampling can be used as a basis for categorizing various work areas in terms of potential exposure risks. Such information can be tabulated or graphically displayed to indicate the relative dustiness of areas within the plant.

4. General area sampling is extremely useful in evaluating the performance of engineering controls, the effect of process changes on dust concentrations, and the effectiveness of administrative controls.

General workroom or process-area samples of respirable airborne dust should be collected as follows:

1. Prepare and calibrate the sampling pump in accordance with the procedures discussed previously.
2. Place the battery-operated sampling pump in a secure location within the area to be tested. A secure location (1) is representative of the general work areas which employees occupy, and (2) is a site where the pump is not likely to be damaged as a result of normal work operations. In certain instances, it may be necessary to fasten the pump to a stationary, rigid object. The more closely the conditions at the chosen location approximate those of the areas workers occupy, the more representative and meaningful the resulting sample will be in terms of workers' exposures. For comparative general area dust analyses, sampling stations should be established where all samples will be collected for a given area using the same exact location.
3. After selecting a sampling location and positioning the pump, attach the sampling apparatus (consisting of a cyclone and a 37-millimeter-diameter cassette, described above) to the inlet (suction) side of the pump using a length of tubing. Particular care must be taken to ensure that the height of the filtration apparatus approximates that of the breathing zone of workers in the area.

From this point, the procedure is similar to that for personal sampling and includes recording pertinent information, checking the pump's flow rate, removing the sampler at the end of the sampling period, and shipping the exposed filters and blanks to the laboratory for analysis.

DIRECT-READING INSTRUMENTS

A powerful and often overlooked tool in achieving the lowest possible workplace dust exposure levels in an expeditious manner is the personal data real-time aerosol monitor (PDR). The PDR provides an instantaneous reading of total respirable dust via a liquid crystal display, but contains data logging capabilities permitting the analysis of total respirable dust concentrations over a specific period of time. The PDR may be used in three primary ways:

1. As a spot checker of total respirable dust concentrations
2. As a logger of general area total respirable dust concentrations
3. As a logger of personal total respirable dust concentrations

When the PDR is used as a spot checker of total respirable dust concentrations, a set of strategic locations within the workplace must first be identified. Once these locations are identified, the PDR is taken from location to location with instantaneous total respirable dust concentrations recorded. Over time, analysis and trending of the data may be performed to help identify areas or equipment requiring improvement.

When used as a logger of general area total dust concentrations, the PDR is set-up in one workplace location and left for a set period of time. During the sampling period, the PDR will log total respirable dust concentrations as frequently as defined by the user (i.e. as frequently as every second, although typical logging periods range from 10 to 60 seconds). At the conclusion of sampling, the logged PDR data can be downloaded for analysis.

The most effective use of a PDR is as a logger of personal total respirable dust concentrations. When used as a personal logger, the PDR is affixed to a worker in much the same way as a conventional sampling pump. The worker carries the PDR on his or her body over the course of a shift; the PDR logs total respirable dust concentrations as the worker moves from place to place. At the completion of the worker's shift, the logged data can be downloaded and compared to the Employee Activity Log (Appendix B, Form B-3) for analysis (see Figure 3-7). Analysis of this data can often pinpoint the exact locations or work practices that are contributing most to the worker's time weighted average exposure level.

These meters are not acceptable by MSHA for compliance sampling, although they are used by MSHA as diagnostic tools. In addition, these meters only provide data for respirable dust; they do not provide data that can be compared with the allowable dust limit at the sampled location, since they cannot determine the crystalline silica content of the dust. They only measure total respirable dust rather than a specific type.

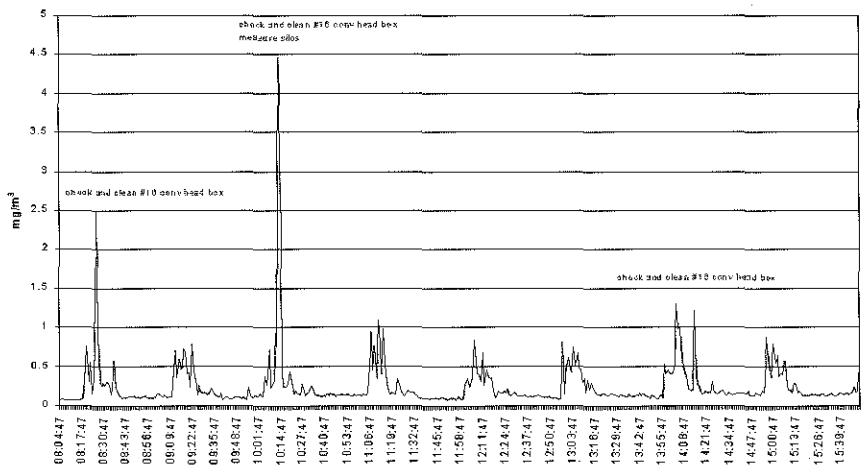


FIGURE 3-7—PDR GRAPH - TIME VS RESPIRABLE DUST CONCENTRATION

Analytical Procedures

For the most part, NISA member companies rely on commercial laboratories to perform the two analytical procedures required for respirable samples: (1) determining the weight of dust collected on the filter, and (2) measuring the amount of crystalline silica in the dust. This discussion covers selecting a laboratory for analyzing samples and specifying the method for determining the amount of crystalline silica. A detailed discussion of the analytical procedures can be found in the NIOSH *Manual of Analytical Methods* or obtained from the laboratory performing analyses for your company.[8]

Laboratory Selection

Many laboratories are qualified to conduct the analytical procedures required by the OHP. The American Industrial Hygiene Association (AIHA) conducts an accreditation program for laboratories that analyze industrial hygiene samples. As part of its laboratory accreditation, AIHA conducts an analytical reference and quality assurance program known as the Proficiency Analytical Testing (PAT) program. Under the PAT program, prepared spiked samples of known quantities of a contaminant (analyte) are periodically sent to participating laboratories for analysis. The laboratories report results to the PAT program, and the data are subjected to statistical analyses for precision and accuracy. Laboratories whose results are outside of control limits are removed from the program. Quartz is one of the contaminants that can be selected when a laboratory elects to participate in the program. NISA urges its member companies to use only AIHA-accredited laboratories for their analytical services and participate in the PAT program for quartz determination. A list of AIHA accredited laboratories may be found at the AIHA website (http://www.aiha.org).

Crystalline Silica Analytical Method

For the purposes of the OHP, analyses of crystalline silica should be performed in accordance with NIOSH Method 7500, which is an X-ray diffraction technique.[8] Although other acceptable methods, such as infrared analysis, are available, the X-ray method is considered appropriate for crystalline silica. Therefore, in procuring analyses of crystalline silica, NIOSH Method 7500, *X-Ray Powder Diffraction,* should be specified. Both OSHA and MSHA use this method for respirable crystalline silica determination in their enforcement activities.

Sampling Records

To provide proper documentation and historical data for future reference, proper sampling records must be maintained. These records provide the tools to track personnel and compliance histories and are invaluable in conducting epidemiology studies.

Pump Calibration Record

The Pump Calibration Record (Appendix B, Form B-1) is used to document proper pump calibration and is an integral part of a complete sampling program. Two samples of pump calibration forms can be found in Appendix B. In lieu of forms, a calibration record in a bound laboratory notebook can be used to record pump calibration.

Respirable Dust/Silica Sampling Data Sheet

The most important of the required records is the Respirable Dust/Silica Sampling Data Sheet (Appendix B, Form B-2), which lists all pertinent information about a particular sample and analytical results. The completed Form A-2 should be retained indefinitely, since future exposure studies will rely on the form's data to accurately determine exposure levels.

Respirable Crystalline Silica Sampling Summary

The Respirable Crystalline Silica Sampling Summary (Appendix B, Form B-4) is a useful tool for tracking exposure trends. It is suggested that one sampling summary be used to track all samples taken at a plant, with additional summaries devoted to specific job classifications or areas.

Employee Activity Log

The Employee Activity Log (Appendix B, Form B-3) is used to document the activity of the worker wearing the dust sampler. This log may be useful in determining areas that contribute to high dust measurements, work practices that influence dust measurements, respirator-wearing practices that mitigate dust inhalation, and so forth. Employees participating in dust sampling should be instructed to specifically make note on their activity logs of any visible dust they encounter during their shift. This can greatly help identify sources of dust.

It should be mentioned that soiled clothing, outerwear, and gloves can have a significant negative impact on silica dust sampling results and can lead to false assumptions as to potential sources of dust.

In addition to Forms B-1 through B-4, information should be retained regarding manufacturers' specifications for dust sampling equipment, laboratory analysis, and other data pertinent to sampling.

Sampling Frequency

The number of personal dust samples to be collected at each location within a plant is a function of the size of the workforce at the location, the uniformity of dust emissions at the location, and the overall dustiness of operations at each location. When a sampling frequency

program is established for a plant, Table 3-1 can be used to determine the number of employees to be sampled at each process or operation within the plant.

It is essential that the exposure for each employee be characterized. If a number of people perform the same function, a representative of the group can be sampled; the results will therefore be characteristic of the others who work in the same operation. However, if certain tasks are being performed by different workers and involve subtle differences between the two, dust sample result differences can be significant. An example of this subtle difference would be if one worker carefully places a filled bag on a pallet, while the other worker drops a filled bag on a pallet from several inches. Ultimately, personal samples should be obtained for each person exposed to industrial sand. This means that sampling in a particular operation will be rotated among the individuals working in that operation.

Once the initial group of employees has been sampled, the exposure results obtained will be used to determine the frequency of periodic sampling.

Number of Employees Exposed	Number of Time-Weighted Average Determinations
1–20	50% of the total number of workers
>20	10 plus 25% of the excess over 20 workers

TABLE 3-1—NUMBER OF EMPLOYEES TO BE INITIALLY SAMPLED AT A PLANT OPERATION OR PROCESS

DISCUSSION OF RESULTS

The vast majority of dust samples collected by MSHA from the industrial sand industry are collected in the breathing zone of individuals. These samples are analyzed to determine the concentration of respirable dust and the amount of crystalline silica in the dust. Sampling in this

manner represents the amount and kind of material that would enter a person's lungs during a particular period of sampling. Every sampling program should therefore follow that of MSHA, although, as discussed above, individual companies may also elect to collect samples that represent a given area of their plant or facility.

Dust sampling filters are normally purchased from an analytical laboratory, and each filter is labeled with a number affixed by the laboratory. This number is a reference to the weight of the filter as shipped from the laboratory. Since each filter used is pre-weighed at the servicing analytical laboratory, reweighing the filter at that laboratory after sampling and noting the difference in weight determines the amount of respirable dust collected during the sampling period.

The following example follows a sample through the entire dust collection sequence. For this example, the filter contained 0.110 milligram of dust after sampling.

Note: Filters must be sent to the originating laboratory for analysis, since this is the only facility that has information about the original weight of each filter.

Sampling was done using a known airflow rate: 1.7 liters per minute (lpm) of room or plant air passing through the filter via the battery-operated pump attached to the person being sampled. Multiplying the sampling flow rate by the total number of minutes in the sampling period provides the volume of air passing through the filter. For example, an 8-hour workday consists of 480 minutes. The volume of air sampled would then be 1.7 lpm for 480 minutes, or 816 liters. Exposure limits are expressed in terms of cubic meters of air, so 816 liters is equivalent to 0.816 cubic meters (1 cubic meter = 1000 liters).

The sample weight and volume of air sampled are combined in an expression of weight per unit volume, milligrams of dust per cubic meter of air sampled. In this example, therefore,

the average concentration of respirable dust in the air during the sampling period was 0.110 milligram, divided by 0.816 cubic meter of air passing through the filter, or 0.13 milligram per cubic meter. This value represents the concentration of respirable dust sampled during this particular period.

The next step is to evaluate the sample result. Normally, samples results are evaluated based on the PEL for silica dust specified by MSHA. This is the concentration of respirable dust that may not be exceeded for a given percentage of crystalline silica, averaged over a work shift. The evaluation will determine whether the sample result is above or below the PEL and by how much. The MSHA PEL for respirable silica dust is determined by the following formula:

$$PEL = \frac{10}{Quartz\ \% + 2}$$

Where:

PEL = Permissible exposure limit, in milligrams per cubic meter.

Quartz (%) = percentage of respirable quartz.

So far, the percentage of respirable quartz contained in the dust collected on the filter is unknown. This determination requires another laboratory procedure. In addition to being weighed, the filter is subjected to X-ray diffraction analysis to determine the amount of quartz within the dust on the filter. The results sent by the laboratory will include the concentration of dust and the amount of quartz for each filter. The amount of quartz in dust varies from plant to plant and within each plant or mining process. For example, respirable dust collected from a front-end loader at the quarry may only contain about 10 percent quartz, but samples collected from a mill operator at the product end of a plant after mined material has been processed may contain 98 percent quartz.

Note: The percentage of quartz is determined for each sample submitted to the laboratory. You may send six samples to the laboratory for analysis, and the percentage of quartz can be different for each sample. In the above example, assume that the laboratory determined the sample to contain 36 percent quartz. This means that of the dust on the filter, 36 percent was quartz and the rest was other dust material of respirable size. The exposure limit would then be 10/(36 + 2), or 0.26 milligram per cubic meter. Since the measured dust concentration was 0.13 milligrams per cubic meter and the exposure limit was calculated to be 0.26 milligrams per cubic meter, this particular sample does not exceed the PEL.

A *sample result comparison,* sometimes referred to as *Severity Index* (the sample value compared with the PEL) can be expressed as *exposure.* This expression is similar to *dose.* For example, MSHA obtains employee noise exposure data using a noise dosimeter, and the results are reported in terms of *dose as percentage:* 100 percent dose is the maximum allowed by regulation, lower values are within regulatory limits, and values greater than 100 percent exceed the limits. Percentage exposure for dust is similar: 100 percent is the maximum allowed, or the exposure limit. Percentage exposure values below 100 percent mean that dust sample results are below the exposure limit, and percentage exposure values above 100 percent mean that sample results exceed the exposure limit. Exposure, as expressed in percentage, is determined by dividing the sample dust concentration by the PEL and multiplying by 100.

In the above example, the Exposure ($E_{\%}$) would be as follows:

$$E_{\%} = \left(\frac{0.13}{0.26}\right)(100) \approx 50$$

This means the person sampled was experiencing about one-half the allowable exposure to that particular respirable dust. Percentage exposures should always be maintained below 100 percent. Percentage exposures that exceed 100 percent should be evaluated in a timely manner, and steps should be taken to reduce the exposure to an allowable level.

This example is further illustrated in Appendix B as a completed Form B-2 that uses the data from the example.

MANAGEMENT OF EXPOSURE DATA

The previous discussion of evaluating sample results provides an example of comparing the results of a single measurement with the MSHA PEL for compliance purposes. While this type of comparison, referred to as compliance sampling, is useful for determining legal compliance with a federal regulation, a measurement-by-measurement comparison considers only the variability associated with each measurement. It provides no useful information about the variability that occurs due to the separate tasks involved in a job or due to workers who perform the same job but employ different work practices. It also gives no meaningful conclusions related to variability of the time of day, the month of the year, the shift being sampled, and the location within the mine or mill. The measurement-by-measurement variability (compliance sampling) is very small compared with the variability related to these other factors.

For these reasons, and because of the fact that as the sampling program database of measurements grows year-by-year, consideration should be given to using other statistical techniques to analyze sampling data. The subject of statistical analyses of large databases is complex and beyond the scope of this manual, but a brief description of two methods is included here, and some examples are included in Appendix C. For a more in depth understanding, the reader should study additional sources of information listed in Appendix C and consider using an industrial hygiene consultant to develop a program for data analyses.

Descriptive and Inferential Statistics

Descriptive statistics are used to describe the basic features of sampling data.[1,3] They provide simple summaries about its central tendency and the dispersion. The central tendency of a distribution of sampling measurements is the estimate of the "center" of that distribution. Some central tendency measurements of interest include the arithmetic mean (average), median, mode,

and geometric mean. The dispersion of data refers to the spread around the central tendency. Three common measures of the dispersion are the range, the standard deviation, and the geometric standard deviation. Most descriptive statistics can be calculated using a spreadsheet such as Excel or a scientific calculator with statistical functions. In addition, there are many university statistical websites that will calculate statistics once data is entered [AIHA Strategy].[1] The following descriptive statistics can be calculated from the sampling data and can provide more information about its statistical features:

- number of samples
- maximum exposure (max)
- minimum exposure (min)
- range
- percent of exposures above the PEL (%>PEL)
- mean of exposure ($\bar{\chi}$) [Need mean symbol which is a bar over small x]
- standard deviation of exposure (s)
- geometric mean (GM)
- geometric standard deviation (GSD)

Sampling data can be understood by simply comparing the descriptive statistics with the PEL.[1] This is often the case when the sampling data is clustered well below or well above the PEL. However, if the distribution of the sampling data contains measurements approaching or above the PEL, then inferential statistics can be useful in understanding the data and assessing the potential hazard represented by the data. With inferential statistics, a dataset is used to arrive at conclusions that extend beyond the data.[2] In other words, confidence limits are calculated in order to quantify uncertainty in the arithmetic mean and measures of central tendency. One method often used to ensure workers are adequately protected is to calculate a 95^{th} percentile of a

dataset and compare the result with the occupational exposure limit. The 95th percentile is the value of a dataset below which 95 percent of the observations fall. Using this approach in analyzing a set of dust measurements gives some assurance that if operations are sampled 100 times, 95 of those times the measurement would be below the 95th percentile value. Examples and calculations using these techniques are shown in Appendix C.

Bayesian Statistics

A strategy gaining use among industrial hygienists for analyses of exposure sampling data uses Bayesian statistical techniques for determining, from a limited dataset, the exposure profile and severity of exposure for a similar group of data.[3] The strength of the Bayesian decision analysis (BDA) is that it allows the analyst to factor in professional judgment or other information into the statistical calculations. BDA is especially useful when interpreting small datasets of 10 or fewer samples of an operation. However, for sample sizes from 10 to 20 or larger, calculating descriptive and inferential statistics is recommended. The BDA technique includes complex calculations that are best undertaken with adequate training. References are included in Appendix C for those seeking additional information on this technique. Training courses are also available for applying BDA techniques to industrial hygiene sampling data.

Note: Individual sample results reflect the exposure of an individual at the time of sampling; that is, the results relate to the work the individual was performing and the quartz content of the material in question during the particular sampling period. The results may or may not represent the person's "normal" or average exposure. This is why a structured sampling program, in which average exposures can be determined based on periodic sampling, is recommended. Because of variations in work activities, even for an individual, it is important to record the type of work performed during the sampling period. This information can be recorded on the Employee Activity Log (Appendix B, Form B-3). Although the discussion of sampling centers on specific calculations, sampling is best discussed in terms of a program. Information collected during sampling becomes more meaningful as a database of sample results develops. A program that comprises sampling frequencies and locations tailored to each facility will enable the dust exposures of workers to be characterized.

Worker Notification of Dust Sampling Results

Timely worker notification of dust sample results ensures that workers are kept apprised of NISA member company efforts to improve the working environment while maintaining transparency in the process of evaluating hazards in the workplace.

General Area Dust Sample Result Notification

Within 15 days of receiving the results of laboratory analysis, general area dust sample results are to be posted conspicuously (e.g. bulletin boards) for worker review.

Personal Dust Sample Result Notification

Within 15 days of receiving the results of laboratory analysis, personal area dust sample results are to be provided to the affected worker via Form A-5—Employee Notification of Dust Sample Results.

SAMPLING STRATEGY

This subsection provides a strategy that member companies can use to determine a sampling frequency based on personal exposures. Sampling frequency is based on average exposure profiles of personal exposures in a job or operation.

Personal exposures with exposure profiles of less than 50 percent of the PEL to respirable crystalline silica dust in which no operational, engineering, or administrative process changes have been implemented should be sampled at least once every 12 months. This is done to ensure confidence that levels of respirable crystalline silica dust have been maintained at the exposure profile.

Personal exposures with exposure profiles of 50–100 percent of the PEL to respirable crystalline silica dust in which no operational, engineering, or administrative process changes have been implemented should be sampled at least once every six (6) months. This is done to

ensure that levels of respirable crystalline silica dust have been maintained at levels less than the limit.

Personal exposures with exposure profiles greater than 100 percent of the PEL to respirable crystalline silica dust should be sampled on a basis that is consistent with any engineering, operational, or administrative process changes. Control measures should be implemented in a timely manner to reduce exposures below the limit. Repeat dust sampling with the same worker doing essentially the same job procedures but with the corrective control measures in place. Provided the result of this sample is below the PEL, two additional samples should be collected under the same circumstances to confirm the results and to ensure exposures are below the PEL.

When operational, engineering, or administrative changes that could increase or decrease dust emissions are made to a process, personal sampling should be undertaken monthly until two consecutive sample results are less than the PEL.

This strategy has been developed to provide member companies with some degree of confidence that exposure levels are measured and corrective measures are taken if needed. Table 3-2 provides guidance in this strategy.

Exposure Classification	Time-Weighted Average Exposure	Frequency of Sampling
I	<50%	Every 12 months
II	50–100%	Every 6 months
III	>100%	Every 3 months (minimum)*

TABLE 3-2—SAMPLING FREQUENCY BASED ON PERSONAL EXPOSURES

SECTION 4—MEDICAL SURVEILLANCE FOR SILICA EXPOSURE

PURPOSE

The objective of this recommended medical surveillance program is to prescribe baseline and periodic health evaluations of workers exposed to crystalline silica. The guidance in this section is modeled after an official American Thoracic Society (ATS) statement, adopted in June 1982,[1] the guidance of an Evidenced Based Statement of the American College of Occupational and Environmental Medicine (ACOEM), Medical Surveillance of Workers Exposed to Crystalline Silica,[2] the ASTM Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica,[3] and the National Kidney Foundation's Clinical Practice Guidelines for Chronic Kidney Disease.[4]

Medical surveillance is accomplished by performing screening examinations, which are not necessarily the same as diagnostic tests (see Table 4-1).[5] The key distinction is that medical surveillance is performed on a worker because the worker is at risk from a specific occupational exposure, whereas a diagnostic test is performed on a patient because of a specific medical complaint or finding. Abnormal findings detected by screening examinations must be confirmed and then referred for diagnostic studies to determine their relationship to occupational exposure and their true significance. ***This manual should be provided as guidance to physicians and allied health professionals who conduct medical surveillance for member company employees.*** Consideration should be given to specifying appropriate criteria of this section in contracts and procurement agreements with medical providers.

Screening Examination
Performed periodically on a worker who is judged to be at risk from an occupational exposure **Example:** Periodic chest X-ray on a brick worker

Diagnostic Examination
Performed on a patient because of a specific medical complaint or finding **Example:** Sputum culture on a patient with pneumonia

TABLE 4-1— SCREENING VERSUS DIAGNOSTIC EXAMINATION

MEDICAL SURVEILLANCE PROGRAM

The medical surveillance program has the following objectives:

1. To establish a baseline from which to assess changes that may develop in the individual at a future date. Thus, each worker serves as his or her own control, and the ability to recognize early change is greatly enhanced.
2. To detect abnormalities that might be consistent with the health effects of silica exposure at an early stage, when intervention can lead to disease reversal or cessation of disease progression.[2]
3. To prevent the development of silicosis that could produce pulmonary impairment in the worker.
4. To prevent the development of other occupational conditions that might be associated with exposure to silica.
5. To disclose to the worker occupationally and non-occupationally related abnormalities for appropriate medical follow-up.
6. To identify potentially hazardous working conditions and underscore the need for improvements in control measures.
7. To develop data on which epidemiological studies of crystalline silica exposure can be based.

COMPONENTS OF A MEDICAL SURVEILLANCE PROGRAM FOR SILICA

The primary focus of a medical surveillance program for silica exposure has traditionally been conducted for the early detection of silicosis. However, with more recent studies finding a possible association between silica exposure and kidney disease, and given that kidney diseases are suitable for screening and early detection, some components have been included in the OHP medical surveillance to assess kidney function, and to gather information on potential risk factors for kidney disease. The medical surveillance program for silica exposure consists of the following components:

1. A medical history that focuses on the presence of respiratory symptoms, smoking habits, and risk factors for kidney disease.
2. A comprehensive occupational history that details prior exposure to potentially harmful dusts, chemicals, and other physical agents. Any adverse effects related to these exposures must be recorded.
3. A physical examination to assess the general condition and respiratory status of the worker.[2]
4. A 14-by-17-inch posterioranterior (PA) chest X-ray, preferably obtained using a high-kilovoltage technique. A PA chest X-ray exposure means the X-ray beam penetrates the individual from the back to the front of the chest with the film to be exposed in front of the subject. For silicosis and other pneumoconioses, films should be interpreted by qualified board-certified radiologists who are NIOSH-certified B readers.* Films should be classified in accordance with the 2000 *Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses*.[6] Many advances have been made in the past decade in

* NIOSH B-Reader information and a listing of certified B-Readers can be accessed online. Accessed on line at: http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html

digital chest radiography. While the International Labour Organization (ILO) system still requires conventional radiographs for classification, studies have shown that digitized images are an acceptable alternative to interpretation of conventional film images.[7,8,9] All indications are that the conversion from conventional films to digital radiography in medical settings will continue. For these reasons, in addition to accepting conventional chest X-rays, the NISA OHP program will accept good quality digital chest images reproduced on film to be used with the current ILO system for classification of the pneumoconioses. **

5. Pulmonary function tests that include spirometric measurements of forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC). Such tests should be performed, calculated, and interpreted in accordance with the ATS 1994 Update Standardization of Spirometry and the 2005 ATS-ERS Standardization of Spirometry guidelines.[10,11]
6. The baseline tuberculin skin test reactivity status of workers should be established.[12,13,14] Early inactive tuberculosis infection can be detected using two kinds of tests: the tuberculin skin test (TST) or a QuantiFERON blood test (QF test). Either the QuantiFERON-TB Gold test or the QuantiFERON-TB Gold In-Tube test is acceptable.[15,16] TST should be performed by intradermal injection of purified protein derivative (PPD), using the Mantoux technique. A two-step TST should be performed for initial, baseline testing, following current Centers for Disease Control and Prevention (CDC) guidelines for the detection and evaluation of tuberculosis.[15] Alternatively, initial baseline testing can use a single QF test. Subsequent periodic testing should be done using a single TST or QF test.[16] Because of the high risk that

** (Note: In 2008 NIOSH hosted a workshop to address issues for classifying digital radiographs for subjects with pneumoconioses. Information can be accessed online. Accessed online June 5, 2009 at: http://www.cdc.gov/niosh/docs/2008-139/. When ILO guidelines for acquisition and viewing of digital chest images and ILO standard radiographs become available in digital format, classification can be performed on viewing workstations that meet ILO guidelines or the minimum American College of Radiology guidelines for viewing of digital images.)

untreated inactive or latent TB infection (LTBI) could progress, early detection by periodic testing for LTBI should be performed annually in those with X-ray evidence of silicosis (1/0 or greater profusion category using the ILO classification).[17] Periodic testing should also be considered for those with more than 25 years of silica exposure but without evidence of silicosis.[13]

7. The National Kidney Foundation recommends three basic tests to screen for kidney disease: a quantitative test for protein or albumin in the urine (proteinuria), a calculation of glomerular filtration rate (GFR) based on a serum creatinine measurement, and a blood pressure measurement.[18,19,20]

MEDICAL AND OCCUPATIONAL HISTORY

A medical history, including respiratory symptoms and smoking history, should be completed with the assistance of a trained interviewer such as a physician, physician's assistant, or nurse-practitioner. If a trained interviewer is not available, the forms can be completed by the worker to the best of his or her ability. Sample forms and examples for these purposes are provided in Appendix C. The OHP forms have been developed as guidelines for obtaining medical and work history information specific to the chest and related lung disorders. The medical information in Appendix D, Form D-1, should be gathered as part of the OHP, either by administering this portion of the examination separately or by including these items in the questionnaire used by the examining health professional. If the worker is uncertain about a response, the question should be left blank. A separate record detailing the subject's occupational history and potential exposures should be obtained. Such a record consists of a chronological entry of all jobs, setting forth the specific duties of the person and the nature of potential occupational exposures. The job history should contain a question regarding hobbies that might

affect the respiratory system. All jobs up to the present employment—even part-time work—should be accounted for. If the employer cannot ascertain from personnel records the jobs held by a worker, then this information should be included on the occupational history form. A form for obtaining an occupational history is included as Appendix D, Form D-2.

MEDICAL EXAMINATION

The physical examination should be focused on the general condition and respiratory.[2] Where examination by a physician is not practicable, a physician's assistant or nurse-practitioner can conduct a routine examination and refer abnormalities to a physician for further evaluation; alternatively, clinical data collected by a mobile medical-evaluation service and reviewed by a physician can be used for follow-up medical evaluation. It is important that NISA member companies determine that a mobile medical service provider is reputable and capable of providing high quality examinations that meet the specifications referenced in this manual. The physician or other person conducting the examination should be provided with a description of the duties and physical abilities required by the job, respiratory protective equipment used by the worker, an estimate of the crystalline silica exposure level, and other information pertinent to the clinical assessment. If possible, the person conducting the examination should gain first-hand knowledge of the workplace conditions by visiting the work site to observe the job requirements. The examination should note whether observations relating to the chest, such as symmetry, expansion, percussions, breath sounds, and palpitations are normal, and whether wheezes, rales, and rubs are present. An assessment of the worker's ability to wear a respirator during the course of work should be made and documented.

CHEST X-RAYS

Radiographic changes in workers exposed to crystalline silica are the most practicable means of early detection of silicosis; that is, abnormalities are usually seen radiographically before pulmonary function loss can be detected spirometrically or before symptoms appear. A high resolution chest computed tomography (HRCT) scan is more sensitive in identifying the parenchymal opacities of silicosis. However, the lack of standardized imaging techniques and widely accepted methods of classification make HRCT implementation as a surveillance tool impractical at this time.[2] HRCT has been found to be useful as a follow-up to conventional radiographs in interpreting and attributing subtle changes consistent with silicosis from other pathology. Chest radiography is also useful for monitoring the progression of silicosis as well as for identifying treatable complications including mycobacterial diseases such as TB.[2] Periodic chest X-rays are therefore a vital part of medical surveillance.

Chest radiography is one of the most commonly performed radiographic examinations, but it is often difficult to obtain consistently high-quality radiographs. The proper interpretation of the subtle findings of pneumoconiosis depends on a technically superior chest radiograph.[6,21] Radiographs should be produced using the best current techniques, and films produced under any lower standard are not acceptable.

Specifications

Although other X-rays may be ordered by an examining physician, a PA projection on a film no less than 14x17 inches and no more than 16x17 inches at full inspiration is essential to the program for detection of the pneumoconioses.[21] The film must be exposed quickly enough to avoid blurring as a result of motion and must use factors adequate for optimum penetration without "graying" caused by scattered radiation. Ancillary measures, such as the use of a grid,

may be necessary. A high-kilovoltage technique with a grid is the preferred method, but adequate films can in some instances be obtained by a lower voltage method.

Guidelines providing comprehensive discussion of the importance of proper equipment and technique in producing radiographs for evaluating pneumoconioses have been published.[1,6,22,23,24] Detailed specifications for chest X-rays for the NIOSH Underground Coal Miner X-Ray Surveillance Program can be found in the *Code of Federal Regulations,* Title 42, Part 37, which describes factors important in obtaining high-quality X-rays.[25] These specifications should be brought to the attention of the medical facility or provider contracted to perform the X-rays and are reproduced in Appendix D. Questions concerning the suitability of a facility to perform X-rays and exceptions to these specifications should be brought to the attention of the radiologist performing the interpretation.

Over the past decade, there have been remarkable advances in the technology of chest imaging.[26] Because of inherent advantages over chest films, digital radiography for chest imaging is rapidly replacing film screen-based chest units in the radiology departments of most academic hospitals and is spreading to community hospitals and clinics as well. Digital radiography can produce consistent high quality images that can be archived and retrieved easily, eliminating the problem of the "lost film." Perhaps the greatest advantage of the newer digital techniques is the evolving advancements being made by linking to sophisticated computer programs that will aid the physician in computer-aided diagnosis. A number of studies have shown that the interpretation of small opacities using digital imaging is comparable to their detection using conventional chest X-rays.[7,8,9] For these reasons, the NISA OHP program has determined it will accept good quality computed radiography (CR) or digital radiography (DR) chest images reproduced on film to be used with the current ILO system for classification of the pneumoconioses.

Interpretations

In clinical practice, it is customary for physicians reporting radiological findings from chest films to do so in non-quantitative, narrative form. For most clinical purposes, this is satisfactory. However, when information is to be used for medical surveillance or for epidemiological studies, the reporting must be more quantitative.[23]

ILO Classification System

For the OHP, the radiographic changes associated with pneumoconioses must be classified according to the 2000 *Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses*.[6] The interpretation must be recorded on a form, as shown in Appendix D. All pertinent observations must be recorded on the interpretation forms. These documents should be provided as a requirement for radiologists engaged to interpret chest X-rays as part of the OHP.

The ILO system is designed to classify the appearances of pneumoconioses on a PA chest radiograph. The classification system does not attempt to define specific medical diagnoses, but it is very important in recording the type and extent of radiographic changes as well as in describing any progressive changes, when comparing successive studies. It has been used extensively internationally for epidemiological research, the surveillance of those in dusty occupations, and for clinical purposes.[6,23]

The ILO classification system provides a means of systematically recording the radiographic abnormalities in the chest caused by the inhalation of dusts .[6] As noted in the *ILO Guidelines:*

The object of the Classification is to codify the radiographic abnormalities of pneumoconiosis in a simple reproducible manner. The Classification does not define pathologic characteristics, nor take into account the ability of the person to perform work (working

capacity). The Classification does not imply legal definitions of pneumoconiosis for compensation purposes, nor set, nor imply a level at which compensation is payable.

The ILO classification system requires the codification of a chest radiograph according to its pulmonary (parenchymal) and pleural abnormalities. The chest film or image must also be graded as to its technical quality.[24] Four grades of technical quality are used:

1. Good;
2. Acceptable, with no technical defect likely to impair classification;
3. Acceptable, with some technical defect but still adequate for classification; and
4. Unacceptable for classification.

When it is not possible to replace a grade 3 radiograph with a better one, more details about the technical defects should be recorded.

Pleural findings are not discussed in this manual because pleural changes are not considered to be associated with silica exposure but are instead regarded as a marker of exposure to fibers such as asbestos. Classification is performed by viewing a worker's chest X-ray, considering all affected zones of the lung, and comparing the worker's film with a set of ILO standard radiographs. With respect to pulmonary findings, the system divides lung opacities into two categories, small and large, with each defined in specific quantitative terms.

Small opacities are recorded according to four characteristics: shape, size, profusion, and extent. Figure 4-1 illustrates shape and size classification for small opacities. Two shapes are recognized—small rounded and small irregular. For each shape, opacity size is graded in three categories; for example, rounded opacities (p,q,r) are grouped according to the approximate diameter of the predominant lesions as follows:

1. Opacities (p) up to 1.5 millimeters in diameter.
2. Opacities (q) greater than 1.5 millimeters and up to about 3 millimeters in diameter.

3. Opacities (r) exceeding about 3 millimeters and up to about 10 millimeters in diameter.

Diameter or Width (min)	Letter Designation	Rounded Opacities	Letter Designation	Irregular Opacities
< 1.5	p		s	
1.5-3	q		t	
3-10	r		u	

FIGURE 4-1—SHAPE AND SIZE CLASSIFICATION FOR ROUNDED AND IRREGULAR OPACITIES*

Irregular opacities (s,t,u) are classified according to the approximate width of the predominant lesions as follows:

1. Fine linear opacities (s) up to about 1.5 millimeters.
2. Medium opacities (t) greater than about 1.5 millimeters and up to about 3 millimeters.
3. Coarse, blotchy opacities (u) greater than about 3 millimeters and up to about 10 millimeters.

Two letters are used to record shape and size. If the reader considers that virtually all the opacities are of one shape and size, this should be noted by recording the appropriate symbol twice, separated by an oblique stroke (for example, q/q). If, however, another, less predominant shape or size is observed, this should be recorded as the second letter (for example, q/t). Hence, q/t would mean that the predominant small opacity is round and of size q but that significant numbers of small irregular opacities of size t are present. Figure 4-2 illustrates recordings of shape and size classifications. In the ILO Classification system only the two most prominent size and shape opacities are recorded.

* Adapted from Reference 6.

The term profusion refers to the concentration or number of small opacities in the affected zones of the lungs. The right and left lungs are divided into three zones (upper, mid, and lower) by horizontal lines drawn at approximately one-third and two-thirds of the vertical distance between the lung apices and the domes of the diaphragms. The determination of profusion is based on a comparison of the observed opacities with a series of ILO standard radiographs. The 22-film set and the 14-film Quad Set of standard radiographs can be obtained from ILO. In early versions of the system, profusion was graded only in four major categories:

Category 0. Small opacities are absent or less profuse than in Category 1.

Categories 1, 2, and 3. Small opacities are increasingly profuse, as defined by the corresponding radiograph.

In 1968, the codification of small-opacity profusion was modified by the expansion of the profusion scale from four major mid-categories (0-3) to a total of 12 categories. This expansion to a twelve category scale with minor categories flanking the major categories was a reflection of the varied appearance of radiographs and the difficulty with borderline films that did not closely meet the mid-category definition. Figure 4-3 illustrates the scale as it relates to the profusion of small opacities.

The current notation designating the divisions of the 12-point scale is as follows:

0/–	0/0	0/1
1/0	1/1	1/2
2/1	2/2	2/3
3/2	3/3	3/+

The first number in each subcategory indicates the major category to which the subject radiograph belongs; the second number indicates whether the profusion level is judged to be somewhat less than, equal to, or somewhat greater than the profusion level corresponding to the

major category indicated. Thus, the notation 2/1 is used to indicate a profusion level that is Category 2 but at less than the midpoint of that category.

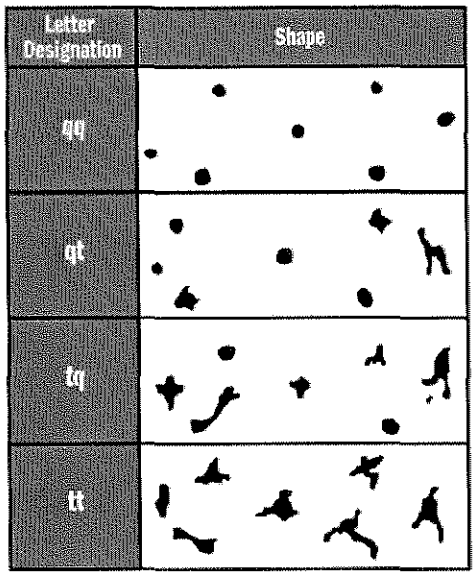


FIGURE 4-2—EXAMPLES OF RECORDINGS OF SHAPE AND SIZE CLASSIFICATIONS *

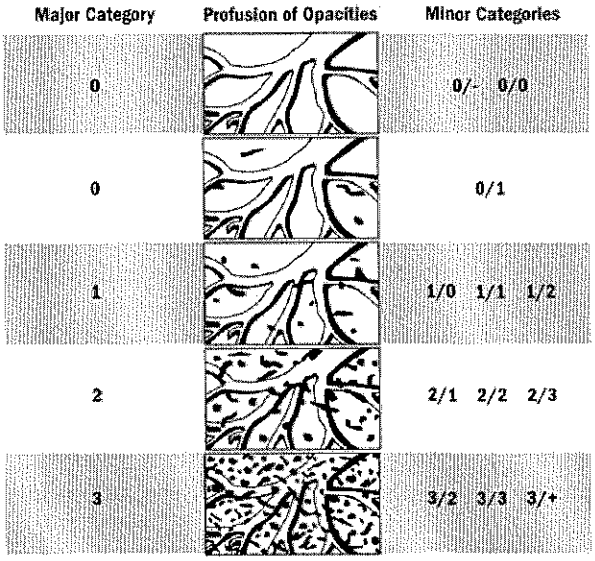


FIGURE 4-3—TWELVE-POINT SCALE AND ITS RELATIONSHIP TO PROFUSION OF OPACITIES*

* Adapted from Reference 6.

The category of profusion is based on comparison of the subject radiograph to the ILO Standard Radiographs. For profusion, the written descriptions are a guide, but the standard radiographs take precedence. The appropriate category is chosen by comparison with the standard radiographs that define the levels of profusion characteristic of the centrally placed subcategories (0/0, 1/1, 2/2, 3/3). The category is recorded with the corresponding symbol followed by an oblique stroke (0/, 1/, 2/, 3/). If no alternative category was seriously considered, the subject radiograph is classified into the central subcategory (0/0, 1/1, 2/2, 3/3). If an alternative category was seriously considered, that category symbol is placed after the oblique stroke, i.e. 2/1. A subcategory 2/1 refers to a radiograph with profusion similar in appearance to that depicted on the subcategory 2/2 standard radiograph, but category 1 was seriously considered as an alternative.[6]

The fourth characteristic of small opacities that must be recorded in the ILO classification system is the spatial distribution of pulmonary disease. To record this parameter, the lungs are divided into three zones on each side, corresponding to the upper, middle, and lower thirds of the lungs. Figure 4-4 provides an example of coding of the zones of lung involvement for small-opacity profusion. In reporting the extent of disease, the B-reader simply checks off the zones affected. The zones can be coded R or L for right or left lung; U, M, or L correspond to the upper, mid, or lower lung zone (e.g. RU = right upper).

Of the four characteristics of small opacities requiring codification, profusion is very important, for it is a good indicator of the concentration of any dust disease that may be present. When profusion levels vary from one portion of the lung fields to another, the category of profusion to be recorded is determined by considering the profusion as a whole, over the affected lung zones. Where there is a marked difference in profusion (three minor categories or more)

among different zones, the zone or zones that show less profusion are ignored for classification purposes.

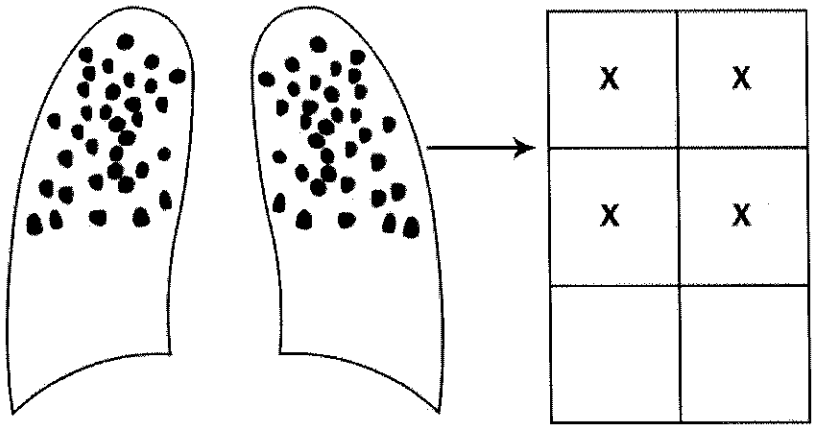


FIGURE 4-4—EXAMPLE OF CODING OF LUNG ZONES OF INVOLVEMENT OF OPACITIES

A large opacity is considered to be present when an opacity presents its longest dimension exceeding one centimeter and is evident on a chest film in which there is sufficient evidence to suggest the presence of a pneumoconiosis. The classification excludes nonpneumoconiotic large opacities due to other causes such as lung cancer. Simple silicosis is said to be present when a profusion of small opacities (1/0 to 3/+) exists, and complicated silicosis is said to occur when large opacities are present. Figure 4-5 illustrates the classification of large opacities. Most often, a background of small opacities will exist when dust-induced large opacities are present.

Large opacities are codified in three categories, depending on the size of the lesions:

Category A. A single opacity whose greatest diameter exceeds about 1 centimeter but is no more than about 5 centimeters, or several opacities, each greater than about 1 centimeter in diameter, the sum of whose diameters does not exceed about 5 centimeters.

Category B. One or more opacities larger or more numerous than those in Category A whose combined area does not exceed the equivalent of the right upper zone of the lung.

Category C. One or more opacities whose combined area exceeds the equivalent of the right upper zone of the lung.

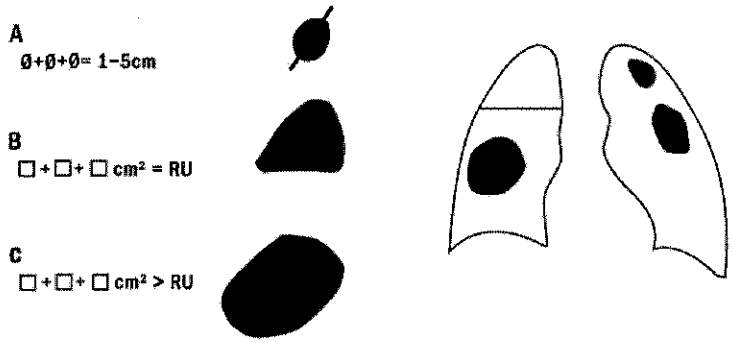


FIGURE 4-5—CLASSIFICATION OF LARGE OPACITIES*

Narrative Radiology Report

Although it is not an OHP requirement, companies may also wish to have chest films evaluated by a narrative method, as is customary among radiologists. In such a report, each facet of the film is noted, and a statement about it is included. A narrative evaluation can include adequacy of technique; soft tissues and bones of the thorax; position and shape of the diaphragm; costophrenic angles; the size and shape of the cardiac shadow; the size, shape, and position of the hila; the appearance and distribution of the bronchovascular markings; the appearance of the pleura and the lung parenchyma, including a statement about whether or not abnormal parenchymal opacities are present; a summary of the findings; and a statement about whether the film is normal or abnormal. If the chest film is determined to be abnormal, the narrative should

* Adapted from Reference 6.

describe the way in which it is abnormal and what the abnormality means. An example of a narrative report is presented in Appendix D.

Cumulative Radiology Report

Another approach to industrial surveys of chest X-rays is a cumulative radiology report.[27] A cumulative radiology report contains a listing of serial interpretations and findings in chronological order, or reverse chronological order, analogous to clinical progress notes. Putting serial X-ray reports into a single- or multiple-page format improves the quality of the report and conveys the information to the industry client in an effective, understandable manner. This style of report can be produced on a personal computer, but some customization of a commercial word processing package will be necessary.[27] An example of a cumulative radiology report is presented in Appendix D.

Reader Variability, B-Readers, and Consensus Readings

Repeated classification of the same radiograph may vary considerably, not only from reader to reader (inter-reader variability) but also among multiple readings by the same reader (intra-reader variability). This variability has been reported in the medical literature[28, 29, 30, 31, 32] and is greatest when profusion levels are near the lower end of the ILO 12-point scale. Generally speaking, B-readers have more difficulty distinguishing a series of radiographs at the boundary between Categories 0 and 1, namely, 0/1 and 1/0.

To improve the proficiency of readers and minimize the variability of readings, NIOSH, in conjunction with the American College of Radiology, has conducted training programs and instituted a proficiency examination for physicians who want to demonstrate competence in the classification system.[24] Those who successfully pass the examination are certified as B-readers and are periodically required to pass a recertification examination. Physicians who only attend an

instructional course on the ILO classification system or submit other documentation to NIOSH are called A-readers and are not generally as proficient as B-readers.

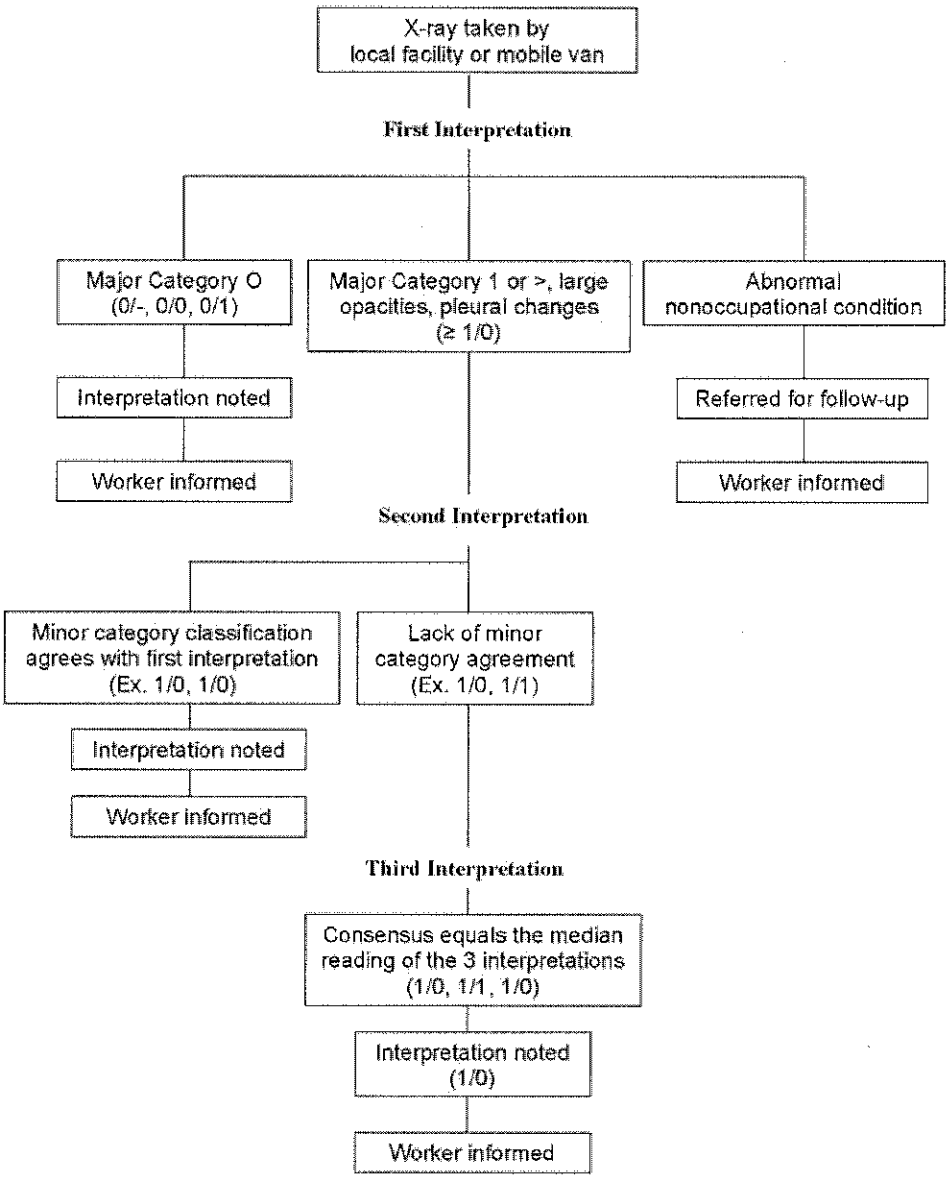


FIGURE 4-6—NISA CONSENSUS PROCEDURE FOR X-RAY INTERPRETATIONS

For the purposes of the NISA OHP, all chest X-rays should be interpreted by a physician who is certified as a B-reader, is board-certified in radiology, and has considerable experience in occupational lung diseases. Because of the inter- and intra-reader variability in readings, the ILO

Guidelines recommend that at least two, and preferably three, independent readings be made for each radiograph.[6]

NISA recommends that multiple interpretations of all films 1/0 or greater be obtained and that five to ten percent of the films interpreted as 0/1 receive multiple interpretations, according to the decision logic shown in Figure 4-6. Such a system will allow a consensus interpretation or median reading to be noted. NISA has identified an expert panel of radiologists who are willing to participate in a consensus interpretation methodology. Any company that would like to have a listing of the members of the NISA Radiology Panel should contact NISA headquarters. Any NISA member may choose to participate in the consensus reading program. Selection of radiologists and other physicians proficient in ILO classification is vital to the X-ray component of the OHP. Other member companies and the NISA staff can provide information on selecting B-readers.

Retention and Storage of Film

Chest X-rays *must* be stored safely for an indefinite period in a place from which they can be retrieved for subsequent comparisons. Copies are *not* acceptable for this purpose. Hospitals and X-ray facilities are known for purging old X-rays to relieve storage-space problems and to recover silver from the X-ray film's emulsion. X-ray films should be kept for 30 years after the worker ceases employment; companies may want to consider taking possession and self-storing X-ray films to ensure that inadvertent destruction does not occur. It may be advisable to arrange for centralized storage of films at a medical facility, with a written agreement specifying storage conditions.

The International Standards Organization (ISO) has developed a standard 18911, *Imaging Material —Processed Safety Photographic Films—Storage Practices*, which provides guidance for storing and preserving photographic film.[33]

One of the most important factors affecting the storage life of radiographs is the amount of residual thiosulfate left in the radiograph after processing and drying. Residual thiosulfate comes from the fixer chemicals; thorough washing of the film after developing and fixing is important. Testing for residual thiosulfate is beyond the capability of most member companies, therefore it may be advisable to confirm with the X-ray provider that processing of the films meets ISO criteria.

General guidelines for NISA members storing radiographs are as follows:

1. Store films at a temperature of 32°F–75°F and a relative humidity of 30 to 50 percent. Peak temperatures for short time periods should not exceed 90°F, and relative humidity should not exceed 60 percent.
2. Avoid cycling of temperature (± 4° F) and relative humidity (± 5% RH).
3. Avoid storage in the presence of chemical vapors.
4. Place each film in a protective folder, or if several films are stored in a single folder, place interleaving paper between films
5. Never store unprotected films in sunlight or other bright light.
6. Avoid pressure damage caused by stacking a large number of films or by forcing more radiographs than fit easily in a file drawer or on a shelf.
7. Avoid storage locations in which water damage could occur.

Quality Control

Technical quality control is an exceedingly important factor for chest radiographs, since it has a dramatic effect on the interpretation and categorization of pneumoconioses. Film quality ratings of Grades 1 and 2 are acceptable for the interpretation of pneumoconioses. Grade 4 or unreadable film is unacceptable, and occurrences of Grade 4 film should be reduced to zero. Grade 3 films, which are "poor," contain technical defects but are still acceptable for

classification purposes. Though not stated[30], it is implied that the technical defects associated with Grade 3 films could affect the ILO classification process. In occupational health surveillance activities, when more than 1 in 10 chest films are considered to be Grade 3 or worse, a review of the factors influencing technical quality is in order. This should serve as a minimum goal. One must bear in mind, however, that reader assessment of quality is somewhat subjective and that agreement among readers on quality grade is often poor. Thus, procedures for providing feedback to stationary and mobile X-ray facilities and X-ray technicians to upgrade quality and achieve high standards is a factor that must not be overlooked.

SPIROMETRY TESTING

BACKGROUND

Spirometry is a medical screening test that measures various aspects of breathing and lung function. It is performed using a spirometer, a special device that measures the volume of air a subject inhales or exhales and the rate at which the air is moved into or out of the lungs. The most common spirometric tests require that the subject exhale as forcefully as possible after taking in a full, deep breath. The subject's effort is called the forced expiratory maneuver.

Spirometry is an important component of the NISA respiratory medical surveillance program but is one that requires special attention from the spirometry provider to provide quality data useful in a surveillance program. It should be emphasized that pulmonary function tests are nonspecific; one can seldom make a diagnosis based on spirometric findings alone.[5,34] The total clinical presentation, including medical history, physical examination, chest X-ray, and appropriate ancillary laboratory studies, must be considered. Experience has shown that most abnormalities on screening spirometry are not due to work-related disorders. Smoking,

nonoccupational pulmonary disease, and other variables are more common causes of alterations in pulmonary function.

In the past, spirometry practices in the industrial setting have experienced drawbacks due to inadequate training of technicians, nurses and physicians to perform and interpret test results, and certain spirometers have been found to be technically deficient. This has improved largely due to the efforts of the ATS in upgrading spirometric instruments and practices.[12] Spirometry is used to affect decisions about individual employees, such as: "Does this worker have enough evidence of impaired lung function to preclude working at a specific job? Should this person have further tests to evaluate his/her lung function? How likely are these changes a result of his/her dust exposure? Should treatment be considered?"

Answers to each of these questions based on spirometric maneuvers can have a dramatic effect on a person's lifestyle, standard of living, and future treatment. For these reasons, NISA members are encouraged to ensure that spirometry is conducted to meet stringent quality control parameters. The physician or health professional performing spirometry for a member company should be thoroughly familiar with and meet the guidelines in this subsection and the criteria of the ATS.

The routine assessment of ventilatory function with a spirometer is a common practice in occupational medicine.[5,34] Properly conducted, spirometry is regarded as a useful component of respiratory medical surveillance programs for baseline evaluation and periodic monitoring.

Routine follow-up studies of workers exposed to respirable crystalline silica can detect pulmonary function loss in its earliest stages, although radiographic changes consistent with silicosis will normally precede losses detected by spirometry that result from the inhalation of respirable crystalline silica.

Fundamentals of Spirometry

Spirometry is used to detect lung abnormalities that show obstructive or restrictive patterns, or a combination of the two. Obstructive diseases or abnormalities interfere with the flow of air into and out of the lungs. The underlying disease process frequently alters the diameter or integrity of the airways, causing increased airflow resistance from bronchospasm, mucosal edema, and increased production of secretions. Emphysema is one form of obstructive disease. When individuals with emphysema exhale, especially if they exhale forcefully, the airways narrow further or collapse. Asthma and chronic bronchitis are other common obstructive diseases. Restrictive diseases, such as asbestosis and silicosis, are caused by the development of fibrotic (scar) tissue in the lungs that reduces the ability of the lungs to expand (i.e., they have low compliance) but does not necessarily affect air flow. Disorders that affect the neuromuscular functioning of the chest wall may also produce a restrictive pattern. Other lung diseases, such as pneumonia, may show both obstructive and restrictive patterns.

There are two types of spirometers: (1) those that record the amount of air exhaled or inhaled within a certain time (volume) and (2) those that measure how fast the air flows in or out as the volume of air inhaled or exhaled increases (flow). Both are used in screening for lung disease. If the primary measurements of interest are forced expiratory volume at one second ($FEV_{1)}$ and forced vital capacity (FVC), which are volume measures, then an instrument that measures volume directly will, in general, be superior to an instrument that measures flow and derives volume. The main advantage of flow-measuring devices is their smaller size and portability. However, flow-measuring devices are usually less accurate and more difficult to calibrate and maintain. For the NISA OHP, volume spirometers are preferred over flow spirometers.

Certain diseases or conditions affect the rate at which air moves through the lungs (obstructive diseases) or the ability of the lungs to expand (restrictive diseases). Since spirograms reveal both the rate of air flow and the volume of air moved, they identify individuals who have these diseases or conditions.

Three measurements obtained through spirometry are particularly useful: FVC, FEV_1, and the ratio of the FEV_1 to the FVC.

The FVC is the total volume of air exhaled after a forced expiratory maneuver (the act of exhaling as hard and fast as possible after maximal inspiration). FVC should not be confused with vital capacity (VC), defined as the maximum amount of air the subject can breathe out after the deepest inspiration, whether or not the air was exhaled forcefully. In subjects without airways obstruction, the FVC is usually equal to the VC. The FEV_1 is the amount of air a person breathes out during the first second of a forced expiratory maneuver (See Figure 4- 7).

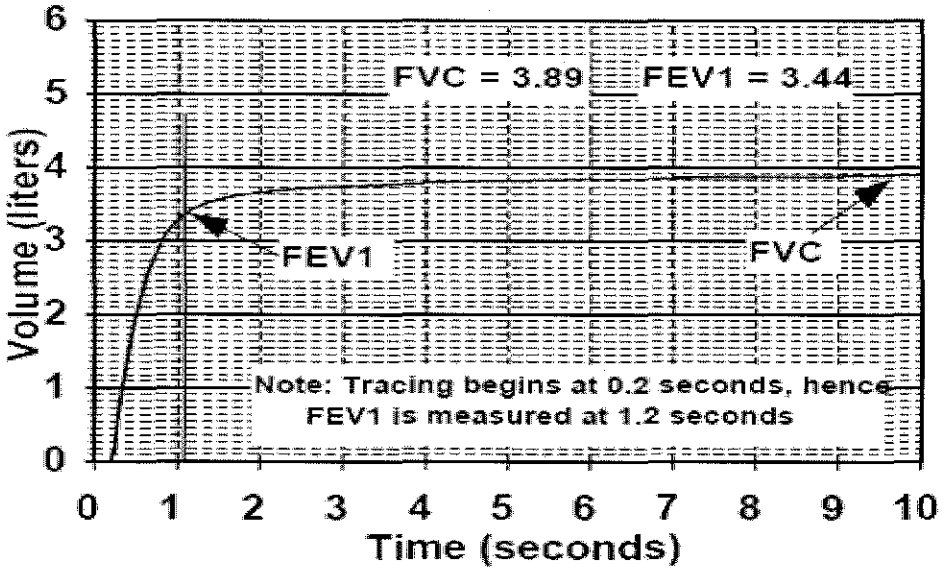


FIGURE 4-7—FVC AND FEV_1 ON A NORMAL VOLUME TIME CURVE

The ratio of the FEV_1 to the FVC is obtained by dividing the FEV_1 by the FVC. See Figure 4-8 for an example on computing the FEV_1/FVC ratio. A person with a low FVC may have a restrictive disease while a low FEV_1/FVC ratio may indicate an obstructive disease.

DEFINITION: FEV_1 as a Percentage of FVC (FEV_1/FVC) is the percent of the total observed FVC that is exhaled in the first second (FEV_1). This calculation is useful for detecting obstructive disease. A person with healthy lungs can exhale 70-80% of the FVC in the first second, while a person with airways obstruction may be able to exhale 60% or less of the FVC in the first second.

HOW TO CALCULATE:

1. Calculate the *largest acceptable* FVC and FEV_1, even if they are not from the same tracing.
2. Divide the FEV_1 by the FVC.
3. Multiply the answer by 100 to obtain the percentage.

EXAMPLE: Calculation of FEV_1/FVC%:

Assume the largest acceptable FVC is 3.75 L.

Assume the largest acceptable FEV_1 is 3.15 L.

$FEV_1/FVC\% = (3.15/3.75) \times 100 = 84\%$

FIGURE 4-8—FEV_1 AS A PERCENTAGE OF FVC (FEV_1/FVC)

See Figures 4-9 and 4-10 of a pattern of restrictive and obstructive impairment compared with a curve of a normal individual when using a volume spirometer.

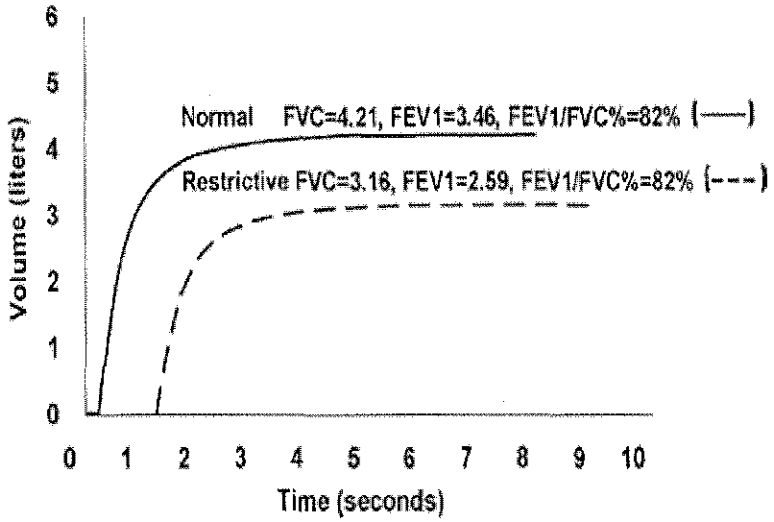


FIGURE 4-9— PATTERN OF RESTRICTIVE IMPAIRMENT

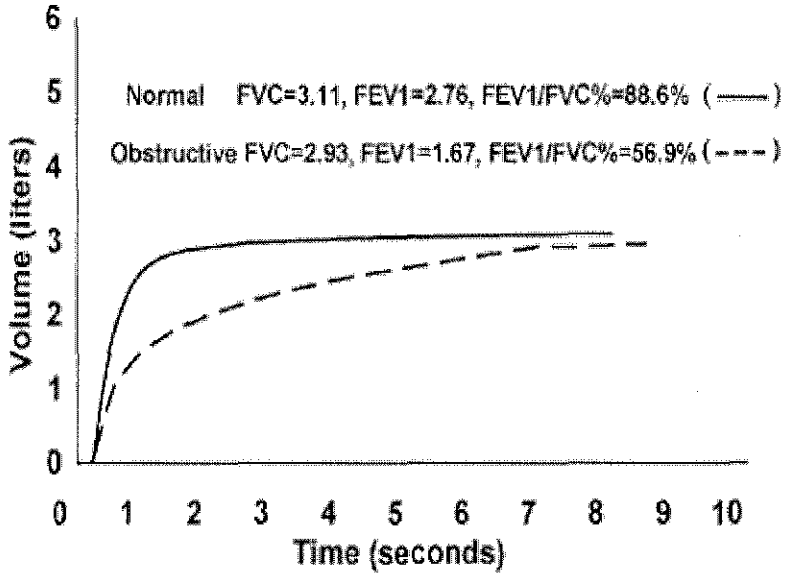


FIGURE 4-10— PATTERN OF OBSTRUCTIVE IMPAIRMENT

For example, on the average, 70 to 80 percent of the FVC is exhaled in the first second from a person who is healthy, while a person with airways obstruction may only be able to exhale 60 percent or less of the FVC in the first second, even though the FVC may be normal. A person with a low FVC typically will also have a low FEV_1, indicating a possible restrictive pattern. Some individuals may also show evidence of a combination of both airways obstruction (low FEV_1) and restriction (low FVC). See Figure 4-11 of a mixed pattern (restrictive and obstructive) compared with a curve from a normal individual. It should be noted that some clinicians may consider these curves to show an obstructive pattern instead of a mixed pattern. In many cases, the low FVC of a mixed impairment pattern is secondary to the air-trapping and incomplete expiration of moderate or severe airways obstruction.

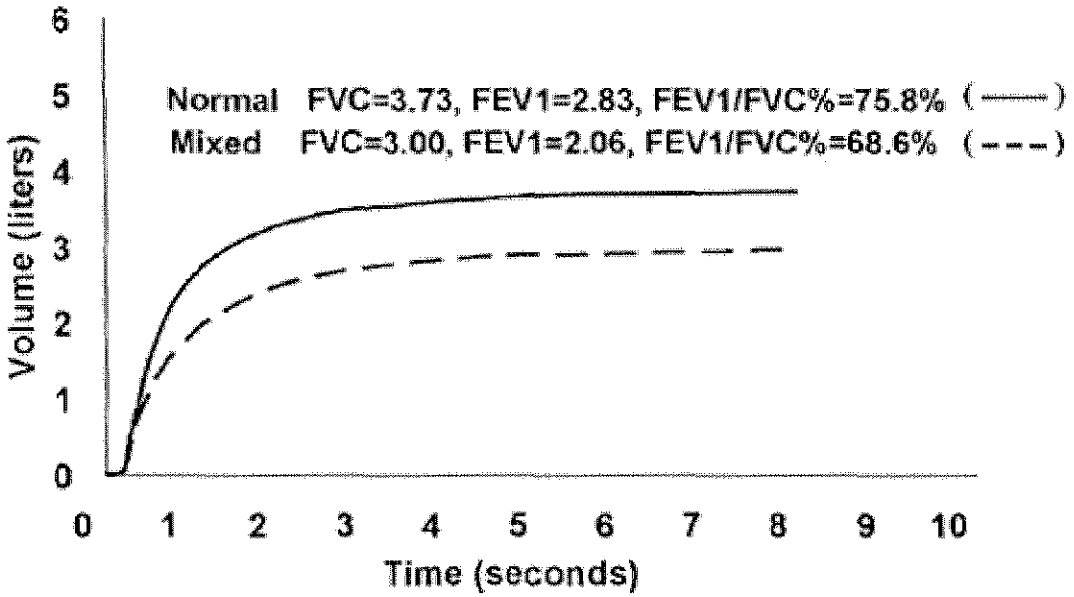


FIGURE 4-11—MIXED PATTERN OF IMPAIRMENT (RESTRICTIVE AND OBSTRUCTIVE)

Interpretation of Spirometry Results

Lung function increases rapidly with growth during childhood and adolescence, reaches a peak sometime between the ages of 18 and 35, and then begins to slowly decline, even in healthy persons.[35] Persons who grow relatively tall also have relatively large lungs when compared to those who are shorter in stature. Women, on average, have lungs that are about 20 percent smaller than men of the same height and age.[36] For a given standing height, African-American men, on the average, have longer legs and a correspondingly shorter trunk size than Caucasian men and therefore slightly smaller lungs.[37,38,39] This explains most of the differences between predicted values for Caucasian and African-American men. All of the above factors mean that to optimally interpret spirometry results (observed values), you must first know the employee's age, height, gender, and race or ethnicity.

There have been dozens of studies published that have determined spirometry reference values from groups of relatively healthy persons (normal values). NIOSH recommends following

the most recent update of the ATS recommendations for interpretation of spirometry and selecting reference values based on the third National Health and Nutrition Examination Survey (NHANES III), published in 1999.[35] It is crucial that providers of spirometry services for NISA member companies use the NHANES III reference values for comparison purposes. The NHANES III study provides a separate set of spirometry reference equations for men and women of African-American, Caucasian, and Mexican-American ethnic groups. The NHANES III study did not provide spirometry reference equations for Asian-Americans, American Indians, East Indians, or other ethnic groups.

The decision about whether spirometric tests are "normal" is made by comparing the workers results with the NHANES III predicted normal values. In all studies of predicted normal values, several factors, including age, height, sex, and race, have been found to affect lung capacity and flow rates. Just as with eyesight and hearing, pulmonary function declines predictably with advancing age. Taller individuals tend to have larger lung volumes, so when height is measured, the subject should be in stocking feet to preclude the influence of heels of varying heights. Men generally have larger lung volumes than do women of the same age and height.

The subject's FVC or FEV_1 can be expressed as a percentage of their predicted normal values:

$$\%\,\mathrm{Pr}edicted\,FVC = \frac{Observed\,FVC}{\mathrm{Pr}edicted\,FVC}\,x100$$

$$\%\,\mathrm{Pr}edicted\,FEV_1 = \frac{Observed\,FEV_1}{\mathrm{Pr}edicted\,FEV_1}\,x100$$

Spirometry results must be interpreted by a physician, preferably one trained in pulmonary medicine. A diagnosis of pulmonary disease can seldom be made based on

spirometry alone; however, spirometry is an important part of the total clinical presentation. Most pulmonary abnormalities measured by spirometry are not due to work-related disorders but rather to smoking, nonoccupational pulmonary disease, and other respiratory conditions. Certain patterns of disordered lung function can be recognized, and although the patterns are seldom characteristic of a specific disease, they can be used to identify the various types of clinical illnesses related to the type of abnormal lung function.

Chronic obstructive pulmonary disease (COPD), which includes emphysema and chronic bronchitis, is characterized by a pattern of airway obstruction and reduced airflow. Chronic bronchitis is diagnosed when an individual has excessive airway mucus secretion (sputum), leading to a persistent productive cough. The production of excessive mucus can lead to a narrowing of the large and small airways, making it more difficult to move air in and out of the lungs. Emphysema is characterized by a permanent destruction of the alveoli, the lungs' tiny elastic air sacs, where exchange of carbon dioxide and oxygen takes place. The destruction of the alveoli causes small air passages, called bronchioles, to narrow or collapse, which in turn limits airflow out of the lung.

When airways narrow as a result of chronic bronchitis or collapse as a result of emphysema, the affected individual has difficulty exhaling air from the lungs. Airway obstruction is determined by using spirometry to measure FEV_1 and FVC, expressed as a percentage of FVC, namely, FEV_1/FVC%. In obstructive airway disease, these measurements are reduced. Figure 4-12 shows a narrowed airway from bronchitis, a form of obstructive pulmonary disease.

Restrictive lung diseases caused by pulmonary fibrosis, such as silicosis, lead to a stiffening of the lungs as a result of the presence of fibrotic tissue. Rather than obstructing or collapsing the airways, as with chronic bronchitis and emphysema, fibrosis increases the stiffness

of the lungs, restricting the lungs' ability to expand fully on inhalation. Spirometry showing a restrictive response pattern is characterized by a reduction in lung volumes and ventilatory capacity, measured by a reduction in FVC, with normal $FEV_1/FVC\%$.

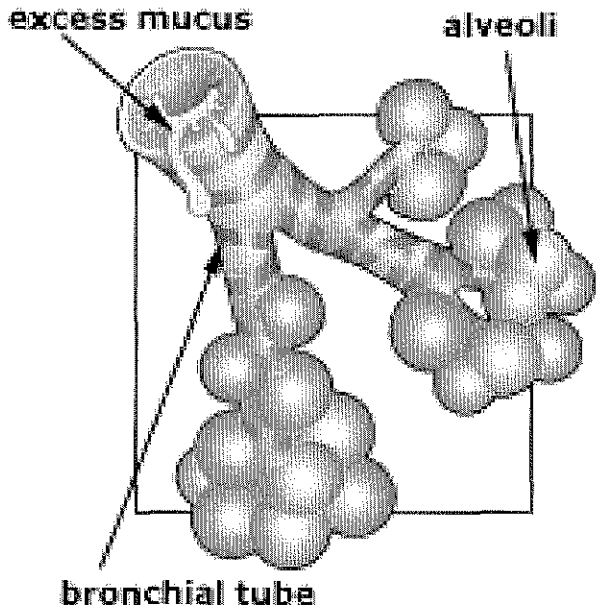


FIGURE 4-12—BRONCHITIC AIRWAY SHOWING THE NARROWING OF THE AIRWAY CHARACTERISTIC OF AN OBSTRUCTIVE PATTERN OF PULMONARY IMPAIRMENT

A mixed pattern of obstructive and restrictive impairment may be present in a worker with complicated silicosis or when more than one disease process (for example, silicosis and emphysema) is present. In complicated silicosis, large masses of fibrosis reduce the ability of the lungs to expand and reduce FVC. Obstruction may also be present, presumably because of increased airway resistance and alveolar abnormalities.

Table 4-2, Lung Diseases and Spirometry Results, shows the possible relationships between spirometry results and lung disease, and Table 4-3, Guidelines for Assessing Degree of Ventilatory Impairment, provides useful guidance for comparing spirometry results with normal values to assess the degree of pulmonary impairment.

LUNG DISEASES AND SPIROMETRY RESULTS			
Interpretation	**$FEV_1/FVC\%$**	**FVC**	**FEV_1**
Normal person	**normal**	**normal**	**normal**
Airway Obstruction	low	normal or low	low
Lung Restriction	normal	low	low
Combination of Obstruction/Restriction	low	low	low

Adapted from Chronic Obstructive Pulmonary Disease, 5th Edition [1977]. American Lung Association (46).

TABLE 4-2—LUNG DISEASES AND SPIROMETRY RESULTS

GUIDELINES FOR ASSESSING DEGREE OF VENTILATION IMPAIRMENT		
Interpretation	**Obstructive Pattern**	**Restrictive Pattern**
Normal	**$FEV_1/FVC\% > LLN$**	**$FVC \geq LLN$**
Borderline	$FEV_1/FVC < LLN$ & $FEV_1 \geq LLN$	
Mild	$FEV_1 < 100$ & $> 70\%$ Pred	$FVC < LLN$ & $> 70\%$ Pred
Moderate	$FEV_1 < 70 > 50\%$ Pred	$FVC < 70$ & $> 50\%$ Pred
Severe	$FEV_1 \geq 50\%$ Pred	$FVC \geq 50\%$ Pred

Adapted from American Thoracic Society: Lung function testing: Selection of reference values and interpretative strategies [1991]. American Review of Respiratory Diseases 144:1202-1218 (30).

TABLE 4-3—GUIDELINES FOR ASSESSING DEGREE OF VENTILATORY IMPAIRMENT

ATS Standardization of Spirometry

As discussed above, it is imperative that spirometry be conducted to meet stringent quality control parameters. The physician or health professional performing spirometry for a member company should be thoroughly familiar with and meet the published guidelines for conducting spirometry. Guidance can be found in ATS 1994 (Appendix F), ATS-ERS (European Respiratory Society) (Appendix G) and ACOEM (Appendix H). Spirometry providers should be familiar with and follow the guidelines adopted by these organizations.

A checklist, developed from the criteria of these publications, of some of the items to assess in choosing a spirometry provider is provided in Appendix H. Questions concerning the adequacy of spirometry testing should be directed to the company physician or independent pulmonologist who evaluates the spirograms. Manufacturers should provide documentation that their instruments have been tested by an independent laboratory. If such documentation is not available, the equipment should be approached with caution—it may not meet the ATS criteria. A laboratory widely recognized for providing independent testing of spirometers is the laboratory of the Latter Day Saints Hospital, Salt Lake City, Utah.

TUBERCULIN TESTING

It has been known for a very long time that tuberculosis (TB) can complicate silicosis. Sufficient silica exposure, with or without silicosis, can decrease the ability to fight lung infections caused by TB, non-tuberculous mycobacteria, and fungi.[12,13] A type of cell called a macrophage is needed to kill these kinds of infectious organisms. With sufficient exposure to silica, macrophage killing ability is impaired, and resistance to infection is decreased. Impaired defense mechanisms in the lung increase the risk that TB infections will get out of control and progress to serious, contagious disease. Thus, it is important to detect and treat TB infection early to prevent progression.

Early inactive tuberculosis infection, called latent tuberculosis infection (LTBI), can be detected using two kinds of tests: the tuberculin skin test (TST) or a blood test (either the QuantiFERON-TB Gold test or the QuantiFERON-TB Gold In-Tube test (referred to as the "QF test").[15,16] TST should be performed by intradermal injection of purified protein derivative (PPD), using the Mantoux technique. A two-step TST (TTST) should be performed for initial baseline testing, following current Centers for Disease Control and Prevention (CDC) guidelines for detecting and evaluating tuberculosis.[15] Depending on the company's location, it may be

appropriate to have testing performed by the state or local health department, since medical personnel at these locations may have more experience administering the TST. Alternatively, initial baseline testing can use a single QF test. Subsequent periodic testing would use a single TST or QF test.[16] A positive TST or QF test is evidence of TB infection but does not differentiate between LTBI (inactive) and active disease. Because these are treated differently, further medical study is required to evaluate those people found to have TB infection.

Baseline testing using TTST or a single QF test should be considered upon entry into employment associated with silica exposure. If not already done, baseline testing should be performed in workers with more than 25 years of exposure and those with radiological evidence of silicosis (1/0 or greater profusion category using the ILO classification).[12,13,14] Because of the high risk that untreated LTBI could progress, early detection by periodic testing for LTBI should be performed annually in those with X-ray evidence of silicosis (1/0 or greater profusion category using the ILO classification). Periodic testing should also be considered for workers with more than 25 years of silica exposure but without evidence of silicosis. Those with significant silica exposure histories or silicosis who are exposed to individuals with active TB should be at high priority for follow-up TST or QF testing in contact investigations.[15,16,17]

To prevent progression to active disease, anyone with a significant silica exposure history or silicosis who is found to have LTBI should be offered antimicrobial treatment.[15]

KIDNEY TESTS

As discussed in Section 2, whether or not silica exposure is associated with kidney diseases has not been established at the present time through medical studies.[40,41,42,43,44,45,46] Nonetheless, because there have been some studies indicating a possible link, and because there are screening tests available that will allow early detection, the OHP includes blood pressure measurement and some routine urine and blood tests to determine how well the kidneys are

functioning. In addition to recommending blood pressure measurement, the National Kidney Foundation recommends a check for protein or albumin in the urine (proteinuria), and a calculation of glomerular filtration rate (GFR) based on a serum creatinine measurement.[18,19,20] Measuring urea nitrogen in the blood (BUN) provides additional useful information.

Blood Pressure Measurement

High blood pressure can lead to kidney disease. It can also be a sign that kidneys are already impaired. The only way to know whether blood pressure is high is to have a health professional measure it with a blood pressure cuff. The result is expressed as two numbers. The top number, called the systolic pressure, represents the pressure when the heart is beating.[20] The bottom number, called the diastolic pressure, shows the pressure when the heart is resting between beats. Blood pressure is considered normal if it stays below 120/80 (expressed as "120 over 80"). The National Heart Lung and Blood Institute (NHLBI) recommends that patients with hypertension (high blood pressure) use antihypertensive medications to achieve a blood pressure goal of 140/90, and for people with kidney disease or diabetes use whatever therapy is necessary, including lifestyle changes and medicines, to keep their blood pressure below 130/80.[20]

Protein in the Urine

Healthy kidneys remove creatinine and urea from the blood but leave protein.[20] Impaired kidneys may allow albumin to leak across glomerular membranes. At first, only small amounts of albumin may leak into the urine, a condition known as microalbuminuria, a sign of deteriorating kidney function. As kidney function worsens, the amount of albumin and other proteins in the urine increases, and the condition is called proteinuria.

The OHP recommends a quantitative measurement for protein or albumin in the urine involving laboratory measurement and calculation of the protein-to-creatinine or albumin-to-creatinine ratio. If a laboratory test shows high levels of protein, the test will be repeated one to

two weeks later.[20] If the second test also shows high levels of protein, additional tests may be necessary to evaluate kidney function.

Glomerular Filtration Rate (GFR) Based on Creatinine Measurement

GFR is a calculation of how efficiently the kidneys are filtering wastes from the blood. Creatinine is a waste product in the blood created by the normal breakdown of muscle cells during activity.[20] Healthy kidneys take creatinine out of the blood and put it into the urine to leave the body. When kidneys are not working well, creatinine builds up in the blood.

The blood is tested to see how many milligrams of creatinine are in one deciliter ($1/10^{th}$ of a liter) of blood (mg/dL) [20]. Creatinine levels in the blood can vary, and each laboratory has its own normal range, usually 0.6 to 1.2 mg/dL. If creatinine levels are only slightly above this range, a person probably will not feel sick, but the elevation is a sign that the kidneys are not working at full strength. Because creatinine values are so variable and can be affected by diet, a GFR calculation is more accurate for determining whether a person has reduced kidney function.

The new GFR calculation uses the person's creatinine measurement along with weight, age, and values assigned for gender and race.

Blood Urea Nitrogen (BUN)

Blood carries protein to cells throughout the body. After the cells use the protein, the remaining waste product is returned to the blood as urea, a compound that contains nitrogen. Healthy kidneys take urea out of the blood and put it in the urine. If kidneys are not working well, the urea will stay in the blood.

A deciliter of normal blood contains 7 to 20 milligrams of urea. If BUN is more than 20 mg/dL, the kidneys may not be working at full strength.[20] Other possible causes of an elevated BUN include dehydration and heart disease.

MEDICAL ASSESSMENT OF THE ABILITY TO WEAR A RESPIRATOR

A worker should not be assigned to a job requiring the use of a respirator unless it has been determined that he or she is physically able to perform the work and use the respirator properly and safely. This assessment should be made by a physician or other licensed health care professional (PLHCP) and should take into account the employee's health, the respirator, and the work conditions. Where examination by a physician is not practicable, OSHA allows other licensed health care providers to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire. The term PLHCP means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide some or all of the health care services required by OSHA for medical evaluation.

The following medical evaluation guidelines are adapted from NIOSH Publication 2005-100, *NIOSH Respirator Decision Logic NIOSH Resp Decision Logic*, Appendix H, Medical Aspects of Wearing Respirators, of NIOSH Publication 91-119,[47] NIOSH *Criteria for a Recommended Standard — Occupational Exposure to Ethylene Glycol Monomethyl Ether, Ethylene Glycol Monoethyl Ether and Their Acetates,*[48] and the OSHA Respiratory Protection Standard codified at 29 Code of Federal Regulations 1910.134(e).[49] This guidance should be provided by NISA member companies to the PLHCP who assesses the workers' ability to use respirators.

The following guidelines assume that workers are wearing air-purifying respirators under moderate exercise conditions, as typically found at industrial sand facilities. If workers are required to wear heavy respirators, such as self-contained atmosphere-supplying types, or are required to perform tasks equivalent to heavy exercise, then the stress on the cardiovascular

system can be significant. Under such conditions, the references above and other respirator literature should be consulted.[50,51]

Physician's Evaluation

The PLHCP should make the medical determination of the worker's fitness to wear a respirator by considering the worker's health, the type of respirator, and the work conditions. This recommendation satisfies the OSHA standard and leaves the medical decision about an individual's fitness to wear a respirator to a person qualified to evaluate the clinical variables.[49,52] Much of the clinical and other data can be gathered by other personnel. It should be emphasized that the clinical examination alone is only one part of the fitness determination and that collaboration with foremen, industrial hygienists, and others may often be needed to better assess the work conditions and other factors that affect an individual's fitness to wear a respirator. OSHA has developed a Respirator Medical Evaluation Questionnaire that is mandatory in providing the medical evaluation for respirator use. The form for the evaluation can be found in 29 CFR 1910.134, Appendix J.

Medical History and Physical Examination

The medical evaluation should emphasize the evaluation of the cardiopulmonary system and elicit any history of respirator use. The history is an important tool in medical evaluation and can be used to detect most problems that might require further evaluation. The physical examination should confirm the clinical impression based on the history and detect any important medical conditions (such as hypertension) that may be asymptomatic.

NIOSH recommends that the person conducting the evaluation consider the following conditions in selecting or permitting the use of respirators:[48]

- History of spontaneous pneumothorax (collapsed lung).
- Claustrophobia or anxiety reaction.

- Moderate or severe pulmonary disease.
- Angina pectoris, significant arrhythmias, or recent myocardial infarction.
- Symptomatic or uncontrolled hypertension.
- Age.

It seems unlikely that wearing a respirator would play any significant role in causing lung damage such as pneumothorax. However, without evidence that wearing a respirator does not cause such lung damage, it is prudent to prohibit an individual with a history of spontaneous pneumothorax from wearing a respirator.

Moderate lung disease is defined by ATS/ERS as forced expiratory volume in one second (FEV_1), divided by a forced vital capacity (FVC), that is, FEV_1/FVC, of 60 to 69 percent.[11] Similar limits can be set for age and hypertension. It seems more reasonable, however, to combine several risk factors into an overall estimate of fitness to wear respirators under certain conditions. Here, the judgment and clinical experience of the physician are needed. In many cases, even impaired workers are able to work safely while wearing respirators if they can control their own pace and are allowed adequate rest breaks.[53,54]

Chest X-Ray and Spirometry

Although, a chest X-ray and/or spirometry may be medically indicated in some fitness determinations, these tests need not be routinely performed for assessing the ability to wear a respirator. For industrial sand workers, the medical surveillance guidelines for silicosis prescribe periodic chest X-ray examinations and optional spirometry for exposed workers. Because the results of these tests are available, they may be used by the physician in determining fitness to wear a respirator; however, chest X-rays and spirometry are not routinely recommended for respirator fitness evaluations. In most cases, if the worker's history and physical examination

result in a negative clinical evaluation, X-rays and spirometry are unlikely to influence the fitness determination. In general, chest X-rays do not accurately reflect a person's cardiopulmonary status, and limited studies suggest that in most cases, mild to moderate impairment detected by spirometry does not preclude the wearing of a respirator. Spirometric values alone cannot be used to determine a worker's fitness to wear a respirator and may even give misleading indications of fitness.

Psychological and Physiological Problems of First-Time Wearers

The first-time respirator wearer should be observed for a trial period to evaluate potential psychological and physiological problems. In addition to assessing medical considerations, the physician or another qualified person should determine if wearing a given respirator will cause extreme anxiety or a claustrophobic reaction in the individual. This can be done during training while the worker is wearing the respirator, and the respirator should be worn continuously for at least 30 minutes. During at least part of this time, the worker should engage in exercise that approximates the actual work situation.

A worker should be provided the opportunity to wear the respirator "in normal air for a long familiarity period."[48] This period should also be used to evaluate the ability and tolerance of the worker to wear the respirator.[49] This trial period need not be associated with respirator fit testing and should not compromise the vital fit-testing procedure.

Frequency of Respirator Fitness Determinations

At a minimum, OSHA requires that additional medical evaluations take place if a worker reports medical signs or symptoms related to his or her ability to wear a respirator; the PLHCP or administrator of the respirator program finds that the worker needs to be reevaluated; feedback from the respirator protection program, including fit testing and program evaluation, indicates a

need for reevaluation; or there is a change in job duties (e.g., physical demand of work, additional protective equipment requirements, temperature extremes) that might result in increased physiological burden to the worker. NISA member companies should consider including a respirator evaluation as part of the periodic medical evaluation for exposure to crystalline silica. These guidelines are based on clinical judgment and, like the other recommendations in this section, should be adjusted as clinically indicated.

Summary of Respiratory Fitness Determinations

Individual judgment is needed in determining the factors affecting an individual's fitness to wear a respirator. Although many of the guidelines above are based on limited evidence, they provide a useful starting point for a respirator-fitness screening program. In general, if a worker is able to do his or her job safely without a respirator, he or she will usually be able to do it safely while wearing a respirator.

RECORD KEEPING AND WORKER NOTIFICATION

All medical records obtained on workers should be retained for at least 30 years after the worker ceases employment. This is necessary because of the chronic nature and long latency of silicosis, and because the records may also be useful in assessing the adequacy of occupational standards.

The examining physician or other health professional should provide the employer with the results of the medical examination. Any abnormalities detected, whether occupational or nonoccupational, should be disclosed to the employee with an appropriate recommendation for medical follow-up. The opinion should be prepared to (1) assist the company in developing baseline measurements on the employees, (2) inform the company about any medical condition or change in an employee's condition from exposure to silica or other job-related factor, (3)

recommend restrictions regarding a worker's exposure to silica, and (4) advise the company regarding the worker's ability to wear a respirator or other protective equipment. The worker should be provided a copy of the examination results, and evidence that this has been done should be obtained.

Frequency of Examinations

Baseline Examinations

Before a worker is assigned to a job with potential exposure to crystalline silica, a medical examination should be completed to establish a baseline on the worker's respiratory health status. The examination should include, as a minimum, a medical history, including a respiratory symptom questionnaire and smoking history; a complete occupational and job history; a medical evaluation of the thorax, as indicated; a PA chest X-ray; spirometry, tuberculin testing, and any additional tests ordered by the company or examining physician.

Periodic Examinations

With the exception of chest X-rays, medical evaluations should be administered at least every 2 years and should be comprehensive examinations that include the elements of the baseline examination.

The frequency of X-ray examinations depends on the number of years since first exposure to silica dust, the age of the worker, and whether any signs or symptoms are present. During the first eight years following a worker's exposure to silica dust, X-rays should be taken at four-year intervals. After eight years from the first job-related exposure to silica, the age of the worker will determine the frequency of X-ray examinations. Up until age 35, X-rays should be taken at four-year intervals. After age 35 and a combined eight years of silica exposure, X-rays

should be taken every two years. Table 4-4 summarizes the recommended frequency of X-ray examinations.

Workers who experience respiratory symptoms such as shortness of breath should receive X-rays as determined by a physician. Likewise, workers whose X-rays show changes consistent with pneumoconiosis should receive X-rays and medical evaluations more frequently, as medically indicated, to monitor any progression or changes.

Age of Employee Years Since First Silica Exposure	**15–35**	**>35**
0–8	Every 4 years	Every 4 years
>8	Every 4 years	Every 2 years

TABLE 4-4—FREQUENCY OF CHEST X-RAYS

SECTION 5—REFERENCES

REFERENCES— SECTION 2—HEALTH EFFECTS OF EXPOSURE TO CRYSTALLINE SILICA

1. Morgan, W.K.C., and and Lapp, N. L., "Diseases of the Airways and Lungs," in *Occupational Diseases—A Guide to Their Recognition.* (M. M. Key, A. F. Henschel, J. Butler, R. N. Ligo, and I. R. Tabershaw, Eds.). Washington, D.C.: U.S. Department of Health and Human Services, National Institutes for Occupational Safety and Health, U.S. Government Printing Office, 1977.
2. Morgan, W.K.C. and Seaton, A., *Occupational Lung Diseases* (3rd ed.). Philadelphia: W. B. Saunders, 1995.
3. NIOSH Silicosis and Silicate Disease Committee, "Diseases Associated With Exposure to Silica and Nonfibrous Silicate Minerals," *Archives of Pathology and Laboratory Medicine*, 1988, Vol. 112, pp. 673-720.
4. National Institute for Occupational Safety and Health, *NIOSH Hazard Review: Health Effects of Occupational Exposure to Respirable Crystalline Silica*; Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2002-129, 2002.
5. Electronic Library of Construction Safety and Health (eLCOSH) Website. *Silicosis Alert* Hosted on the Centers for Disease and Prevention Website at: http://www.cdc.gov/elcosh/docs/d0400/d000487/d000487.html.
6. International Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risks of Chemicals to Humans-Silica, Some Silicates, Coal Dust and para-*

Aramid Fibrils (Volume 68). Lyon, France: World Health Organization, International Agency for Research on Cancer, 1997.

7. American Thoracic Society (ATS), "Adverse Effects of Crystalline Silica Exposure," *American Journal of Respiratory and Critical Care Medicine*, 1997, Vol. 155, pp. 761-765.
8. 54 Fed. Reg. 2521 (January 19, 1989).
9. National Heart, Lung and Blood Institute, *NHLBI Data Fact Sheet: Chronic Obstructive Pulmonary Disease*, Bethesda, Maryland: U.S. Department of Health and Human Services, NIH, NHLBI. NIH Publication No. 03-5229, March 2003.
10. American Medical Association, *JAMA Patient Page: Chronic Obstructive Pulmonary Disease*, JAMA, 2003, 290(17): 2362.
11. Hunter MH and King DE, COPD: Management of Acute Exacerbations and Chronic Stable Disease, Am. Fam. Physician, 2001; 64:604-612.
12. American Lung Association, *Disease Data*: COPD, 2008, New York, NY. Available at: http://www.lungusa.org/atf/cf/{7a8d42c2-fcca-4604-8ade-7f5d5e762256}/ALA_LDD08_COPD_FINAL.PDF
13. Becklake MR, Irwig L, Kielkowski D, Webster I, DeBeer M, Landau S [1987]. The predictors of emphysema in South African gold miners. Am Rev Respir Dis 135:1234–1241
14. Chatgidakis CB [1963]. Silicosis in South African white gold miners: A comparative study of the disease in its different stages. South Afr J Adv Med Sci 9:383–392.
15. Cowie RL, Hay M, Thomas RG [1993]. Association of silicosis, lung dysfunction, and emphysema in gold miners. Thorax 48:746–749.
16. Hnizdo E, Sluis-Cremer GK, Abramowitz JA [1991]. Emphysema type in relation to silica dust exposure in South African gold miners. Am Rev Respir Dis 143:1241–1247.

17. Hnizdo E, Sluis-Cremer GK, Baskind E, Murray J [1994]. Emphysema and airway obstruction in non-smoking South African gold miners with long exposure to silica dust. Occup Environ Med 51:557–563.

18. *JAMA Patient Page: Systemic Lupus Erythematosus*, JAMA, 2005; 293(24) 3130.

19. Rindfleisch JA and Muller D. Diagnosis and Management of Rheumatoid Arthritis. Am. Fam. Physician, 2005; 72:1037-1047.

20. National Institutes of Arthritis and Musculoskeletal Diseases, *Rheumatoid Arthritis*, U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 04-4179, 2004.

21. National Institutes of Arthritis and Musculoskeletal Diseases, *Scleroderma*, U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 06-4271, 2006.

22. National Institutes of Arthritis and Musculoskeletal Diseases, *Systemic Lupus Erythematosus*, U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 03-4178, 2003.

23. National Women's Health Information Center, 2005, *Autoimmune Diseases: Overview*, U.S. Department of Health and Human Services, Office on Women's Health, Accessed online June 4, 2009, at : http://womenshealth.gov/faq/autoimmune-diseases.pdf .

24. Silman AJ and Hochberg MC. Occupational and Environmental Influences on Scleroderma, Rheumatic Disease Clinics of North America, 1996; 4: 737-749.

25. Silman AG and Jones S. What is the contribution of occupational environmental factors to the occurrence of scleroderma in men? Annals of the Rheumatic Diseases, 1992: 51:1322-1324.

26. Steenland NK, Thun MJ, FergusonCW, Port FK [1990]. Occupational and other exposures associated with male end-stage renal disease: A case/control study. Am J Public Health 80(2):153–159.

27. Calvert GM, Steenland K, Palu S [1997]. End-stage renal disease among silica-exposed gold miners: A new method for assessing incidence among epidemiologic cohorts. J Am Med Assoc 277(15):1219–1223.

28. Steenland K, Brown D [1995]. Mortality study of gold miners exposed to silica and nonasbestiform amphibole minerals: An update with 14 more years of follow-up. Am J Ind Med 27:217–229.

29. Nuyts GD, Van Vlem E, De Vos A, Daelemans RA, Rorive G, Elseviers MM, Schurgers M, Segaert M, D'Haese PC, De Broe ME [1995]. Wegener granulomatosis is associated to exposure to silicon compounds: A case-control study. Nephrol Dial Transplant 10:1162–1165.

30. Steenland K, Sanderson W, Calvert GM. Kidney disease and arthritis in a cohort study of workers exposed to silica. Epidemiology. 2001 Jul;12(4):405-12.

31. de Klerk NH, Musk AW[1998]. Silica, compensated silicosis, and lung cancer in Western Australian goldminers. Occup Environ Med 55:243–248.

32. McDonald JC, McDonald AD, Hughes JM, et al. Mortality from lung and kidney disease in a cohort of North American industrial sand workers: an update. Ann Occup Hyg. 2005 Jul;49(5):367-73. Epub 2005 Feb 22.

33. Rosenman KD, Moore-Fuller M, Reilly MJ. Kidney disease and silicosis. Nephron. 2000 May; 85(1):14-9.

34. Steenland K, Rosenman K, Socie E, Valiante D. Silicosis and end-stage renal disease. Scand J Work Environ Health. 2002 Dec; 28(6):439-42.

35. TLV Airborne Contaminants Committee, *Threshold Limit Values for Chemical Substances in Workroom Air*. Cincinnati: American Conference of Governmental Industrial Hygienists, 1973.

36. National Institute for Occupational Safety and Health, 1974, Criteria for a rrecommended standard: Occupational exposure to crystalline silica. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Health Services and Mental Health Administration, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 75–120

37. TLV Airborne Contaminants Committee, *Threshold Limit Values for Chemical Substances in Workroom Air.* Cincinnati: American Conference of Governmental Industrial Hygienists, 1968.

38. TLV Airborne Contaminants Committee, *Threshold Limit Values for Chemical Substances in Workroom Air.* Cincinnati: American Conference of Governmental Industrial Hygienists, 2005.

REFERENCES— SECTION 3—WORKPLACE DUST SURVEYS

1. Bullock WH and Ignacio JS (eds.): A Strategy for Assessing and Managing Occupational Exposures, 3rd Edition. Fairfax, VA, American Industrial Hygiene Association, 2006.
2. Trochim, William M: The Research Methods Knowledge Base, 2nd Edition. Internet WWW page, at URL: <http://www.socialresearchmethods.net/kb/> (version current as of September 2, 2009).

3. Hewett P, Logan PM, Mulhausen J, et al. Rating Exposure Control Using Bayesian Decision Analysis, Journal of Occupational and Environmental Hygiene, 2006, 3:568-581.

REFERENCES— SECTION 4—MEDICAL SURVEILLANCE FOR SILICA EXPOSURE

1. American Thoracic Society (ATS), "Surveillance for Respiratory Hazards in the Occupational Setting," American Review of Respiratory Disease, 1982, Vol. 126, pp. 952-956.
2. American College of Occupational and Environmental Medicine (ACOEM), Evidenced Based Statement—Medical Surveillance of Workers Exposed to Crystalline Silica. Prepared by the ACOEM Occupational and Environmental Lung Disorder Committee, 2005.
3. ASTM International, E1132-99a Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, Developed by Subcommittee E34.16. Available at www.astm.org.
4. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Kidney Disease Outcome Quality Initiative. Am J Kidney Dis. 2002; 39:S1-246.
5. Horvath, EP, Brooks, SM, and Hankinson, JL, Manual of Spirometry in Occupational Medicine. Cincinnati: U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, 1981.
6. International Labour Organization (ILO). Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses. Occupational Safety and Health (Series 22; rev.), Geneva: International Labour Office, 2000.

7. Mannino DM, Kennedy RD, Hodous TK. Pneumoconiosis: comparison of digitized and conventional radiographs. Radiology 1993; 187(3):791–796.
8. Gurney JW. Pneumoconiosis assistant: a hypermedia-based classification of the pneumoconioses. J Thorac Imaging 1993;8(2):143–151.
9. Kundel HL, Mezrich JL, Brickman I, et al. Digital chest imaging: Comparison of two film image digitizers with a classification task. Radiology 1987, 165: 747-752.
10. ATS. "Standardization of Spirometry—1994 Update," American Journal of Respiratory and Critical Care Medicine, 1995, Vol. 152, pp. 1107-136.
11. American Thoracic Society/European Respiratory Society (ATS/ERS). Interpretive Strategies for Lung Function Tests, ATS/ERS Task Force: Standardization of Lung Function Testing. European Respiratory Journal; 26: 948-968, 2005.
12. NIOSH, NIOSH Hazard Review: Health Effects of Occupational Exposure to Respirable Crystalline Silica, 2002, Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2002–129.
13. ATS, Adverse effects of crystalline silica exposure. Am J Respir Crit Care Med, 1997, 155:761–768.
14. Rosenman KD. Recommended medical screening protocol for silica exposed workers. Accessed online November 2, 2008 at: http://www.oem.msu.edu/Resources/SilicaScrnProtocol_rev8-22-07.pdf
15. ATS/CDC (American Thoracic Society/Centers for Disease Control and Prevention), Joint Statement, Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, Recommendations of the Committee on Latent Tuberculosis Infection. MMWR, 49(RR06);

1-54, 2000. ATS, Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, Am J Respir Crit Care Med, 2000, 161: 5221-5247.

16. Mazurek GH, Jereb J, Lobue P, Iademarco MF, Metchock B, Vernon A. Guidelines for using the QuantiFERON-TB Gold test for detecting mycobacterium tuberculosis infection, United States. MMWR Recomm Rep. 2005 Dec 16;54(RR-15):49-55. Erratum in: MMWR Morb Mortal Wkly Rep. 2005 Dec 23;54(50):1288.
17. Electronic Library of Construction Safety and Health (eLCOSH), Silicosis Alert. Accessed online October 31, 2008 at: http://www.cdc.gov/elcosh/docs/d0400/d000487/d000487.html.
18. National Kidney Foundation. K/DOQI, Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification. Am J Kidney Dis 2002;39(2 suppl 1):S1-266. Accessed online November 4, 2008, at: http://www.kidney.org/professionals/KDOQI/ .
19. Levey AS, Coresh J, Balk E, Kausz AT, Levin A, Steffes MW. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Ann Intern Med 2003; 139:137-47.
20. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Your Kidneys and How they Work, NIDDK, National Institutes of Health, U.S. Department of Health and Human Services, NIH Publication No. 06-4241, November, 2005. Accessed online November 4, 2008, at: http://kidney.niddk.nih.gov/kudiseases/pubs/pdf/yourkidneys.pdf
21. Sargent EN, Technique for Chest Radiography for Pneumoconiosis. Chicago: American College of Radiology, 1982.
22. Lincoln TA, Kelly FJ, Lusbaugh CC, et al. Guidelines for Use of Routine X-Ray Examinations in Occupational Medicine: Committee Report, Journal of Occupational Medicine, 1979, Vol. 21, pp. 500–502.

23. Jacobson G, Bohlig H, and Kivolvoto R, "Essentials of Chest Radiology," Radiology, 1970, Vol. 95, pp. 445–450.

24. Morgan RH, "Radiology," in Occupational Respiratory Disease (J. A. Merchant, Ed.). Cincinnati: U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, 1986.

25. 42 CFR 37, Specifications for Medical Examinations of Underground Coal Miners.

26. McAdams HP, Samei E, Dobbins J, Tourassi GD, Ravin CE. Recent Advances in Chest Radiography, Radiology, 2006, 241: 663-683.

27. Wheeler P.S, and Raymond S, "The Computer-Based Cumulative Report: Improvement in Quality and Efficiency," Radiology, 1992, Vol. 182, No. 2, pp. 355–357.

28. Reger RB, and Morgan,W.KC, "On the Factors Influencing Consistency in the Radiologic Diagnosis of Pneumoconiosis," American Review of Respiratory Disease, 1970, Vol. 102, pp. 905–915.

29. Reger RB, Amandus HE, and Morgan WKC, "On the Diagnosis of Coalworkers' Pneumoconiosis—Anglo American Disharmony," American Review of Respiratory Disease, 1973, Vol. 108, pp. 1186–1191.

30. Morgan RH, "Decision Processes and Observer Error in the Diagnosis of Pneumoconiosis by Chest Roentgenography," American Journal of Roentgenology, 1979, Vol. 132, pp. 803–808.

31. Felson B, Morgan WKC, Briston L J, Pendergrass EP. Dessen EL, Linton OW, and Reger RB, "Observations on the Results of Multiple Readings of Chest Films in Coal Miners' Pneumoconiosis," Radiology, 1973, Vol. 109, No. 1, pp. 19–23.

32. Amandus HE, Pendergrass EP, Dennis JM. and Morgan,WKC, "Pneumoconiosis: Inter-Reader Variability in the Classification of the Type of Small Opacities in the Chest Roentgenogram," American Journal of Roentgenology, 1974, Vol. 122, No. 4, pp. 740–743.

33. International Standards Organization (ISO), Imaging Materials—Processed Safety Photographic Films—Storage Practices, Standard 18911, American National Standards Institute, 1430 Broadway, New York, NY 10018, (212) 642-4900.

34. NIOSH, NIOSH Spirometry Training Guide, 2003, Morgantown, WV: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

35. Hankinson JL, Odencrantz JR, and Fedan KB,. Spirometric reference values from a sample of the general U.S. population. American Journal of Respiratory and Critical Care Medicine 1999; 159: 179-187.

36. American Thoracic Society. "Lung function testing: Selection of reference values and interpretive strategies." American Review of Respiratory Disease 1991; 144: 1202-1218.

37. Hankinson JL, Kinsley KB, and Wagner, GR,. Comparison of spirometric reference values for caucasian and African-American nonexposed blue-collar workers. Journal of Occupational and Environmental Medicine 1996; 38: 137-143.

38. Enright, PL, Arnold A, Manolio TA, and Kuller LH,. Spirometry reference values for healthy elderly blacks. The Cardiovascular Health Study Research Group. Chest 1996; 110(6):1416-1424.

39. Harik-Khan RI, Fleg,JL, Muller DC, and Wise RA,. The effect of anthropometric and socioeconomic factors on the racial difference in lung function. American Journal of Respiratory and Critical Care Medicine 2001; 164(9):1647-1654.

40. Steenland NK, Thun MJ, Ferguson CW, Port FK [1990]. Occupational and other exposures associated with male end-stage renal disease: A case/control study. Am J Public Health 80(2):153–159.

41. Calvert GM, Steenland K, Palu S [1997]. End-stage renal disease among silica-exposed gold miners: A new method for assessing incidence among epidemiologic cohorts. J Am Med Assoc 277(15):1219–1223.

42. Steenland K, Brown D [1995]. Mortality study of gold miners exposed to silica and nonasbestiform amphibole minerals: An update with 14 more years of follow-up. Am J Ind Med 27:217–229.

43. Nuyts GD, Van Vlem E, De Vos A, Daelemans RA, Rorive G, Elseviers MM, Schurgers M, Segaert M, D'Haese PC, De Broe ME [1995]. Wegener granulomatosis is associated to exposure to silicon compounds: A case-control study. Nephrol Dial Transplant 10:1162–1165.

44. Steenland K, Sanderson W, Calvert GM. Kidney disease and arthritis in a cohort study of workers exposed to silica. Epidemiology. 2001 Jul;12(4):405-12.

45. de Klerk NH, Musk AW [1998]. Silica, compensated silicosis, and lung cancer in Western Australian gold miners. Occup Environ Med 55:243–248.

46. McDonald JC, McDonald AD, Hughes JM, et al. Mortality from lung and kidney disease in a cohort of North American industrial sand workers: an update. Ann Occup Hyg. 2005 Jul; 49(5):3 67-73. Epub 2005 Feb 22.

47. NIOSH, NIOSH Respirator Decision Logic, 2004, Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2005-100.

48. NIOSH, Criteria for a Recommended Standard—Occupational Exposure to Ethylene Glycol Monomethyl Ether, Ethylene Glycol Monoethyl Ether and Their Acetates, 1991, Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for

Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 91-119.

49. Code of Federal Regulations, Title 29, Occupational Safety and Health Administration, Department of Labor, Part 1910, Section 134(e).
50. Harber P. "Medical Evaluation for Respirator Use," Journal of Occupational Medicine, 1984, Vol. 26, No. 7, pp. 496-502.
51. Hodous TK. Screening Prospective Workers for the Ability to Use Respirators, Journal of Occupational Medicine, 1986, 28:1074-1080.
52. OSHA, Small Entity Compliance Guide for the Revised Respiratory Protection Standard, 1998, Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration. Accessed online November 5, 2008 at: http://www.osha.gov/Publications/SECG_RPS/secgrev-current.pdf
53. 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, 128:943-948.
54. Hodous TK, Boyles C, Hankinson J. Effects of industrial respirator wear during exercise in subjects with restrictive lung disease. Am Ind Hyg Assoc J. 1986:176-180.

Appendix A—Table of International Exposure Limits Values (in mg/m^3) for Crystalline Silica

TABLE A-1—TABLE OF INTERNATIONAL EXPOSURE LIMITS VALUES (IN MG/M^3) FOR CRYSTALLINE SILICA

	OEL Name	Adopted by	Quartz	Cristobalite	Tridymite
Argentina			0.1	0.05	0.05
Australia	National Exposure Standard	National Occupational Health and Safety Commission	0.1	0.1	0.1
Austria	Maximale ArbeitsplatzKoncentration	Bundesministerium für Arbeit und Soziales	0.15	0.15	0.15
Belgium		Ministère de l'Emploi et du Travail	0.1	0.05	0.05
Canada – Alberta			0.1		
Canada- Nova Scotia			0.1		
Canada- Ontario			0.1		
Canada – Quebec			0.1		
Denmark	Threshold Limit Value	Direktoratet fot Arbeidstilsynet	0.1	0.05.	0.05
Finland	Occupational Exposure Standard	National Board of Labour Protection	0.2	0.1	0.1
France	Empoussiérage de reference	Ministère de l'Industrie (RGIE)	5 25k/Q[1]		
	Valeur limite de Moyenne d'Exposition	Ministère du Travail	0.1	0.05	0.05
Germany	Grenzwert nach TRGS 900	Bundesministerium für Arbeit	-[2]	-	-
Greece		Legislation for mining activities	0.1[3]	0.05	0.05
Ireland		2002 Code of Practice for the Safety, Health & Welfare at Work (CoP)	0.05	0.05	0.05
Italy	Threshold Limit Value	Associazone Italiana Degli Igienisti Industriali	0.05	0.05	0.05

[1] Where k = noxious coefficient (equal to 1) and Q = quartz percentage.

[2] In Germany there are no OELs for crystalline silica since 2005; instead of an OEL there is a workers health protection system.

[3] According to Mining Legislation Code and the Presidential Decree 307/1986, the occupational exposure limit value to respirable crystalline silica is calculated according to the following formula: OEL = 10/ (%Q+2) where Q= % concentration of free crystalline silica in the respirable fraction of the dust.

TABLE A-1—TABLE OF INTERNATIONAL EXPOSURE LIMITS VALUES (IN MG/M^3) FOR CRYSTALLINE SILICA

	OEL Name	Adopted by	Quartz	Cristobalite	Tridymite
Luxembourg	Grenzwert nach TRGS 900	Bundesministerium für Arbeit	0.15	0.15	0.15
Netherlands	Maximaal Aanvarde Concentratie	Ministerie van Sociale Zaken en Werkgelegenheid	0.075	0.075	0.075
Norway	Administrative Normer (8hTWA) for Forurensing I ArbeidsmiljØet	Direktoratet for Arbeidstilsynet	0.1	0.05	0.05
Portugal	Threshold Limit Value	Instituto Portuges da Qualidade, Hygiene & Safety at Workplace	0.1	0.05	0.05
South Africa			0.1		
Spain	Valores Limites	1) Instituto Nacional de Seguridad e Higiene	0.1	0.05	0.05
		2) Reglamento General de Normas Basicas de Seguridad Minera	5 25k/Q[1]		
		2.1) New proposal (except coal mining)	0.1	0.05	0.05
Sweden	Yrkeshygieniska Gränsvärden	National Board of Occupational Safety and Health	0.1	0.05	0.05
Switzerland	Valeur limite de Moyenne d'Exposition		0.15	0.15	0.15
United Kingdom	Workplace Exposure Limit	Health & Safety Executive	0.1	0.1	0.1

Appendix B—Sampling Forms

Note: At the user's discretion, either Form B-1a or Form B-1b may be used to record pump calibration data.

NISA Occupational Health Program
FORM B-1A—PUMP CALIBRATION RECORD

Location _____ Pump Number _____

Date	Calibrated Flow Rate	Calibration Method	Sampling Location	Person Performing Calibration

Note: At the user's discretion, either Form B-1a or Form B-1b may be used to record pump calibration data.

NISA Occupational Health Program
FORM B-1B—PUMP CALIBRATION RECORD

Date _____ Pump number _____ Calibrated flow rate _____

Location where pump calibration was performed

Sampling location

Mine name and location

Calibration method

Date when pump flow rate was rechecked _____ ☐ Acceptable ☐ Not acceptable

_____
Signature of person performing calibration

Note: At the user's discretion, either Form B-1a or Form B-1b may be used to record pump calibration data.

NISA Occupational Health Program
FORM B-1A—PUMP CALIBRATION RECORD (SAMPLE)

Location Millville Corporate Office Pump Number 02295

Date	Calibrated Flow Rate	Calibration Method	Sampling Location	Person Performing Calibration
1/15/96	1.7 lpm	Mini-Buck	Mauricetown	C. Abel
1/30/96	1.7 lpm	Mini-Buck	Goff	C. Abel
2/15/96	1.7 lpm	Mini-Buck	Upper Twp	D. Smith
3/1/96	1.7 lpm	Mini-Buck	Port	E. Jones
3/15/96	1.7 lpm	Mini-Buck	Goff	C. Abel
4/10/96	1.7 lpm	Mini-Buck	Accurez	E. Jones
5/15/96	1.7 lpm	Mini-Buck	Divid. Creek	M. Johnson
6/12/96	1.7 lpm	Mini-Buck	Mauricetown	C. Abel
7/1/96	1.7 lpm	Mini-Buck	Accurez	E. Jones

Note: At the user's discretion, either Form B-1a or Form B-1b may be used to record pump calibration data.

NISA Occupational Health Program
FORM B-1B – PUMP CALIBRATION RECORD (SAMPLE)

Date 6/12/10 Pump number 02295 Calibrated flow rate 1.7 lpm

Location where pump calibration was performed

East Division
Lunc room

Sampling location

East #1 dryer operation

Mine name and location

East Division
ABC Corporation
Winchester, VA

Calibration method

Mini-Buck Calibrator

Date when pump flow rate was rechecked 7/1/10 ☒ Acceptable ☐ Not acceptable

Ed Jones
Signature of person performing calibration

NISA Occupational Health Program
FORM B-2—RESPIRABLE-DUST/SILICA SAMPLING DATA SHEET

Plant _____ Sample number _____

Type of sample: ☐ Personal breathing zone ☐ Work area ☐ Other
If breathing-zone sample; was respirator used? ☐ Yes ☐ No
Employee _____ Social Security no. _____
Date of sample _____ Obtained by _____
Description of job activity/work area: _____
_____

Weather conditions: ☐ Clear ☐ Overcast ☐ Rain/snow ☐ Windy
Filter no. _____ Pump no. _____ Calibration date _____
Time: Start _____ Stop _____
Rotameter reading (liters per minute): Start _____ Stop _____
Filter blank no. _____

Average flow rate (liters per minute) × Duration of sample (minutes) × 0.001 = Volume of air sampled (cubic meters)
_____ × _____ × 0.001 = _____

Analytical Results:
Respirable dust _____ (mg) Respirable silica _____ (mg) or _____ (%)
Analytical method _____ Name of lab _____

$$\% \text{ Respirable silica} = \frac{\text{Respirable silica (milligrams)}}{\text{Respirable dust (milligrams)}} \times 100 = \_\_\_\_\_ \%$$

$$\text{Exposure limit} = \frac{10}{2 + \% \text{ Respirable silica}} = \_\_\_\_\_ \text{ milligrams per cubic meter}$$

(If % = 25, use 25, not 0.25.)

$$\text{Respirable dust concentration} = \frac{\text{Respirable dust (milligrams)}}{\text{Volume of air sampled (cubic meters)}} = \_\_\_\_\_ \text{ milligrams per cubic meter}$$

$$\% \text{ Exposure} = \frac{\text{Respirable dust concentration}}{\text{Exposure limit}} \times 100 = \_\_\_\_\_ \%$$

(If result exceeds 100%, the exposure limit is exceeded.)

% Exposure	Exposure Classification (Circle One)
<50	I
50–100	II
>100	III

Data approved and filed:

_____ _____
Signature Date

NISA Occupational Health Program
FORM B-2 (SAMPLE)

Plant Number 1 Sample number _____

Type of sample: ☒ Personal breathing zone ☐ Work area ☐ Other
If breathing-zone sample; was respirator used? ☒ Yes ☐ No
Employee George Wilson Social Security no. 018-64-8192
Date of sample August 16, 1994 Obtained by O. K. Sampler
Description of job activity/work area: Cleaning screens

Weather conditions: ☒ Clear ☐ Overcast ☐ Rain/snow ☒ Windy
Filter no. 2692 Pump no. 03 Calibration date 8/16/94
Time: Start 8:00 a.m. Stop 4:00 p.m.
Rotameter reading (liters per minute): Start 1.7 liters/min Stop 1.7 liters/min
Filter blank no. 2693

Average flow rate (liters per minute) × Duration of sample (minutes) × 0.001 = Volume of air sampled (cubic meters)
1.7 × 480 × 0.001 = 0.816

Analytical Results:
Respirable dust 0.110 (mg) Respirable silica 0.040 (mg) or Respirable silica 36 (%)
Analytical method X-ray Name of lab Green Mount

$$\% \text{ Respirable silica} = \frac{\text{Respirable silica (milligrams)}}{\text{Respirable dust (milligrams)}} \times 100 = 36\ \%$$

$$\text{Exposure limit} = \frac{10}{2 + \% \text{ Respirable silica}} = 0.26 \text{ milligrams per cubic meter}$$

(If % = 25, use 25, not 0.25.)

$$\text{Respirable dust concentration} = \frac{\text{Respirable dust (milligrams)}}{\text{Volume of air sampled (cubic meters)}} = 0.13 \text{ milligrams per cubic meter}$$

$$\% \text{ Exposure} = \frac{\text{Respirable dust concentration}}{\text{Exposure limit}} \times 100 = 50\ \%$$

(If result exceeds 100%, the exposure limit is exceeded.)

% Exposure	Exposure Classification (Circle One)
<50	I
50–100	(II)
>100	III

Data approved and filed:

_____ Signature _____ Date

NISA Occupational Health Program
FORM B-3—EMPLOYEE ACTIVITY LOG FOR DUST SAMPLING

Plant _____ Employee wearing sampling pump _____
Dept. _____ Date _____ Shift _____

The decriptions below must accurately reflect ALL ACTIVITIES performed by the employee. Please note any SPECIAL CONDITIONS observed.

Hour 1 (ending ____:____ a.m. / p.m.)

Hour 2 (ending ____:____ a.m. / p.m.)

Hour 3 (ending ____:____ a.m. / p.m.)

Hour 4 (ending ____:____ a.m. / p.m.)

Hour 5 (ending ____:____ a.m. / p.m.)

Hour 6 (ending ____:____ a.m. / p.m.)

Hour 7 (ending ____:____ a.m. / p.m.)

Hour 8 (ending ____:____ a.m. / p.m.)

NISA Occupational Health Program
FORM B-3—EMPLOYEE ACTIVITY LOG FOR DUST SAMPLING (SAMPLE)

Plant Mauricetown Employee wearing sampling pump Sam Smith
Dept. Dryer Date 2/10/96 Shift 6:00am-2:00pm

The decriptions below must accurately reflect ALL ACTIVITIES performed by the employee. Please note any SPECIAL CONDITIONS observed.

Hour 1 (ending 7:00 **(a.m.) / p.m.)**	Checked bins 2 times 5 minutes each time
Hour 2 (ending 8:00 **(a.m.) / p.m.)**	Changed screens -- 60 mesh 15 minutes
Hour 3 (ending 9:00 **(a.m.) / p.m.)**	Control room, entire hour
Hour 4 (ending 10:00 **(a.m.) / p.m.)**	Loaded 3 dump trucks with 60 sand
Hour 5 (ending 11:00 **(a.m.) / p.m.)**	Control room, 50 minutes Checked bins 1 time, 10 minutes
Hour 6 (ending 12:00 **a.m. / (p.m.))**	Lunch room, 30 minutes Control room, 30 minutes
Hour 7 (ending 1:00 **a.m. / (p.m.))**	Changed screens -- 40 mesh 15 minutes
Hour 8 (ending 2:00 **a.m. / (p.m.))**	Control room, 45 minutes Cleanup, 15 minutes

NISA Occupational Health Program
FORM B-4—RESPIRABLE CRYSTALLINE SILICA SAMPLING SUMMARY

Company _____ Plant _____

Date	Sample Number	Description of Sample		Source	Percent Silica	TWA Concentration of Respirable Dust (mg/m³)	Permissible Exposure Limit (mg/m³)	% Exposure (concentration/ exposure limit)	TWA Concentration of Respirable Crystalline Silica (mg/m³)
		Job	Area						

Note: TWA = time-weighted average.

NISA Occupational Health Program
FORM B-4—RESPIRABLE CRYSTALLINE SILICA SAMPLING SUMMARY (SAMPLE)

Company ABC Company Plant Anyplant

Date	Sample Number	Description of Sample		Source	Percent Silica	TWA Concentration of Respirable Dust (mg/m³)	Permissible Exposure Limit (mg/m³)	% Exposure (concentration/ exposure limit)	TWA Concentration of Respirable Crystalline Silica (mg/m³)
		Job	Area						
6/16/96	0106169503	Dryer oper		Dryer	50%	0.276	0.192	143%	0.138
6/16/96	0106169504	Bulk Loader		Dryer	40%	0.333	0.238	139%	0.135
6/16/96	0106169505	Load-out		Dryer	36%	0.171	0.263	65%	0.061
6/16/96	0106169506	Laborer		Bagger	25%	0.010	0.370	2%	0.024
6/16/96	0106169507	Loader oper		Yard	27%	0.312	0.370	84%	0.085
6/16/96	0106169508		Bin room	Dryer	32%	1.850	0.294	629%	0.590
6/16/96	0106169509		Bagger	Bagger	50%	0.070	0.192	36%	0.035

Note: TWA = time-weighted average.

NISA Occupational Health Program

FORM B-5—GUIDE FOR EMPLOYEE NOTIFICATION OF DUST SAMPLE RESULTS

This document provides notification guidelines for informing employees of dust sampling results. Notification is primarily directed at personal sample results; those samples collected by both government regulators and the company or its designated agent.

The following constitutes guidelines for notification:

Employee Notification of Dust Sample Results

Plant: _____

Employee Sampled: _____

The results of your dust sampling for [date] showed a result of [XXXX mg/m^3].
The Exposure Limit is [XXXX mg/m^3] and therefore your exposure was within [or in excess of] this limit. During the sampling period, your activity log indicated that you were doing [work activity description]. The following actions [for excessive exposures] are being investigated to reduce future exposures to yourself [list actions].

Date Notified: _____

Supervisor Signature: _____

For documentation purposes the above notification should be delivered orally and in writing.

APPENDIX C—DESCRIPTIVE AND INFERENTIAL STATISTICS

For instructive purposes, imagine the sampling data below in Table J-1 came from a plant where the samples were taken over approximately an 18-month period at a dryer operation. The jobs sampled were of the dryer operator and his helper. Notice the initial samples taken on June 16, 2004 were quite a bit above the PEL with the operator exposed at 43 percent above the PEL of 0.192 mg/m^3 and the helper's exposure at 39 percent above the PEL of 0.238 mg/m^3. No doubt because of these samples, corrective actions were taken and the results of follow-up measurements in November were reduced to 65 percent and 76 percent of the PELs for the operator and his helper, respectively. Apparently additional measures were taken to reduce dust, and the percentage of exposure to the workers continued to fall.

Table C-1—Dryer Operation Dust Sampling Data

Company: ABC Company Plant: Any

Date	Source	Job	% Silica	TWA Conc. of Respirable Dust	PEL	% Exposure
6-16-04	Dryer	Dryer Operator	50	0.276	0.192	143
6-16-04	Dryer	Dryer Helper	40	0.333	0.238	139
11-26-04	Dryer	Dryer Operator	36	0.171	0.263	65
11-26-04	Dryer	Dryer Helper	25	0.283	0.370	76
7-11-05	Dryer	Dryer Operator	27	0.171	0.345	50
7-11-05	Dryer	Dryer Helper	32	0.145	0.294	49
1-27-06	Dryer	Dryer Operator	54	0.051	0.179	28
1-27-06	Dryer	Dryer Helper	44	0.063	0.217	29

This data can be analyzed using various statistical formulas, using computer statistical packages, or by using formulas that are embedded in spreadsheets such as Microsoft Excel. A special application for industrial hygiene data can be obtained from the website of the American

Industrial Hygiene Association. This spreadsheet can be found by connecting to www.aiha.org, mousing over the "Inside AIHA" menu option, and clicking the "Volunteer Groups" menu option. On the "Volunteer Groups" page, choose the "Exposure Assessment Strategies Committee" option. On the Exposure Assessment Strategies Page, click the icon "New IHSTAT with multi languages" An Excel spreadsheet similar to the one shown below in Figure C-1 will open (two graphs in the lower half of the IHSTAT sheet have been cropped from Figure C-1). To avoid returning to the AIHA website each time you want to use IHSTAT, you can save it on your hard drive. All of the formulas for the statistical calculations are embedded in the Excel spreadsheet and you are ready to start using IHSTAT with your data.

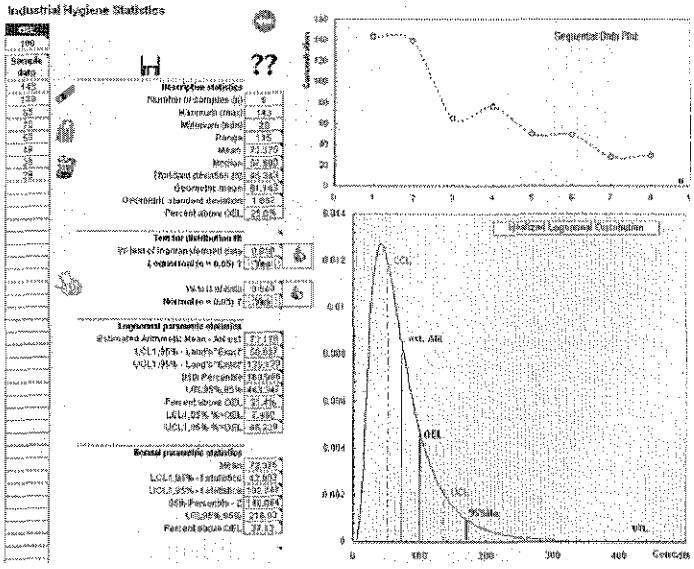


Figure C-1—IHSTAT Display of Dryer Data from Table C-1.

IHSTAT will calculate a vast amount of statistical data that is useful to the industrial hygienist. It is beyond the scope of this document to explain the significance of all of this data, but some basic results can be useful in providing an understanding the distribution of data and how inferences can be drawn to estimate with some precision conclusions that extend beyond the samples taken.

To use the IHSTAT spreadsheet for calculating statistics for respirable dust that contains crystalline silica, the concentration of respirable dust from Table C-1 expressed in mg/m^3 cannot be entered into the spreadsheet. As discussed in Section 3 of this manual, MSHA, in its regulation of crystalline, uses a formula that establishes a limit as an amount of respirable dust containing a certain percentage of crystalline silica. As the percentage of crystalline in each sample changes, the respirable dust limit expressed in mg/m^3 changes. To enter data into the IHSTAT spreadsheet and have it run the many calculations it is programmed to compute, an occupational exposure limit (OEL) that remains constant has to be entered. The OEL in IHSTAT can be considered to be the same as the MSHA PEL. Because the MSHA PEL for the respirable dust varies with the percentage of crystalline silica, there is no constant PEL. To get around this with silica-containing dust data, you will need to enter the data in the "% Exposure" column of Table J-4 into the IHSTAT spreadsheet rather than the data in the "TWA Conc. of Respirable Dust" column. In IHSTAT the OEL should be entered as "100" which represents 100 percent of the MSHA PEL.

When IHSTAT is opened, some sample data have already been entered. If the "eraser" icon is clicked, the example data will be deleted. Now, enter the data from Table C-1 into the IHSTAT spreadsheet.

Looking at the IHSTAT spreadsheet, as seen in Figure C-1, notice the column on the far left that has "OEL" and "Sample data." Notice in Figure C-1 that 100 has been entered as the OEL and the "%Exposure" from Table J-1 (132, 139, 65, 76, 50, 49, 28, 29) have been entered as "Sample data." Once the data is entered, IHSTAT does the rest automatically. The column to the right of where the OEL" and sample data have been entered displays statistical calculations from the dataset in Table C-1 and displays the data in graphical format as well.

In the text of this manual that discussed Management of Exposure Data, some of the descriptive statistics suggested as being useful in understanding the statistical features of dust data are in the bullets below. IHSTAT calculated the data as follows. The column to the right of the data shows:

- number of samples = 8
- maximum exposure (max) =143
- minimum exposure (min) = 28
- range = 115 (range = maximum — minimum exposure)
- percent of exposures above the PEL (%>PEL) = 25.0
- mean of exposure ($\bar{\chi}$) [Need mean symbol which is a bar over small x] = 72.375
- standard deviation of exposure (s) = 45.343
- geometric mean (GM) = 61.143
- geometric standard deviation (GSD) = 1.862

IHSTAT did all the basic descriptive calculations and many more. For inferential statistics, the manual suggested that a statistic that can aid in the understanding of the hazard represented by a set of dust data was the 95th percentile of the distribution. Under "Lognormal parametric statistics," the 95th Percentile has been calculated and is equal to 169.946. If the exposures did not steadily decline over the sampling period (~ 1 ½ years) in Table J-1, the 169.496 would indicate there is a big problem since it would mean that excursions well above the PEL are taking place on days when sampling was not being done. Because the exposures declined steadily and only the first two exceeded the MSHA PEL, it appears that this operation is now under control. However, it is likely that workers at this operation prior to controls being implemented were overexposed to crystalline silica and at some risk of developing silicosis. If

the exposures in Table C-1 are used, but the data are reordered so there is not a consistent decline in the exposure pattern over time, the interpretation would be quite different. The same data in Table C-1 was rearranged in Table C-2 in an order that does not show a continual decline over the sampling period.

Date	Source	Job	% Silica	TWA Conc. of Respirable Dust	PEL	% Exposure
6-16-04	Dryer	Dryer Operator	44	0.063	0.217	29
6-16-04	Dryer	Dryer Helper	27	0.171	0.345	50
11-26-04	Dryer	Dryer Operator	36	0.171	0.263	65
11-26-04	Dryer	Dryer Helper	54	0.051	0.179	28
7-11-05	Dryer	Dryer Operator	40	0.333	0.238	139
7-11-05	Dryer	Dryer Helper	32	0.145	0.294	49
1-27-06	Dryer	Dryer Operator	25	0.283	0.370	76
1-27-06	Dryer	Dryer Helper	50	0.276	0.192	143

Table C-2—Dryer Operation Dust Sampling Data

Now the picture does not look so good. Rather than a consistent decline in the exposure there is no consistent pattern, and exposures vary widely. As one would expect, the same data in IHSTAT it will give the same statistical calculations as shown in Figure C-1. Go ahead—try it. Of course the 95th percentile has not changed and remains 169.496. In other words, if 100 samples were collected at this dryer operation, one would expect 95 of the samples to be below 169. Since the acceptable exposure limit (MSHA PEL) is 100, the number of exposures would be above the PEL, which of course is unacceptable.

In another sample operation, a screen operator is sampled once a year over a 3-year period. His exposures compared to the MSHA PEL were 65, 92, and 29 percent (See Table C-3). Though there may be less concern with these exposures, one would prefer to see the 92 percent exposure lower. However, the last sample was the lowest of the three, which is acceptable because they are all below the PEL. Furthermore there is no way the company could have been

cited by MSHA for a violation. See below for how IHSTAT provides some understanding of this exposure pattern.

Date	Source	Job	% Silica	TWA Conc. of Respirable Dust	PEL	% Exposure
2-26-04	Screen	Screen Operator	36	0.171	0.263	65
2-11-05	Screen	Screen Operator	51	0.173	0.189	92
1-27-06	Screen	Screen Operator	44	0.063	0.217	29

Table C-3—Screen Operation Dust Sampling Data

Look at Figure C-2 for a presentation of the data from the screening operation. The descriptive statistics look pretty good with a mean of 62.667 and a standard deviation of ± 30.567. Therefore, most of the samples should fall in a distribution from 32.1 to 93.234 (62.667 ± 30.567) and be less than our 100 percent exposure (MSHA PEL), which should not be exceeded. However, the inferential indicator shows the 95th percentile is at 142.218, which represents troubling data, leading to the conclusion that there are days when the screen operator is being overexposed.

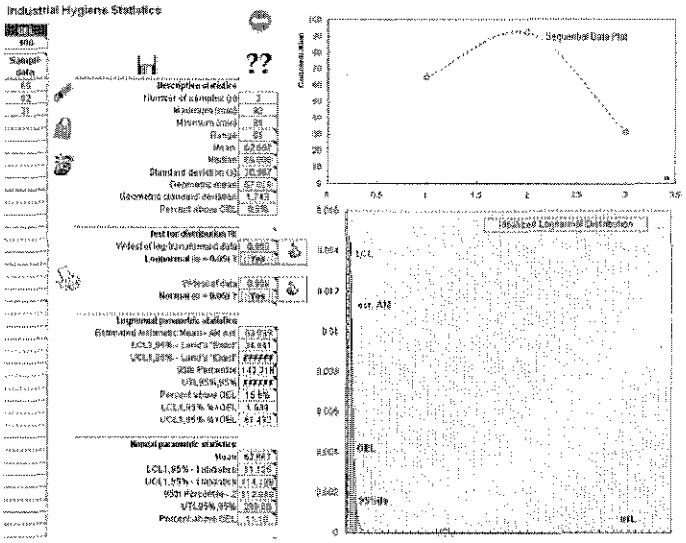


Figure C-2—IHSTAT Display of Screen Data from Table C-3.

Because of these concerns, more sampling of this operation is recommended. Generally speaking, the more data on an exposure, the better on the understanding, leading to a decision to sample this operation more frequently and take three more samples. The results with the additional samples are shown in Table C-4.

Date	Source	Job	% Silica	TWA Conc. of Respirable Dust	PEL	% Exposure
2-26-04	Screen	Screen Operator	36	0.171	0.263	65
2-11-05	Screen	Screen Operator	51	0.173	0.189	92
1-27-06	Screen	Screen Operator	44	0.063	0.217	29
3-16-06	Screen	Screen Helper	32	0.124	0.294	42
6-28-06	Screen	Screen Operator	44	0.061	0.217	28
10-14-06	Screen	Screen Helper	27	0.141	0.345	41

Table C-4—Screen Operation Dust Sampling Data

Figure C-3 presents the data from Table C-4 and shows a mean of 49.550 ± 24.729 and a 95th percentile of 96.709—a more favorable outcome suggesting the company can return to an annual sampling frequency for this operation. Try this example.. Notice that the additional samples are quite low and all are below 50 percent of the PEL. To understand this data distribution, enter these last three samples into IHSTAT (42, 28, 41). The result should be a mean of 37, a standard deviation of ± 7.81, and a 95th percentile of 52.913. Of course, the company should continue to sample this operation but with greater confidence that the operator is not being overexposed, and more importantly, is not at risk of developing silicosis.

Hopefully these examples have illustrated the importance of using statistics to further one's understanding of sampling data and to gain insight into exposure profiles of workers and operations. Furthermore, this data can be useful in explaining to employees and management the importance of a sound safety and health program, and the necessity of having solid control

measures in place. Other useful information is referenced at the end of the appendix for further study on this topic.

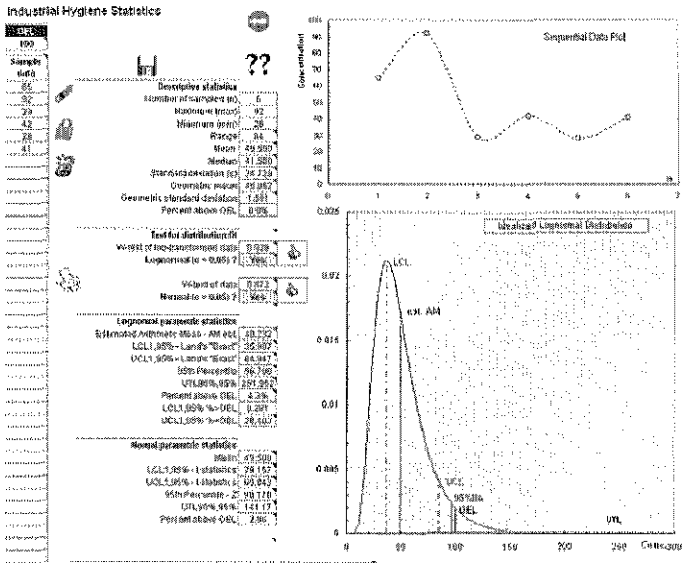


Figure C-3—IHSTAT Display of Screen Data from Table C-4.

USEFUL WEBSITES WITH INDUSTRIAL HYGIENE STATISTICS INFORMATION

American Industrial Hygiene Association Exposure Assessment Strategies Committee
http://www.aiha.org/insideaiha/volunteergroups/Pages/EASC.aspx

American Conference of Governmental Industrial Hygienist (Search "exposure assessment")
http://www.acgih.org/home.htm

Exposure Assessment Solutions, Inc. (Paul Hewett)
http://www.oesh.com/

North Carolina Center for Public Health Preparedness Focus on Field Epidemiology, Volume 3, Issue 6: Data Analysis: Simple Statistical Tests
http://nccphp.sph.unc.edu/focus/vol3/issue6/index.htm

Tufts University, CMG110 Epidemiology and Biostatistics Online Course
http://ocw.tufts.edu/Course/1/Coursehome

Appendix D—Medical Surveillance Forms

[Note: The forms include fictitious examples to demonstrate what type of information is entered into a completed sheet. Someone from the industrial sand industry needs to check the entries and enter information that might be more representative of the industrial sand industry. Some have entries, but they may not be appropriate.]

NISA Occupational Health Program
Form D-1—Medical and Work History

Occupational health screening examinations can only indicate the presence of a possible medical problem. Abnormal findings detected by screening must be confirmed and then referred for diagnostic studies to determine their relationship to occupational exposure and/or their true significance. An accurate and up-to-date medical and work history is an essential part of a health screening examination. Please answer the following questions as completely and frankly as you can. If you are uncertain of a response, leave the answer blank. Your answers will be held in strict confidence in your medical records and may be used in medical studies without public release of your name.

Name _____ Date of birth _____
Social Security no. _____ Home phone _____
Company name _____
Plant Location _____
Job title _____
Physician's name _____ Physician's phone _____
Physician's address _____
City _____ State _____ Zip _____
Your height: _____ feet _____ inches
Your weight: _____ pounds
Waist circumference: _____ inches
Race (optional): □ White □ Black □ Hispanic □ Asian/Pacific □ Alaskan/Indian
Sex: □ Male □ Female

Personal Medical History:

Please indicate whether you have had any of the following medical problems. For any checked yes include approximate date of illness or diagnosis.

High blood pressure (hypertension):
□ Yes □ No Date diagnosed: _____

High cholesterol:
□ Yes □ No Date diagnosed: _____

Heart attack or heart disease:
□ Yes □ No Date diagnosed: _____

Stroke:
□ Yes □ No Date diagnosed: _____

Diabetes:
□ Yes □ No Date diagnosed: _____

Protein in your urine:
□ Yes □ No Date diagnosed: _____

Anemia:
□ Yes □ No Date diagnosed: _____

Circulatory disease in your legs:
□ Yes □ No Date diagnosed: _____

NISA Occupational Health Program
Form D-1—Medical and Work History

Personal Medical History (Continued):

Chronic kidney disease, on kidney dialysis, or have had a kidney transplant:
□ Yes □ No Date diagnosed: _____

Rheumatoid arthritis:
□ Yes □ No Date diagnosed: _____

Lupus:
□ Yes □ No Date diagnosed: _____

Kidney blockage:
□ Yes □ No Date diagnosed: _____

Bronchitis:
□ Yes □ No Date diagnosed: _____

Emphysema:
□ Yes □ No Date diagnosed: _____

Asthma:
□ Yes □ No Date diagnosed: _____

Pneumonia:
□ Yes □ No Date diagnosed: _____

Silicosis:
□ Yes □ No Date diagnosed: _____

Asbestosis:
□ Yes □ No Date diagnosed: _____

Coal workers pneumoconiosis or black lung:
□ Yes □ No Date diagnosed: _____

Other chest problems or conditions:
□ Yes □ No Date diagnosed: _____

Describe: _____

Chest surgery:
□ Yes □ No Date diagnosed: _____

Describe: _____

Do you take any of the painkillers below frequently for chronic (persistent) pain relief?

Ibuprofen (Advil, Motrin):
□ Yes □ No

Naproxen (Alleve):
□ Yes □ No

Acetaminophen (Tylenol):
□ Yes □ No

NISA Occupational Health Program
Form D-1—Medical and Work History

Smoking history:

□ Never Smoked □ Ex-smoker □ Present smoker – do not inhale
□ Present smoker – inhale slightly □ Present smoker – inhale moderately □ Present smoker – inhale deeply

Type of smoker:
□ Cigarettes only □ Pipe only □ Cigars only □ Cigarettes, pipe and cigars □ Cigars only □ Cigars and pipe

If you are an ex-smoker, how much did you smoke per day?
□ ½ pack □ 1 pack □ 1 ½ pack □ 2 packs □ More than 2 packs

Do you use smokeless tobacco?
□ Snuff □ Chewing tobacco

If you currently smoke, how much do you smoke per day (average, including weekends)?

Cigarettes:	□ ½ pack	□ 1 pack	□ 1 ½ pack	□ 2 packs	□ More than 2 packs
Cigars:	□ 1	□ 2-5	□ 6-10	□ 11 or more	
Pipe:	□ ½ oz.	□ 1 oz.	□ 2 oz.	□ More than 2 oz.	

What age were you when you started smoking?
_____ years

For how many years have you smoked?
_____ Years

If you stopped smoking, at what age did you stop?

_____ Years

Do you have any of the above following symptoms while at work?
□ Coughing and wheezing □ Throat irritation □ Nose irritation □ Eye irritation

Do you have any of the above symptoms after work?
□ At night □ On weekends

Have you ever been off work for a shift or longer after acute exposure to gases or fumes?
□ Yes □ No

Respirator Wearing:

Do you have a fear of:
□ Being in closed places □ Wearing a face mask or respirator

Have you ever been told by a physician not to wear a face mask or respirator?
□ Yes □ No

Do you have a problem getting a face mask or respirator to fit properly because of:
□ Facial configuration □ Facial hair

How often do you wear a respirator?
□ 4-8 hours per day □ Less than 4 hours per day □ As needed □ For emergencies only

What are the conditions when you use a respirator?
□ Normal □ Noisy □ Heavy physical work

Can you use a respirator comfortably?
□ Yes □ No

Have you been trained in the proper use of a respirator?
□ Yes □ No

NISA Occupational Health Program
Form D-1—Medical and Work History

Work History:

Have you ever worked:

- □ In dusty places
- □ In a mill processing mined or quarried materials
- □ In a foundry
- □ In construction, insulation, or shipyard work
- □ With X-rays or radioactive substances
- □ In a coal mine
- □ In any other mine
- □ In a pottery
- □ In wielding
- □ In a hard rock or uranium mine
- □ In a quarry, including sand
- □ In abrasive blasting/sand blasting
- □ With asbestos

Have you ever worked where you often or daily breathed any of the following materials? (Check all appropriate.)

- □ Coal dust
- □ Silica or blasting sand
- □ Asbestos dust
- □ Talc, clay, diatomaceous earth
- □ Insect or plant spray
- □ Metal fumes or dust
- □ Plastic or resin fumes
- □ Engine exhaust fumes
- □ Grain dust
- □ Wood dust
- □ Toxic or irritating gases
- □ Toluene diisocyanate
- □ Methyl isocyanate
- □ Other isocyanates
- □ Mold, spores, pollen, yeast, or fungi
- □ Lead
- □ Mercury
- □ Cadmium
- □ Chromium

Have you ever worked where you often or daily breathed any degreaser solvents (for example: trichloroethylene, TCE, methyl chloroform, trichloroethane, perchloroethylene, PERC, Stoddard solvent)?

□ Yes □ No Do you recall the name(s) of any?

NISA Occupational Health Program
Form D-2—Employment History: Preplacement and Biennial Update

Name _____ Social Security No. _____ Date _____

List below all of your employment, with a description of each specific kind of work, the approximate duration of each job, and the materials you used. Begin with the most recent employment and go back to your first job. Be sure to include your present job, along with all of your previous ones.

Kind of Business or Industry	Description of Job	Years Worked		Comments on Products and Materials Used
		From	To	

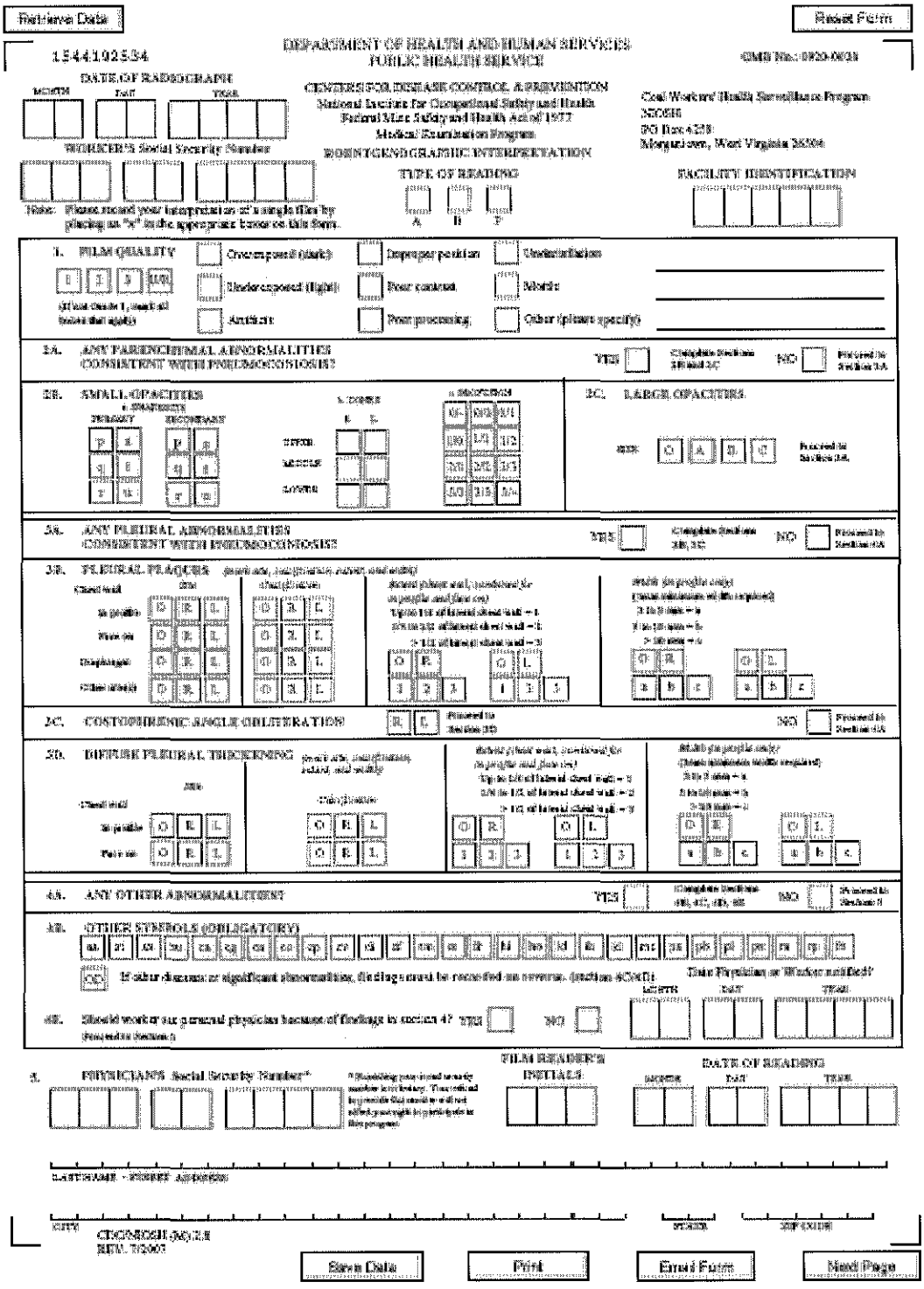
NISA Occupational Health Program
Form D-2—Employment History: Preplacement and Biennial Update (Sample)

Name John Doe Social Security No. 248-82-7681 Date 1/26/08

List below all of your employment, with a description of each specific kind of work, the approximate duration of each job, and the materials you used. Begin with the most recent employment and go back to your first job. Be sure to include your present job, along with all of your previous ones.

Kind of Business or Industry	Description of Job	Years Worked		Comments on Products and Materials Used
		From	To	
Industrial Sand	Single spout bagger	2004	Present	
Industrial Sand	Dryer helper	2000	2004	
Industrial Sand	General laborer	1996	2000	
Welding	Welder apprentice	1993	1996	Welding on both mild & stainless steel.
Construction	General carpenter	1990	1993	Wood dust, concrete dust, noise.
Auto repair	Mechanic	1988	1990	Solvents, paint, body filler.

NISA Occupational Health Program
Form D-3—Roentgenographic Interpretation Based on the 2000 ILO Classification of the Pneumoconioses



NISA Occupational Health Program
Form D-3—Roentgenographic Interpretation Based on the 1980 ILO Classification of the Pneumoconioses

Previous Page

4961192530

4C. MARK ALL BOXES THAT APPLY: (Use of this list is intended to reduce handwritten comments and is optional)

Abnormalities of the Diaphragm
- ☐ Eventration
- ☐ Hiatal hernia

Airway Disorders
- ☐ Bronchovascular markings, heavy or increased
- ☐ Hyperinflation

Page 1

Bony Abnormalities
- ☐ Bony chest cage abnormality
- ☐ Fracture, healed (rost-rib)
- ☐ Fracture, not healed (rost-rib)
- ☐ Scoliosis
- ☐ Vertebral column abnormality

Page 1

Lung Parenchymal Abnormalities
- ☐ Angyo lobe
- ☐ Density, lung
- ☐ Infiltrate
- ☐ Nodule, nodular lesion

Miscellaneous Abnormalities
- ☐ Foreign body
- ☐ Post-surgical changes/sternal wire
- ☐ Cyst

Vascular Disorders
- ☐ Aorta, anomaly of
- ☐ Vascular abnormality

4D. OTHER COMMENTS

Page 1

Save Data | Print | Email Form

NISA Occupational Health Program
Form D-4—Sample of Narrative-Style Chest Radiological Evaluation Report

Name John Doe Plant Oriskany Plant, Virginia
No. 22468 Reading date 6/10/2007
Interpretation of: 14 x 17 PA roentgenogram of chest taken on 6/5/2007

Comments

This film is of good diagnostic quality. The soft tissues and bones of the thorax show no abnormality. The diaphragms are smooth and rounded and in normal position for full inspiration. The costophrenic angles are clear, and there is no abnormal thickening of the pleura. The cardiac and lung root shadows are normal with respect to contour, size, and position. The brohovascular markings are within normal limits, distributed evenly throughout both lungs, and show normal attenuation. No unusual densities are seen in either lung. The appearance of this film is entirely within the limits of normal.

Physician George W. Stevens, M.D. Date 6/10/2007

NISA Occupational Health Program
Form D-5—Sample Cumulative Radiology Report of Chest X-Rays

Company Oriskany Sand Co

Name John Doe ID Number 123-45-6789 Date of birth 05/17/49

June 25, 1991 Chest PA: Marked emphysema left lung with well-defined mass or fibrosis inferior left lower lobe, unknown cause. (I called Oriskany on this finding.) Scarred RUL and apex and possibly upper portion left lung, irregular and small nodular, compatible with probable healed TB or silicotuberculosis with minimal emphysema right lung. CTR: 10/32
07-11-91 10:24 Paul S. Wheeler, MD

July 16, 1992 Chest PA: Moderately large left pneumothorax with partial atelectasis left lung and several bullous blebs are defined by air. Unimin called. Few small calcified granulomata in right lung. No old films but prior report describes right lung disease. CTR: 8/32
09-12-92 11:16 Paul S. Wheeler, MD

CT scan report sent by Mr. Brown at Oriskany 10/13/92:

Aug 23, 1992 Chest CT scan (St. Margaret's Hosp): Gastric hiatus hernia in medial portion left mid and lower lung apparently is the "well-defined mass or fibrosis" which I described on 06-25-91. When a hiatus hernia contains fluid and no air it can look like a mass. They usually are in midline mediastinum and when asymmetrical like this may be paraesophageal which can be complicated by twisting. Suggest getting an upper GI series. CT scan also confirms COPD and some scarring.
10-20-92 11:08 Paul S. Wheeler, MD

Oct 18, 1993 Chest PA: Moderate left diaphragm elevation to level of lower left hilum. Moderate fibrosis RUL with tiny calcified granulomata compatible with healed TB. Moderate emphysema with decreased lung markings left lower lung. Probably dilatation hilar portion pulmonary arteries due to COPD rather than adenopathy. This is a complex case and should be read with prior films. CTR: 14/33
12-07-93 18:47 Paul S. Wheeler, MD

Sep 20, 1994 Chest PA: No old films / Prior report describes this exam. Approximate CTR: 11.5/31.5
01-16-95 11:08 Paul S. Wheeler, MD

Comparing original PA chest film of 07-16-92 with copies of PA views on 10-18-93 and 09-20-94: All show COPD with probable healed TB RUL and apex with irregular scars and several calcified granulomata. Sparing LUL except for few tiny peripheral scars is against silicosis in this case. Moderate pneumothorax with tiny pleural effusion on first film gone on 2nd exam. Elevation or eventration medial portion left hemidiaphragm increased between first 2 films / It could be diaphragmatic rupture but is not a classic hiatus hernia. Underexposure is only change between last two exams.
01-16-95 11:06 Paul S. Wheeler, MD

Feb 10, 1997 Chest PA: Moderate to marked emphysema left lung and healed TB with scars and tiny calcified granulomata right mid and upper lung and few linear scars in right apex and probable blebs in left apex. Moderate left diaphragm eventration to level of lower left hilum or possible healed rupture medial portion diaphragm. Minimal pleural fibrosis blunting left CPA. CTR: 12.5/32
02-20-97 13:56 Paul S. Wheeler, MD

NISA Occupational Health Program
Form D-6—Pulmonary Function Studies Record

Name _____ Location _____ Job name/description _____
Sex: □ Male □ Female Race*** _____ Social Security No. _____

Date	Spirometer Type	Ambient Temp (°C)	Age	Height†	Observed Values (BTPS)			Predicted Normals				Change (±% or iters)			Subject Cooperation (good, fair, poor)
					FEV_1	FVC	FEV_1/FVC%	FEV_1	% Predicted	FVC	% Predicted	FEV_1	FVC	FEV_1/FVC%	

*** For non-Caucasians, the predicted FEV_1 and FVC must be multiplied by 0.85.
† In stocking feet.

NISA Occupational Health Program
Form D-6—Pulmonary Function Studies Record (Sample)

Name John Doe Location Oriskany Plant Job name/description Bagger

Sex: ☒ Male ☐ Female Race*** Caucasian Social Security No. 248-82-7681

Date	Spirometer Type	Ambient Temp (°C)	Age	Height†	Observed Values (BTPS)			Predicted Normals				Change (±% or iters)			Subject Cooperation (good, fair, poor)
					FEV_1	FVC	FEV_1/ FVC%	FEV_1	% Predicted	FVC	% Predicted	FEV_1	FVC	FEV_1/ FVC%	
1/21/92	Rolling Seal	23	26	72	4.71	5.80	81.2	4.60	102.4	5.65	102.7	--	--	--	F
1/24/94	"	22	28	72	4.80	5.84	82.2	4.55	105.5	5.55	105.2	+1.9	+0.7	+1.0	G
1/29/96	"	21.5	30	72	4.60	5.56	82.7	4.50	102.2	5.50	101.1	-4.2	-5.0	+0.5	F
1/14/98	"	23	32	72	4.42	5.48	80.7	4.40	100.5	5.45	100.6	-4.1	-1.4	-2.0	G
1/17/00	"	21	34	72	4.30	5.25	81.9	4.35	98.9	5.40	97.2	-2.7	-4.2	+1.2	G
3/11/02	"	24	36	72	4.23	4.70	90.0	4.28	98.8	5.35	87.9	-1.6	-10.5	+8.9	G
2/10/04	"	22	38	72	54.03	4.20	95.9	4.25	94.8	5.30	79.2	-4.7	-10.6	+5.9	G
1/26/06	"	21.5	40	72	3.04	3.20	95.0	4.20	72.3	5.25	61.00	-24.6	-23.8	-0.9	G

*** For non-Caucasians, the predicted FEV_1 and FVC must be multiplied by 0.85.

† In stocking feet.

Appendix E—42 CFR, Part 37, Specifications for Medical Examinations of Underground Coal Miners

~~so designated shall be provided to the relevant fiscal control office.~~

~~(c) Subject to availability of sufficient funds, monies in the patient fund may be expended for materials, services or activities which contribute to the well-being or morale of patients, including but not limited to provision of reading and entertainment materials, recreation activities, and, in appropriate cases, necessary financial support (including travel expenses, meals, and lodging) of relatives, guardians, or friends of patients to enable such persons to be available for the patient's comfort and support.~~

~~(d) Officers in charge may issue such additional instructions, not inconsistent with this subpart, as may be necessary to implement its provisions.~~

PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF UNDERGROUND COAL MINERS

Subpart—Chest Roentgenographic Examinations

Subpart—Autopsies

AUTHORITY: Sec. 203, 83 Stat. 763; 30 U.S.C. 843, unless otherwise noted.

SOURCE: 43 FR 33715, Aug. 1, 1978, unless otherwise noted.

Subpart—Chest Roentgenographic Examinations

§ 37.1 Scope.

The provisions of this subpart set forth the specifications for giving, interpreting, classifying, and submitting chest roentgenograms required by section 203 of the act to be given to underground coal miners and new miners.

§ 37.2 Definitions.

Any term defined in the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the act. As used in this subpart:

(a) *Act* means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, *et seq.*).

(b) *ALOSH* means the Appalachian Laboratory for Occupational Safety and Health, Box 4258, Morgantown, WV 26505. Although the Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, has programmatic responsibility for the chest roentgenographic examination program, the Institute's facility in Morgantown—ALOSH—is used throughout this subpart in referring to the administration of the program.

(c) *Chest roentgenogram* means a single posteroanterior roentgenographic projection or radiograph of the chest at full inspiration recorded on roentgenographic film.

(d) *Convenient time and place* with respect to the conduct of any examination under this subpart means that the examination must be given at a reasonable hour in the locality in which the miner resides or a location that is equally accessible to the miner. For example, examinations at the mine during, immediately preceding, or immediately following work and a "no appointment" examination at a medical facility in a community easily accessible to the residences of a majority of the miners working at the mine, shall be considered of equivalent convenience for purposes of this paragraph.

(e) *Institute* and *NIOSH* mean the National Institute for Occupational Safety and Health Center for Disease Control, Public Health Service, Department of Health and Human Services.

(f) *ILO-U/C Classification* means the classification of radiographs of the pneumoconioses devised in 1971 by an international committee of the International Labor Office and described in "Medical Radiography and Photography," volume 48, No. 3, December 1972. "ILO Classification" means the classification of radiographs of the pneumoconioses revised in 1980 by an international committee of the International Labor Office and described in "Medical Radiography and Photography" volume 57, No. 1, 1981, and in ILO publication 22 (revised 1980) from the ILO Occupational Safety and Health Series.

(g) *Miner* means any individual including any coal mine construction worker who is working in or at any underground coal mine, but does not include any surface worker who does not have direct contact with underground coal mining or with coal processing operations.

(h) *Operator* means any owner, lessee, or other person who operates, controls, or supervises an underground coal mine or any independent contractor performing services or construction at such mine.

(i) *Panel of 'B' Readers* means the U.S. Public Health Service Consultant Panel of "B" Readers, c/o ALOSH, P.O. Box 4258, Morgantown, WV 26505.

(j) *Preemployment physical examination* means any medical examination which includes a chest roentgenographic examination given in accordance with the specifications of this subpart to a person not previously employed by the same operator or at the same mine for which that person is being considered for employment.

(k) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

(l) *MSHA* means the Mine Safety and Health Administration, Department of Labor.

[43 FR 33715, Aug. 1, 1978, as amended at 49 FR 7563, Mar. 1, 1984]

§ 37.3 Chest roentgenograms required for miners.

(a) *Voluntary examinations.* Every operator shall provide to each miner who is employed in or at any of its underground coal mines and who was employed in underground coal mining prior to December 30, 1969, or who has completed the required examinations under § 37.3(b) an opportunity for a chest roentgenogram in accordance with this subpart:

(1) Following August 1, 1978 ALOSH will notify the operator of each underground coal mine of a period within which the operator may provide examinations to each miner employed at its coal mine. The period shall begin no sooner than the effective date of these regulations and end no later than a date specified by ALOSH separately for each coal mine. The termination date of the period will be approximately 5 years from the date of the first examination which was made on a miner employed by the operator in its coal mine under the former regulations of this subpart adopted July 27, 1973. Within the period specified by ALOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: ALOSH finds that between July 27, 1973, and March 31, 1975, the first roentgenogram for a miner who was employed at mine Y and who was employed in underground coal mining prior to December 30, 1969, was made on January 1, 1974. ALOSH will notify the operator of mine Y that the operator may select and designate on its

plan a 6-month period within which to offer its examinations to its miners employed at mine Y. The 6-month period shall be scheduled between August 1, 1978 and January 1, 1979 (5 years after January 1, 1974).

(2) For all future voluntary examinations, ALOSH will notify the operator of each underground coal mine when sufficient time has elapsed since the end of the previous 6-month period of examinations. ALOSH will specify to the operator of each mine a period within which the operator may provide examinations to its miners employed at its coal mine. The period shall begin no sooner than 3½ years and end no later than 4½ years subsequent to the ending date of the previous 6-month period specified for a coal mine either by the operator on an approved plan or by ALOSH if the operator did not submit an approved plan. Within the period specified by ALOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.5.

Example: ALOSH finds that examinations were previously provided to miners employed at mine Y in a 6-month period from July 1, 1979, to December 31, 1979. ALOSH notifies the operator at least 3 months before July 1, 1983 (3½ years after December 31, 1979) that the operator may select and designate on its plan the next 6-month period within which to offer examinations to its miners employed at mine Y. The 6-month period shall be scheduled between July 1, 1983, and July 1, 1984 (between 3½ and 4½ years after December 31, 1979).

(3) Within either the next or future period(s) specified by ALOSH to the operator for each of its coal mines, the operator of the coal mine may select a different 6-month period for each of its mines within which to offer examinations. In the event the operator does not submit an approved plan, ALOSH will specify a 6-month period to the operator within which miners shall have the opportunity for examinations.

(b) *Mandatory examinations.* Every operator shall provide to each miner who begins working in or at a coal mine for the first time after December 30, 1969:

(1) An initial chest roentgenogram as soon as possible, but in no event later than 6 months after commencement of employment. A preemployment physical examination which was made within the 6 months prior to the date on which the miner started to work will be considered as fulfilling this requirement. An initial chest roentgenogram given to a miner according to former regulations for this subpart prior to August 1, 1978 will also be considered as fulfilling this requirement.

(2) A second chest roentgenogram, in accordance with this subpart, 3 years following the initial examination if the miner is still engaged in underground coal mining. A second roentgenogram given to a miner according to former regulations under this subpart prior to August 1, 1978 will be considered as fulfilling this requirement.

(3) A third chest roentgenogram 2 years following the second chest roentgenogram if the miner is still engaged in underground coal mining and if the second roentgenogram shows evidence of category 1, category 2, category 3 simple pneumoconioses, or complicated pneumoconioses (ILO Classification).

(c) ALOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, ALOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator shall not state the medical reason for the examination nor that it is the third examination in the series. If the miner is notified by ALOSH that the third mandatory examination is due and the operator is not so notified, availability of the roentgenographic examination under the operator's plan shall constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner refuses to take the examination.

(d) The opportunity for chest roentgenograms to be available by an operator for purposes of this subpart shall be provided in accordance with a plan which has been submitted and approved in accordance with this subpart.

(e) Any examinations conducted by the Secretary in the National Study of Coal Workers' Pneumoconiosis after January 1, 1977, but before August 1, 1978 shall satisfy the requirements of

this section with respect to the specific examination given (see § 37.6(d)).

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978, as amended at 49 FR 7563, Mar. 1, 1984]

§ 37.4 Plans for chest roentgenographic examinations.

(a) Every plan for chest roentgenographic examinations of miners shall be submitted on forms prescribed by the Secretary to ALOSH within 120 calendar days after August 1, 1978. In the case of a person who after August 1, 1978, becomes an operator of a mine for which no plan has been approved, that person shall submit a plan within 60 days after such event occurs. A separate plan shall be submitted by the operator and by each construction contractor for each underground coal mine which has a MSHA identification number. The plan shall include:

(1) The name, address, and telephone number of the operator(s) submitting the plan;

(2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;

(3) The proposed beginning and ending date of the 6-month period for voluntary examinations (see § 37.3(a)) and the estimated number of miners to be given or offered examinations during the 6-month period under the plan;

(4) The name and location of the approved X-ray facility or facilities, and the approximate date(s) and time(s) of day during which the roentgenograms will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

(5) If a mobile facility is proposed, the plan shall provide that each miner be given adequate notice of the opportunity to have the examination and that no miner shall have to wait for an examination more than 1 hour before or after his or her work shift. In addition, the plan shall include:

(i) The number of change houses at the mine.

(ii) One or more alternate nonmobile approved facilities for the reexamination of miners and for the mandatory examination of miners when necessary (see § 37.3(b)), or an assurance that the mobile facility will return to the location(s) specified in the plan as frequently as necessary to provide for examinations in accordance with these regulations.

(iii) The name and location of each change house at which examinations will be given. For mines with more than one change house, the examinations shall be given at each change house or at a change house located at a convenient place for each miner.

(6) The name and address of the "A" or "B" reader who will interpret and classify the chest roentgenograms.

(7) Assurances that: (i) The operator will not solicit a physician's roentgenographic or other findings concerning any miner employed by the operator,

(ii) Instructions have been given to the person(s) giving the examinations that duplicate roentgenograms or copies of roentgenograms will not be made and that (except as may be necessary for the purpose of this subpart) the physician's roentgenographic and other findings, as well as the occupational history information obtained from a miner unless obtained prior to employment in a preemployment examination, and disclosed prior to employment, will not be disclosed in a manner which will permit identification of the employee with the information about him, and

(iii) The roentgenographic examinations will be made at no charge to the miner.

(b) Operators may provide for alternate facilities and "A" or "B" readers in plans submitted for approval.

(c) The change of operators of any mine operating under a plan approved pursuant to § 37.5 shall not affect the plan of the operator which has transferred responsibility for the mine. Every plan shall be subject to revision in accordance with paragraph (d) of this section.

(d) The operator shall advise ALOSH of any change in its plan. Each change in an approved plan is subject to the same review and approval as the originally approved plan.

(e) The operator shall promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in plan when

it is submitted to ALOSH. The proposed plan or change in plan shall remain posted in a visible location on the bulletin board until ALOSH either grants or denies approval of it at which time the approved plan or denial of approval shall be permanently posted. In the case of an operator who is a construction contractor and who does not have a bulletin board, the construction contractor must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show ALOSH written evidence that its employees have been notified.

(f) Upon notification from ALOSH that sufficient time has elapsed since the previous period of examinations, the operator will resubmit its plan for each of its coal mines to ALOSH for approval for the next period of examinations (see §37.3(a)(2)). The plan shall include the proposed beginning and ending dates of the next period of examinations and all information required by paragraph (a) of this section.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§37.5 Approval of plans.

(a) Approval of plans granted prior to August 1, 1978 is no longer effective.

(b) If, after review of any plan submitted pursuant to this subpart, the Secretary determines that the action to be taken under the plan by the operator meets the specifications of this subpart and will effectively achieve its purpose, the Secretary will approve the plan and notify the operator(s) submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of section 203 of the act.

(c) Where the Secretary has reason to believe that he will deny approval of a plan he will, prior to the denial, give reasonable notice in writing to the operator(s) of an opportunity to amend the plan. The notice shall specify the ground upon which approval is proposed to be denied.

(d) If a plan is denied approval, the Secretary shall advise the operator(s) in writing of the reasons for the denial.

§37.6 Chest roentgenographic examinations conducted by the Secretary.

(a) The Secretary will give chest roentgenograms or make arrangements with an appropriate person, agency, or institution to give the chest roentgenograms and with "A" or "B" readers to interpret the roentgenograms required under this subpart in the locality where the miner resides, at the mine, or at a medical facility easily accessible to a mining community or mining communities, under the following circumstances:

(1) Where, in the judgment of the Secretary, due to the lack of adequate medical or other necessary facilities or personnel at the mine or in the locality where the miner resides, the required roentgenographic examination cannot be given.

(2) Where the operator has not submitted an approvable plan.

(3) Where, after commencement of an operator's program pursuant to an approved plan and after notice to the operator of his failure to follow the approved plan and, after allowing 15 calendar days to bring the program into compliance, the Secretary determines and notifies the operator in writing that the operator's program still fails to comply with the approved plan.

(b) The operator of the mine shall reimburse the Secretary or other person, agency, or institution as the Secretary may direct, for the cost of conducting each examination made in accordance with this section.

(c) All examinations given or arranged by the Secretary will comply with the time requirements of §37.3. Whenever the Secretary gives or arranges for the examinations of miners at a time, a written notice of the arrangements will be sent to the operator who shall post the notice on the mine bulletin board.

(d) Operators of mines selected by ALOSH to participate in the National Study of Coal Workers' Pneumoconiosis (an epidemiological study of respiratory diseases in coal miners) and who agree to cooperate will have all their miners afforded the opportunity to have a chest roentgenogram required hereunder at no cost to the operator. For future examinations and

for mandatory examinations each participating operator shall submit an approvable plan.

§ 37.7 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of the Secretary based upon the interpretation of one or more of the miner's chest roentgenograms, shows category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), or category 3 (3/2, 3/3, 3/4) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) shall be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is not more than 1.0 mg/m^3 of air, or if such level is not attainable in the mine, to a position in the mine where the concentration of respirable dust is the lowest attainable below 2.0 mg/m^3 of air.

(b) Any transfer under this section shall be in accordance with the procedures specified in part 90 of title 30, Code of Federal Regulations.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978, as amended at 44 FR 23085, Apr. 18, 1979; 49 FR 7563, Mar. 1, 1984]

§ 37.8 Roentgenographic examination at miner's expense.

Any miner who wishes to obtain an examination at his or her own expense at an approved facility and to have submitted to NIOSH for him or her a complete examination may do so, provided that the examination is made no sooner than 6 months after the most recent examination of the miner submitted to ALOSH. ALOSH will provide an interpretation and report of the examinations made at the miner's expense in the same manner as if it were submitted under an operator's plan. Any change in the miner's transfer rights under the act which may result from this examination will be subject to the terms of § 37.7.

§ 37.20 Miner identification document.

As part of the roentgenographic examination, a miner identification document which includes an occupational history questionnaire shall be completed for each miner at the facility where the roentgenogram is made at the same time the chest roentgenogram required by this subpart is given.

Specifications for Performing Chest Roentgenographic Examinations

§ 37.40 General provisions.

(a) The chest roentgenographic examination shall be given at a convenient time and place.

(b) The chest roentgenographic examination consists of the chest roentgenogram, and a complete Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8), and miner identification document.

(c) A roentgenographic examination shall be made in a facility approved in accordance with § 37.42 by or under the supervision of a physician who regularly makes chest roentgenograms and who has demonstrated ability to make chest roentgenograms of a quality to best ascertain the presence of pneumoconiosis.

§ 37.41 Chest roentgenogram specifications.

(a) Every chest roentgenogram shall be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inches and no greater than 16 by 17 inches. The film and cassette shall be capable of being positioned both vertically and horizontally so that the chest roentgenogram will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then the projection shall include both apices with minimum loss of the costophrenic angle.

(b) Miners shall be disrobed from the waist up at the time the roentgenogram is given. The facility shall provide a dressing area and for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(c) Roentgenograms shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm. source (focal spot).

(d) Except as provided in paragraph (e) of this section, roentgenograms

shall be made with units having generators which comply with the following: (1) The generators of existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp.; (2) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

NOTE: A generator with a rating of 150 kVp. is recommended.

(e) Roentgenograms made with battery-powered mobile or portable equipment shall be made with units having a minimum rating of 100 mA at 110 kVp. at 500 Hz, or of 200 mA at 110 kVp. at 60 Hz.

(f) Capacitor discharge and field emission units may be used if the model of such units is approved by ALOSH for quality, performance, and safety. ALOSH will consider such units for approval when listed by a facility seeking approval under § 37.42 of this subpart.

(g) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The beam limiting device shall provide rectangular collimation and shall be of the type described in part F of the suggested State regulations for the control of radiation or (for beam limiting devices manufactured after August 1, 1974) of the type specified in 21 CFR 1020.31. The use of such a device shall be discernible from an examination of the roentgenogram.

(h) To insure high quality chest roentgenograms:

(1) The maximum exposure time shall not exceed 1/20 of a second except that with single phase units with a rating less than 300 mA at 125 kVp. and subjects with chests over 28 cm. posteroanterior, the exposure may be increased to not more than 1/10 of a second;

(2) The source or focal spot to film distance shall be at least 6 feet;

(3) Medium speed film and medium speed intensifying screens are recommended. However, any film-screen combination, the rated "speed" of which is at least 100 and does not exceed 300, which produces roentgenograms with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as "medium speed" may be employed;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) When using over 90 kV., a suitable grid or other means of reducing scattered radiation shall be used;

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

(9) A formal quality assurance program shall be established at each facility.

(i) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(j) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be immediately made. All substandard roentgenograms shall be clearly marked as rejected and promptly sent to ALOSH for disposal.

(k) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(l) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of ALOSH.

(m) Each roentgenogram made hereunder shall be permanently and legibly

marked with the name and address or ALOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the roentgenogram. No other identifying markings shall be recorded on the roentgenogram.

[43 FR 33715, Aug. 1, 1978, as amended at 52 FR 7866, Mar. 13, 1987]

§ 37.42 Approval of roentgenographic facilities.

(a) Approval of roentgenographic facilities given prior to January 1, 1976, shall terminate upon August 1, 1978 unless each of the following conditions have been met:

(1) The facility must verify that it still meets the requirements set forth in the regulations for the second round of roentgenographic examinations (38 FR 20076) and it has not changed equipment since it was approved by NIOSH.

(2) From July 27, 1973, to January 1, 1976, the facility submitted to ALOSH at least 50 roentgenograms which were interpreted by one or more "B" readers not employed by the facility who found no more than 5 percent of all the roentgenograms unreadable.

(b) Other facilities will be eligible to participate in this program when they demonstrate their ability to make high quality diagnostic chest roentgenograms by submitting to ALOSH six or more sample chest roentgenograms made and processed at the applicant facility and which are of acceptable quality to the Panel of "B" readers. Applicants shall also submit a roentgenogram of a plastic step-wedge object (available on loan from ALOSH) which was made and processed at the same time with the same technique as the roentgenograms submitted and processed at the facility for which approval is sought. At least one chest roentgenogram and one test object roentgenogram shall have been made with each unit to be used hereunder. All roentgenograms shall have been made within 15 calendar days prior to submission and shall be marked to identify the facility where each roentgenogram was made, the X-ray machine used, and the date each was made. The chest roentgenograms will be returned and may be the same roentgenograms submitted pursuant to § 37.51.

NOTE: The plastic step-wedge object is described in an article by E. Dale Trout and John P. Kelley appearing in "The American Journal of Roentgenology, Radium Therapy and Nuclear Medicine," Vol. 117, No. 4, April 1973.

(c) Each roentgenographic facility submitting chest roentgenograms for approval under this section shall complete and include an X-ray facility document describing each X-ray unit to be used to make chest roentgenograms under the act. The form shall include: (1) The date of the last radiation safety inspection by an appropriate licensing agency or, if no such agency exists, by a qualified expert as defined in NCRP Report No. 33 (see § 37.43); (2) the deficiencies found; (3) a statement that all the deficiencies have been corrected; and (4) the date of acquisition of the X-ray unit. To be acceptable, the radiation safety inspection shall have been made within 1 year preceding the date of application.

(d) Roentgenograms submitted with applications for approval under this section will be evaluated by the panel of "B" Readers or by a qualified radiological physicist or consultant. Applicants will be advised of any reasons for denial of approval.

(e) ALOSH or its representatives may make a physical inspection of the applicant's facility and any approved roentgenographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(f) ALOSH may require a facility periodically to resubmit roentgenograms of a plastic step-wedge object, sample roentgenograms, or a Roentgenographic Facility Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of ALOSH the quality of roentgenograms or information submitted under this section warrants such action. A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest roentgenograms and shall be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved

plan will be reevaluated by ALOSH in light of this change.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§ 37.43 Protection against radiation emitted by roentgenographic equipment.

Except as otherwise specified in § 37.41, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, shall conform to applicable State and Federal regulations (See 21 CFR part 1000). Where no applicable regulations exist, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used shall conform to the recommendations of the National Council on Radiation Protection and Measurements in NCRP Report No. 33 "Medical X-ray and Gamma-Ray Protection for Energies up to 10 MeV—Equipment Design and Use" (issued February 1, 1968), in NCRP Report No. 48, "Medical Radiation Protection for Medical and Allied Health Personnel" (issued August 1, 1976), and in NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of up to 10 MeV" (issued September 15, 1976). These documents are hereby incorporated by reference and made a part of this subpart. These documents are available for examination at ALOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505, and at the National Institute for Occupational Safety and Health, 5600 Fishers Lane, Rockville, MD 20857. Copies of NCRP Reports Nos. 33, 48, and 49 may be purchased for $3, $4.50, and $3.50 each, respectively, from NCRP Publications, P.O. Box 30175, Washington, DC 20014.

SPECIFICATIONS FOR INTERPRETATION, CLASSIFICATION, AND SUBMISSION OF CHEST ROENTGENOGRAMS

§ 37.50 Interpreting and classifying chest roentgenograms.

(a) Chest roentgenograms shall be interpreted and classified in accordance with the ILO Classification system and recorded on a Roentgenographic Interpretation Form (Form CDC/NIOSH (M)2.8).

(b) Roentgenograms shall be interpreted and classified only by a physician who regularly reads chest roentgenograms and who has demonstrated proficiency in classifying the pneumoconioses in accordance with § 37.51.

(c) All interpreters, whenever interpreting chest roentgenograms made under the Act, shall have immediately available for reference a complete set of the ILO International Classification of Radiographs for Pneumoconioses, 1980.

NOTE: This set is available from the International Labor Office, 1750 New York Avenue, NW., Washington, DC 20006 (Phone: 202/376–2315).

(d) In all view boxes used for making interpretations:

(1) Fluorescent lamps shall be simultaneously replaced with new lamps at 6-month intervals;

(2) All the fluorescent lamps in a panel of boxes shall have identical manufacturer's ratings as to intensity and color;

(3) The glass, internal reflective surfaces, and the lamps shall be kept clean;

(4) The unit shall be so situated as to minimize front surface glare.

[43 FR 33715, Aug. 1, 1978, as amended at 49 FR 7564, Mar. 1, 1984]

§ 37.51 Proficiency in the use of systems for classifying the pneumoconioses.

(a) First or "A" readers:

(1) Approval as an "A" reader shall continue if established prior to (insert) effective date of these regulations).

(2) Physicians who desire to be "A" readers must demonstrate their proficiency in classifying the pneumoconioses by either:

(i) Submitting to ALOSH from the physician's files six sample chest roentgenograms which are considered properly classified by the Panel of "B" readers. The six roentgenograms shall consist of two without pneumoconiosis, two with simple pneumoconiosis, and two with complicated pneumoconiosis. The films will be returned to the physician. The interpretations shall be on the Roentgenographic Interpretation Form (Form CDC/NIOSH (M) 2.8)

(These may be the same roentgenograms submitted pursuant to §37.42), or;

(ii) Satisfactory completion, since June 11, 1970, of a course approved by ALOSH on the ILO or ILO-U/C Classification systems or the UICC/Cincinnati classification system. As used in this subparagraph, "UICC/Cincinnati classification" means the classification of the pneumoconioses devised in 1968 by a Working Committee of the International Union Against Cancer.

(b) Final or "B" readers:

(1) Approval as a "B" reader established prior to October 1, 1976, shall hereby be terminated.

(2) Proficiency in evaluating chest roentgenograms for roentgenographic quality and in the use of the ILO Classification for interpreting chest roentgenograms for pneumoconiosis and other diseases shall be demonstrated by those physicians who desire to be "B" readers by taking and passing a specially designed proficiency examination given on behalf of or by ALOSH at a time and place specified by ALOSH. Each physician must bring a complete set of the ILO standard reference radiographs when taking the examination. Physicians who qualify under this provision need not be qualified under paragraph (a) of this section.

(c) Physicians who wish to participate in the program shall make application on an Interpreting Physician Certification Document (Form CDC/NIOSH (M) 2.12).

[43 FR 33715, Aug. 1, 1978, as amended at 49 FR 7564, Mar. 1, 1984]

§37.52 Method of obtaining definitive interpretations.

(a) All chest roentgenograms which are first interpreted by an "A" or "B" reader will be submitted by ALOSH to a "B" reader qualified as described in §37.51. If there is agreement between the two interpreters as defined in paragraph (b) of this section the result shall be considered final and reported to MSHA for transmittal to the miner. When in the opinion of ALOSH substantial agreement is lacking, ALOSH shall obtain additional interpretations from the Panel of "B" readers. If interpretations are obtained from two or more "B" readers, and if two or more are in agreement then the highest major category shall be reported.

(b) Two interpreters shall be considered to be in agreement when they both find either stage A, B, or C complicated pneumoconiosis, or their findings with regard to simple pneumoconiosis are both in the same major category, or (with one exception noted below) are within one minor category (ILO Classification 12-point scale) of each other. In the last situation, the higher of the two interpretations shall be reported. The only exception to the one minor category principle is a reading sequence of 0/1, 1/0, or 1/0, 0/1. When such a sequence occurs, it shall not be considered agreement, and a third (or more) interpretation shall be obtained until a consensus involving two or more readings in the same major category is obtained.

[43 FR 33715, Aug. 1, 1978, as amended at 49 FR 7564, Mar. 1, 1984; 52 FR 7866, Mar. 13, 1987]

§37.53 Notification of abnormal roentgenographic findings.

(a) Findings of, or findings suggesting, enlarged heart, tuberculosis, lung cancer, or any other significant abnormal findings other than pneumoconiosis shall be communicated by the first physician to interpret and classify the roentgenogram to the designated physician of the miner indicated on the miner's identifcation document. A copy of the communication shall be submitted to ALOSH. ALOSH will notify the miner to contact his or her physician when any physician who interprets and classifies the miner's roentgenogram reports significant abnormal findings other than pneumoconiosis.

(b) In addition, when ALOSH has more than one roentgenogram of a miner in its files and the most recent examination was interpreted to show enlarged heart, tuberculosis, cancer, complicated pneumoconiosis, and any other significant abnormal findings, ALOSH will submit all of the miner's roentgenograms in its files with their respective interprtations to a "B" reader. The "B" reader will report any significant changes or progression of disease or other comments to ALOSH and ALOSH shall submit a copy of the report to the miner's designated physician.

(c) All final findings regarding pneumoconiosis will be sent to the miner by MSHA in accordance with section 203 of the act (see 30 CFR part 90). Positive findings with regard to pneumoconiosis will be reported to the miner's designated physician by ALOSH.

(d) ALOSH will make every reasonable effort to process the findings described in paragraph (c) of this section within 60 days of receipt of the information described in §37.60 in a complete and acceptable form. The information forwarded to MSHA will be in a form intended to facilitate prompt dispatch of the findings to the miner. The results of an examination made of a miner will not be processed by ALOSH if the examination was made within 6 months of the date of a previous acceptable examination.

§ 37.60 Submitting required chest roentgenograms and miner identification documents.

(a) Each chest roentgenogram required to be made under this subpart, together with the completed roentgenographic interpretation form and the completed miner identification document, shall be sumitted together for each miner to ALOSH within 14 calendar days after the roentgenographic examination is given and become the property of ALOSH.

(b) If ALOSH deems any part submitted under paragraph (a) of this section inadequate, it will notify the operator of the deficiency. The operator shall promptly make appropriate arrangements for the necessary reexamination.

(c) Failure to comply with paragraph (a) or (b) of this section shall be cause to revoke approval of a plan or any other approval as may be appropriate. An approval which has been revoked may be reinstated at the discretion of ALOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted to prevent a recurrence.

(d) Chest roentgenograms and other required documents shall be submitted only for miners. Results of preemployment physical examinations of persons who are not hired shall not be submitted.

(e) If a miner refuses to participate in all phases of the examination prescribed in this subpart, no report need be made. If a miner refuses to participate in any phase of the examination prescribed in this subpart, all the forms shall be submitted with his or her name and social security account number on each. If any of the forms cannot be completed because of the miner's refusal, it shall be marked "Miner Refuses," and shall be submitted. No submission shall be made, however, without a completed miner identification document containing the miner's name, address, social security number and place of employment.

REVIEW AND AVAILABILITY OF RECORDS

§ 37.70 Review of interpretations.

(a) Any miner who believes the interpretation for pneumoconiosis reported to him or her by MSHA is in error may file a written request with ALOSH that his or her roentgenogram be reevaluated. If the interpretation was based on agreement between an "A" reader and a "B" reader, ALOSH will obtain one or more additional interpretations by "B" readers as necessary to obtain agreement in accord with §37.52(b), and MSHA shall report the results to the miner together with any rights which may accrue to the miner in accordance with §37.7. If the reported interpretation was based on agreement between two (or more) "B" readers, the reading will be accepted as conclusive and the miner shall be so informed by MSHA.

(b) Any operator who is directed by MSHA to transfer a miner to a less dusty atmosphere based on the most recent examination made subsequent to August 1, 1978, may file a written request with ALOSH to review its findings. The standards set forth in paragraph (a) of this section apply and the operator and miner will be notified by MSHA whether the miner is entitled to the option to transfer.

§ 37.80 Availability of records.

(a) Medical information and roentgenograms on miners will be released by ALOSH only with the written consent from the miner, or if the miner is deceased, written consent from the

miner's widow, next of kin, or legal representative.

(b) To the extent authorized, roentgenograms will be made available for examination only at ALOSH.

Subpart—Autopsies

AUTHORITY: Sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 36 FR 8870, May 14, 1971, unless otherwise noted.

§ 37.200 Scope.

The provisions of this subpart set forth the conditions under which the Secretary will pay pathologists to obtain results of autopsies performed by them on miners.

§ 37.201 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Miner* means any individual who during his life was employed in any underground coal mine.

(c) *Pathologist* means

(1) A physician certified in anatomic pathology or pathology by the American Board of Pathology or the American Osteopathic Board of Pathology,

(2) A physician who possesses qualifications which are considered "Board of eligible" by the American Board of Pathology or American Osteopathic Board of Pathology, or

(3) An intern, resident, or other physician in a training program in pathology who performs the autopsy under the supervision of a pathologist as defined in paragraph (c) (1) or (2) of this section.

(d) *ALFORD* means the Appalachian Laboratory for Occupational Respiratory Diseases, Public Health Service, Department of Health and Human Services, Post Office Box 4257, Morgantown, WV 26505.

§ 37.202 Payment for autopsy.

(a) The Secretary will pay up to $200 to any pathologist who, after the effective date of the regulations in this part and with legal consent:

(1) Performs an autopsy on a miner in accordance with this subpart; and

(2) Submits the findings and other materials to ALFORD in accordance with this subpart within 180 calendar days after having performed the autopsy; and

(3) Receives no other specific payment, fee, or reimbursement in connection with the autopsy from the miner's widow, his family, his estate, or any other Federal agency.

(b) The Secretary will pay to any pathologist entitled to payment under paragraph (a) of this section and additional $10 if the pathologist can obtain and submits a good quality copy or original of a chest roentgenogram (posteroanterior view) made of the subject of the autopsy within 5 years prior to his death together with a copy of any interpretation made.

[35 FR 13206, Aug. 19, 1970, as amended at 38 FR 16353, June 22, 1973]

§ 37.203 Autopsy specifications.

(a) Every autopsy for which a claim for payment is submitted pursuant to this part:

(1) Shall be performed consistent with standard autopsy procedures such as those, for example, set forth in the "Autopsy Manual" prepared by the Armed Forces Institute of Pathology, July 1, 1960. (Technical Manual No. 8–300. NAVMED P–5065, Air Force Manual No. 160–19.) Copies of this document may be borrowed from ALFORD.

(2) Shall include:

(i) Gross and microscopic examination of the lungs, pulmonary pleura, and tracheobronchial lymph nodes;

(ii) Weights of the heart and each lung (these and all other measurements required under this subparagraph shall be in the metric system);

(iii) Circumference of each cardiac valve when opened;

(iv) Thickness of right and left ventricles; these measurements shall be made perpendicular to the ventricular surface and shall not include trabeculations or pericardial fat. The right ventricle shall be measured at a point midway between the tricuspid valve and the apex, and the left ventricle shall be measured directly above the insertion of the anterior papillary muscle;

(v) Size, number, consistency, location, description and other relevant details of all lesions of the lungs;

(vi) Level of the diaphragm;

(vii) From each type of suspected pneumoconiotic lesion, representative microscopic slides stained with hematoxylin eosin or other appropriate stain, and one formalin fixed, paraffin-impregnated block of tissue; a minimum of three stained slides and three blocks of tissue shall be submitted. When no such lesion is recognized, similar material shall be submitted from three separate areas of the lungs selected at random; a minimum of three stained slides and three formalin fixed, paraffin-impregnated blocks of tissue shall be submitted.

(b) Needle biopsy techniques shall not be used.

§ 37.204 Procedure for obtaining payment.

Every claim for payment under this subpart shall be submitted to ALFORD and shall include:

(a) An invoice (in duplicate) on the pathologist's letterhead or billhead indicating the date of autopsy, the amount of the claim and a signed statement that the pathologist is not receiving any other specific compensation for the autopsy from the miner's widow, his surviving next-of-kin, the estate of the miner, or any other source.

(b) Completed PHS Consent, Release and History Form (See Fig. 1). This form may be completed with the assistance of the pathologist, attending physician, family physician, or any other responsible person who can provide reliable information.

(c) Report of autopsy:

(1) The information, slides, and blocks of tissue required by this subpart.

(2) Clinical abstract of terminal illness and other data that the pathologist determines is relevant.

(3) Final summary, including final anatomical diagnoses, indicating presence or absence of simple and complicated pneumoconiosis, and correlation with clinical history if indicated.

FIGURE 1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE—NATIONAL COAL WORKERS' AUTOPSY STUDY

Consent, Release, and History Form Federal Coal Mine Health and Safety Act of 1969

I, _____, (Name) _____ (Relationship) of _____, (Name of deceased miner) do hereby authorize the performance of an autopsy (_____) (Limitation, if any, on autopsy) on said deceased. I understand that the report and certain tissues as necessary will be released to the United States Public Health Service and to _____ (Name of Physician securing autopsy)

I understand that any claims in regard to the deceased for which I may sign a general release of medical information will result in the release of the information from the Public Health Service. I further understand that I shall not make any payment for the autopsy.

Occupational and Medical History

1. Date of Birth of Deceased _____. (Month, Day, Year)
2. Social Security Number of Deceased _____.
3. Date and Place of Death _____, (Month, Day, Year) _____ (City, County, State).
4. Place of Last Mining Employment:
Name of Mine _____
Name of Mining Company _____
Mine Address _____
5. Last Job Title at Mine of Last Employment
(e.g., Continuous Miner Operator, motorman, foreman, etc.)
6. Job Title of Principal Mining Occupation (that job to which miner devoted the most number of years)
(e.g., Same as above)
7. Smoking History of Miner:
(a) Did he ever smoke cigarettes? Yes No _____
(b) If yes, for how many years?_____ Years.
(c) If yes, how many cigarettes per day did he smoke on the average?_____ (Number of) Cigarettes per day.
(d) Did he smoke cigarettes up until the time of his death? Yes _____ No _____
(e) If no to (d), for how long before he died had he not been smoking cigarettes?
8. Total Years in Surface and Underground Employment in Coal Mining, by State (If known) _____, (Years) _____ (State).
9. Total Years in *Underground* Coal Mining Employment, by State (If known) _____, (Years) _____ (State).

(Signature)

(Address)

(Date)

Interviewer:

PART 38—DISASTER ASSISTANCE FOR CRISIS COUNSELING AND TRAINING

AUTHORITY: Sec. 413, Pub. L. 93-288, The Disaster Relief Act of 1974, 88 Stat. 167, 42 U.S.C. 5183, EO 11795, 39 FR 25939, as amended by EO 11910, 41 FR 15681.

SOURCE: 41 FR 52052, Nov. 26, 1976, unless otherwise noted.

§38.1 Purpose; coordination.

(a) *Purpose.* This part establishes standards and procedures for the implementation of section 413 of Pub. L. 93-288, the Disaster Relief Act of 1974 (42 U.S.C. 5183) which authorizes the provision, either directly or through financial assistance to State or local agencies or private mental health organizations, of:

(1) Professional counseling services to victims of a major disaster in order to relieve mental health problems caused or aggravated by such a major disaster or its aftermath; and

(2) Training of disaster workers to provide or assist in providing those professional counseling services.

(b) *Coordination.* The Secretary, acting through the National Institute of Mental Health, will, as provided in 24 CFR 2205.51, carry out section 413 of the Act and this part in coordination with and under the general policy guidance of, the Administrator of the Federal Disaster Assistance Administration. Contracts and grants awarded under this part are subject to all applicable provisions of the Act and the implementing regulations promulgated by the Administrator (24 CFR part 2205).

§38.2 Definitions.

All terms not defined herein shall have the same meaning as given them in the Act. As used in this part:

(a) *Act* means the Disaster Relief Act of 1974 (42 U.S.C. 5121, *et seq.*).

(b) *Administrator* means the Administrator, Federal Disaster Assistance Administration (FDAA), Department of Housing and Urban Development, and any other person to whom he delegates the authority.

(c) *Contractor* means any public agency or private mental health organization which, pursuant to this part, contracts with the Secretary to provide professional mental health crisis counseling services or to provide mental health training for disaster workers.

(d) *Crisis* means the existence of any life situation resulting from a major disaster or its aftermath which so effects the emotional and mental equilibrium of a disaster victim that professional mental health counseling services should be provided to help preclude possible damaging physical or psychological effects.

(e) *Disaster workers* means mental health specialists such as psychiatrists, psychologists, psychiatric nurses, social workers, or qualified agents thereof.

(f) *Federal Coordinating Officer* means the person appointed by the Administrator to coordinate Federal assistance in a major disaster.

(g) *Governor* means the chief executive of a State.

(h) *Grantee* means any public agency or private nonprofit mental health organization which, pursuant to this part, is awarded a grant for the purpose of providing professional mental health crisis counseling services or mental health training for disaster workers.

(i) *Major disaster* means any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, drought, fire, explosion, or other catastrophe in any part of the United States which, in the determination of the President, causes damage of sufficient severity and magnitude to warrant major disaster assistance under the Act above and beyond emergency services by the Federal Government, to

Appendix F—ATS 1994 Spirometry Update

American Thoracic Society
MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

Standardization of Spirometry

1994 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 11, 1994

CONTENTS

The first American Thoracic Society (ATS) Statement on the Standardization of Spirometry was published 15 yr ago and was based on the Snowbird Workshop held in 1979 (1). This initial statement was updated in March 1987 (2) after 8 yr of practical experience with the initial recommendations. The state of the art of spirometry has continued to advance as a result of scientific studies that have provided additional data relating to performance of spirometry. The use of computers for spirometry measurement has become even more commonplace. New statements by the ATS (3) and the European Respiratory Society (4) also underscore the need to update the ATS statement on spirometry. This revision of the standards for spirometry reflects the changes in clinical emphasis and in available technology since the 1987 ATS spirometry update (2) was published. The changes in clinical emphasis and equipment include:

- The strong emphasis on the use of portable peak flow meters to monitor lung function in asthmatics by the National Heart, Lung, and Blood Institute's Asthma Education Program (5), the International Asthma Management Project (6), the British Thoracic Society (7), and others.
- The corresponding development of many new model peak flow monitoring devices, some purely mechanical and some electronic.
- A better understanding of the complexities of correcting spirometric values to BTPS conditions.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. *Members of the committee:* Robert O. Crapo, M.D., Chairman, John L. Hankinson, Ph.D., Charles Irvin, Ph.D., Neil R. MacIntyre, M.D., Karen Z. Voter, M.D., and Robert A. Wise, M.D. *Spirometry Subcommittee:* John L. Hankinson, Ph.D., Subcommittee Chairman, Charles Irvin, Ph.D., Robert A. Wise, M.D. *Invited Spirometry and Deco Workshop participants:* Brian Graham, Ph.D., Carl O'Donnell, Sc.D., Paolo Paoletti, M.D., Josep Roca, M.D., and Giovanni Viegi, M.D. *Corresponding members:* Margaret R. Becklake, M.D., A. Sonia Buist, M.D., Gary duMoulin, Ph.D., Robert L. Jensen, Ph.D., Albert Miller, M.D., and Andrea Rossi, M.D.

Am J Respir Crit Care Med Vol 152. pp 1107–1136, 1995

- A greater appreciation of the importance of the technicians and procedures in achieving good spirometric results.
- An increased concern about the risk of transmission of infectious diseases during pulmonary function testing.

We have responded to these changes by:

- Separating the standards for laboratory or diagnostic spirometers from those of devices designed to be used primarily as monitors.
- Adding BTPS testing to the testing of spirometers.
- Adding a section on performance of slow vital capacity.
- Strengthening and updating the procedural aspects of quality control, including an appendix with sample spirograms.
- Adding a section on hygiene and infection control.

A central goal of any guideline or standardization document is to improve performance and thus decrease the variability of laboratory testing. In 1979 (1), and again in 1987 (2), the perception was that the major source of variability was instrumentation. More recently, instrumentation has improved to a point where other sources of variability can be identified, in particular, procedural problems. In 1991, the ATS Statement on Lung Function Testing: Selection of Reference Values and Interpretation Strategies (3) stated: "The largest single source of within-subject variability is improper performance of the test." More recently, Enright and coworkers (8) have shown a positive impact of an extensive quality control program on spirometric results. As a consequence, there is an effort in the present statement to address issues of test performance and quality control.

The ATS statements on standardization of spirometry have had far-reaching effects on manufacturers and users of spirometers. In some cases, manufacturers have used the document as a minimum performance requirement document. We continue to be concerned with this approach and encourage manufacturers to seek excellence in design so that the state of the art for spirometers will *exceed* ATS recommendations. Some research protocols will necessitate even more stringent requirements than stated here.

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health. Like the simple measurement of blood pressure, it does not suffice in certain situations where more extensive testing is warranted. Spirometric results correlate well with morbidity and life expectancy. Spirometry is used to affect decisions about individual patients, including the nature of the defect, its severity, and the response to therapy. Table 1 lists some of the potential indications for spirometry.

Results from tests based on spirometric maneuvers can have an important effect on a person's lifestyle, standard of living, and future treatment (10). Similarly, accurate and precise spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate spirometers are used or less sensitive if imprecise spirometers are used (11).

Maximizing the clinical usefulness of spirometry depends on a number of steps, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps.

The first step is establishing equipment performance criteria. The Snowbird Workshop (1), 1987 Update (2), and this update give recommendations for equipment used for spirometry.

The second step in the process involves validation that the spirometer design meets the minimum recommendations through the testing of a representative device. Detailed methods for performing the validation testing are outlined later in this statement. The ATS makes equipment recommendations but does not act as a certifying agency to verify compliance with these standards. Spirometer users should carefully select equipment that meets the ATS recommendations to assure that spirometry testing can be done accurately. Before purchasing a spirometer, it is wise to: (1) ask the manufacturer to provide summary data that demonstrates that the device being considered meets or exceeds ATS recommendations, or (2) review results of spirometry testing from independent testing laboratories. This statement does not mandate testing by an independent laboratory. There are many calibrated computer-driven syringes available. When an independent laboratory is not used, manufacturers should make the testing protocol, the raw data, and the summary data available to potential customers for their review.

Even after spirometers have been found to meet ATS recommendations, they (like other mechanical, electrical, or computer equipment) must be routinely checked for performance quality.

TABLE 1

INDICATIONS FOR SPIROMETRY*

- Diagnostic
  - To evaluate symptoms, signs, or abnormal laboratory tests
    - —Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
    - —Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
    - —Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiograms
  - To measure the effect of disease on pulmonary function
  - To screen individuals at risk of having pulmonary diseases
    - —Smokers
    - —Individuals in occupations with exposures to injurious substances
    - —Some routine physical examinations
  - To assess preoperative risk
  - To assess prognosis (lung transplant, etc.)
  - To assess health status before enrollment in strenuous physical activity programs
- Monitoring
  - To assess therapeutic interventions
    - —Bronchodilator therapy
    - —Steroid treatment for asthma, interstitial lung disease, etc.
    - —Management of congestive heart failure
    - —Other (antibiotics in cystic fibrosis, etc.)
  - To describe the course of diseases affecting lung function
    - —Pulmonary diseases
      - Obstructive airways diseases
      - Interstitial lung diseases
    - —Cardiac diseases
      - Congestive heart failure
    - —Neuromuscular diseases
      - Guillain-Barre Syndrome
  - To monitor persons in occupations with exposure to inimical agents
  - To monitor for adverse reactions to drugs with known pulmonary toxicity
- Disability/Impairment Evaluations
  - To assess patients as part of a rehabilitation program
    - —Medical
    - —Industrial
    - —Vocational
  - To assess risks as part of an insurance evaluation
  - To assess individuals for legal reasons
    - —Social Security or other government compensation programs
    - —Personal injury lawsuits
    - —Others
- Public Health
  - Epidemiologic surveys
    - —Comparison of health status of populations living in different environments
    - —Validation of subjective complaints in occupational/environmental settings
  - Derivation of reference equations

* Adapted from reference 9.

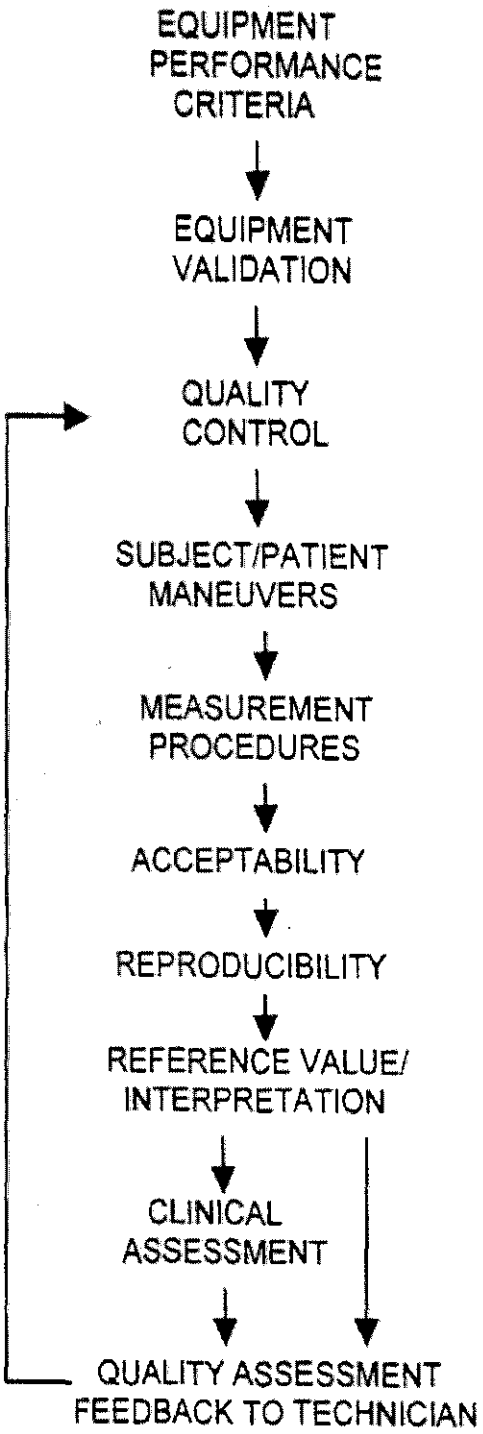


Figure 1. Spirometry standardization steps.

Recommendations for spirometer quality control have been developed by the ATS and are summarized in this statement.

Spirometry is an effort-dependent maneuver that requires understanding, coordination, and cooperation by the patient-subject, who must be carefully instructed. Thus, procedural recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers of adequate quality and then determine if these acceptable maneuvers are reproducible, implying that maximal effort has been achieved. Once spirometry maneuvers have been performed, data are either measured by hand or computer. Measurement procedures are included in this article to help assure that uniform methods are used and comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start-of-test" time (zero point) for measures such as FEV_1 and the criteria to determine the end of the expiratory maneuver. Instruments that provide feedback to the technician in the form of checks on the adequacy of the data are clearly desirable.

The interactions between technicians and subjects are crucial to obtaining adequate spirometry, since it is such an effort-dependent maneuver. Technicians must be trained and must maintain a high level of proficiency to assure optimal results.

The spirogram tracing must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test results are presented, as well as examples of unacceptable maneuvers (*see* APPENDIX A). After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. The ATS 1991 Statement on Lung Function Testing: Selection of Reference Values and Interpretative Strategies provides guidelines for selecting reference values and interpreting the results. Clinical assessment should be an integral part of spirometry. Results obtained from spirometry are only one part of the much more complex patient-care relationship or research study analysis. It is the responsibility of the laboratory director to provide adequate quality control procedures to assure that an attempt to meet these recommendations and criteria has been made.

In both the original ATS statement on spirometry and the 1987 update, a rationale was provided for each recommendation. Since many of these recommendations and their rationales have not changed since the original statements, the reader is referred to the 1987 update (2) for the rationales concerning less controversial recommendations.

DEFINITIONS

All terms and abbreviations used here are based on a report of the American College of Chest Physicians (ACCP)–ATS Joint Committee on Pulmonary Nomenclature (12).

Accuracy and precision are important terms in equipment recommendations and warrant some definition. Accuracy error is the systematic difference between the "true" and the measured value. The accuracy of a spirometer system depends on a number of factors, including linearity and frequency response of the system or processor, sensitivity to environmental conditions, calibration, and adequacy of correction factors. Its precision depends on the signal/noise ratio and on the resolution (i.e., the minimal detectable volume or flow). Precision error, usually denoted reproducibility, is the numerical difference between successive measurements (4). For example, if a volume spirometer's pen is not on zero but at 1 L, all volumes read directly from the graph would be overread by 1 L. The accuracy error would be 1 L, since the measured volume would read 3 L when the true volume is 2 L. However, the precision of the spirometer would remain unchanged, as the spirometer would consistently read 3 L each time 2 L is injected into the spirometer. For some applications, e.g., peak expiratory flow (PEF) monitoring, precision is more important than accuracy.

In several sections of this document, the terms "open circuit" and "closed circuit" technique are used. The term "open circuit" spirometry refers to the method of conducting spirometry where the subject takes a full inspiration before inserting the mouthpiece to perform the test. In this approach, the subject does not inhale from the spirometer or potentially contaminated flow sensor. The term "closed circuit" spirometry refers to the method of conducting spirometry where the subject is attached to the mouthpiece before the inspiration is begun, and often several tidal breaths are obtained. In this approach, the subject does inhale from the spirometer. There are advantages and disadvantages to both of these approaches and both are recommended procedures. For example, an advantage of the closed circuit technique is that it allows measurement of expiratory reserve volume (ERV), tidal volume (TV), and inspiratory flows.

Previous recommendations (1, 2) treated all spirometers alike whether used for clinical, diagnostic, or epidemiologic purposes. However, a new class of device has been added for monitoring purposes. Monitoring devices (portable peak flow meters, etc.) have separate recommendations from diagnostic spirometers for the recorder/display requirements as well as the accuracy requirements. In addition, precision requirements have been added for monitoring devices. Recommendations concerning monitoring devices are identified in this statement by the notation, "Monitoring." We do *not* recommend the use of monitoring devices for diagnostic purposes in the traditional diagnostic setting where one is comparing a measured value with a reference value. In this setting, monitoring instruments are likely to be inadequate because: (*1*) they may be less accurate than diagnostic instruments; (*2*) they usually cannot be calibrated or checked to assure their performance; (*3*) their graphical displays may be missing or inadequate to allow proper evaluation of the subject's effort and overall test quality; and (*4*) current PEF standards of ± 10% allow models of instruments to vary by up to 20%, adding variability to reference values derived when a monitoring instrument is used. However, monitoring instruments may be useful in diagnosing excessive variability in spirometric parameters because they tend to have excellent precision.

EQUIPMENT RECOMMENDATIONS

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that are comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometry system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. Errors at any step in the process can affect the accuracy of the results. For example, if the BTPS correction factor is in error, an accurate, uncorrected FVC will be corrupted when the factor is applied.

Recommendations are first provided for diagnostic spirometers, followed by recommendations for monitoring devices under the subheading, "Monitoring." For example, the equipment recommendations for diagnostic spirometry are summarized in Table 2 and for monitoring devices in Table 3. Spirometers are not required to measure all the following parameters but must meet the recommendations for those parameters that are measured. Accuracy and precision recommendations apply over the entire volume range of the instrument.

TABLE 2

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY*

Test	Range/Accuracy (BTPS)	Flow Range (L/s)	Time (s)	Resistance and Back Pressure	Test Signal
VC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	30		3-L Cal Syringe
FVC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	15	Less than 1.5 cm H_2O/L/s	24 standard waveforms 3-L Cal Syringe
FEV_t	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	1	Less than 1.5 cm H_2O/L/s	24 standard waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ± 10% of reading or ± 0.400 L/s, whichever is greater Precision: ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 14		Same as FEV_1	26 flow standard waveforms
$FEF_{25-75\%}$	7.0 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater	± 14	15	Same as FEV_1	24 standard waveforms
V	± 14 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 14	15	Same as FEV_1	Proof from manufacturer
MVV	250 L/min at TV of 2 L within ± 10% of reading or ± 15 L/min, whichever is greater	± 14 ± 3%	12 to 15	Pressure less than ± 10 cm H_2O at 2-L TV at 2.0 Hz	Sine wave pump

* Unless specifically stated, precision requirements are the same as the accuracy requirements.

Recommendation: Vital Capacity (VC)

VC = The maximal volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. This was previously called the "slow" vital capacity and has been better described as the "relaxed vital capacity" (13). The VC is expressed in liters (BTPS). BTPS is body conditions: normal body temperature (37° C), ambient pressure, saturated with water vapor. When the rebreathing technique is used, an oxygen supply may be provided and carbon dioxide absorbed to account for oxygen consumption and the production of carbon dioxide. In this case, the oxygen supply must account for the total oxygen consumed, maintaining the volume constant at functional residual capacity. If this is not done properly, an incorrect VC could be obtained. Because of this potential error, the rebreathing technique with the absorption of carbon dioxide is discouraged as a technique when only VC is to be measured.

Rationale. In some subjects, a slow or relaxed vital capacity provides a more accurate determination of the vital capacity than those obtained with a forced exhalation. Forced expiratory volumes are usually lower than those obtained with a slow exhalation in subjects with airways obstruction and in older subjects. With severe airways obstruction, VC values may be larger than FVC values by as much as 1 L.

TABLE 3

MINIMAL RECOMMENDATIONS FOR MONITORING DEVICES

Requirement	FVC & FEV_t (BTPS)	PEF (BTPS)
Range	High: 0.50 to 8 L Low: 0.5 to 6 L	High: 100 L/min to ≥ 700 L/min but ≤ 850 L/min Low: 60 L/min to ≥ 275 L/min but ≤ 400 L/min
Accuracy	± 5% of reading or ± 0.100 L, whichever is greater	± 10% of reading or ± 20 L/min, whichever is greater
Precision	± 3% of reading or ± 0.050 L, whichever is greater	Intradevice: ≤ 5% of reading or ≤ 10 L/min, whichever is greater Interdevice: ≤ 10% of reading or ≤ 20 L/min, whichever is greater
Linearity	Within 3% over range	Within 5% over range
Graduations	Constant over entire range High: 0.100 L Low: 0.050 L	Constant over entire range High: 20 L/min Low: 10 L/min
Resolution	High: 0.050 L Low: 0.025 L	High: 10 L/min Low: 5 L/min
Resistance	Less than 2.5 cm H_2O/L/s, from zero to 14 L/s	Less than 2.5 cm H_2O/L/s, from zero to 14 L/s
Minimal detectable volume	0.030 L	–
Test Signal	24 standard volume-time waveforms	26 standard flow-time waveforms

High = high range and low = low range devices.

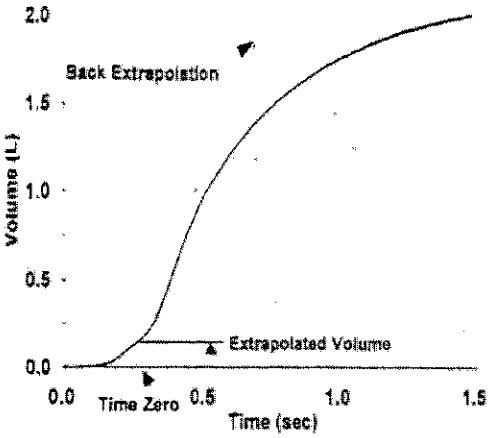


Figure 2. Typical subject waveform of a volume–time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at least* 30 s. Spirometers must be capable of measuring volumes of *at least* 8 L (BTPS) with flows between zero and 14 L/s with a volume accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater.

Recommendation: Forced Vital Capacity (FVC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in liters (BTPS).

The diagnostic spirometer must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The 8-L range requirement applies to newly manufactured instruments; existing spirometers with a 7-L range may continue to be used. The spirometer must be capable of accumulating volume for *at least* 15 s, although longer times are recommended.

Monitoring. Monitoring devices must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. The device must be capable of accumulating volume for *at least* 15 s.

Recommendation: Timed Forced Expiratory Volume (FEV_t)

FEV_t = The volume of air exhaled in the specified time during the performance of the FVC, e.g., FEV_1 for the volume of air exhaled during the first second of FVC, expressed in liters (BTPS).

Measuring FEV_t requires a spirometer capable of measuring volumes of *at least* 8 L. The spirometer must measure FEV_t within an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The start-of-test for purposes of timing *must be* determined by the back extrapolation method (1, 14, 15) or a method shown to be equivalent (Figure 2). For manual measurements, the back extrapolation method traces back from the steepest slope on the volume–time curve (Figure 2) (15, 16). For computer methods of back extrapolation, we recommend using the largest slope averaged over an 80-ms period (17). The total resistance to airflow at 14.0 L/s must be less than 1.5 cm H_2O/L/s. The total resistance must be measured including any tubing, valves, pre-filter, etc., that may be inserted between the subject and the spirometer. Since some devices may exhibit changes in resistance due to water vapor condensation, resistance requirements must be met under BTPS conditions when up to eight successive FVC maneuvers are performed in a 10-min period.

Monitoring. The monitoring device must be capable of measuring FEV_t up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices for FEV_t must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. Resistance should be less than 2.5 cm H_2O/L/s and the start-of-test requirement is the same as for diagnostic spirometry.

Recommendation: PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/second (BTPS).

Measuring PEF requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 0.300 L/s, whichever is greater. Intra-instrument precision must be less than 5% of reading or 0.150 L/s, whichever is greater. Interdevice precision must be less than 10% or 0.300 L/s, whichever is greater.

The following or an equivalent method can be used in the determination of FEF_{max} or PEF for volume–time curves. However, the method used to derive PEF may depend on the measuring instrument (18), and the final determination of compliance should be determined through testing using the standard waveforms (26 flow–time waveforms, APPENDIX D), with PEF derived from the flow–time waveform (Table D1, column 2).

Determination of PEF can be performed from the volume–time data by using a parabolic curve-fitting algorithm, which smooths the data using a least squares parabolic fit to a 40- or 80-ms segment (np = 2 or 4) of the volume–time curve, or:

$$\text{flow}(n) = \frac{\sum_{j=-np}^{np} j \cdot \text{vol}(n+j)}{2 \cdot h \cdot \sum_{j=1}^{np} j \cdot j} \qquad \text{PEF} = \text{Max (flow)}$$

where flow = an array of flow values from start to end of test; n = index of current flow data point (n = [np − 1] to index value of end of test); vol = an array of volume values; j = an index value as indicated in the equation; h = the time between samples (0.01 s in this example); np = the number of data points (for a 40-ms segment, np = 2 and for an 80-ms segment, np = 4); and PEF is the maximum value observed in the array flow.

Rationale. Using the 26 flow–time waveforms to define PEF is a change from the ATS 1987 Update. The PEFs for the 24 standard volume–time waveforms and the FEF_{max} described in the 1987 ATS Spirometry Update used the above algorithm with an 80-ms interval. Manufacturers, through the use of mechanical simulators and the 24 standard volume–time waveforms, have been implementing this or equivalent methods through their attempts to derive PEFs similar to those defined by the 24 standard volume–time waveforms.

In addition, the National Asthma Education Program (NAEP) (5) has adopted ATS standard volume–time waveform number 24 as their standard for portable PEF meters. Hankinson and Crapo (18) have shown that reducing the time interval in the above equation from 80 to 40 ms results in as much as an 8% higher PEF for two of the 24 standard volume–time waveforms and a

5% higher PEF value for waveform number 24. Regardless of this apparent change, PEF is a flow parameter and therefore should be defined based on a flow–time waveform rather than a volume–time waveform (i.e., waveform number 24). The final determination of compliance should be determined through testing using the standard 26 flow–time waveforms (APPENDIX D) and the PEF derived from the flow–time curve (Table D1, column 2). This approach allows all of an instrument's characteristics to be considered, rather than only the PEF computational algorithm. Because PEF is more variable than FVC and FEV_1 and because of the confusion surrounding PEF definition, a relatively large ± 10% accuracy requirement was allowed.

Recommendation (Monitoring): PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/minute (BTPS).

Monitoring PEF also requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz and a resistance less than 2.5 cm H_2O/L/s with flows up to 14 L/s. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 20 L/min, whichever is greater, with PEFs between 60 to 400 L/min for children and from 100 to 850 L/min for adults. The lower limit range of the instrument must be less than or equal to 60 L/min for children and 100 L/min for adults. The upper limit range must be greater than or equal to 275 L/min but less than 400/L min for children and greater than or equal to 700 L/min but less than 850 L/min for adults. If manual reading of the instrument is used, the reader must be able to resolve at least 5 L/min for low range (children) and 10 L/min for high range (adults) (marked PEF intervals [graduations] no greater than 10 L/min for low range and 20 L/min for high range). Intra-instrument precision must be less than or equal to 5% of reading or 10 L/min, whichever is greater. Interdevice precision must be less than 10% or 20 L/min, whichever is greater. Data on the instrument's life span and durability must be provided by the manufacturer, specified as the typical life span over which the instrument will satisfy the requirements of this section.

In addition to the above requirements, PEF measuring devices must also provide a method of reporting values at BTPS. For portable PEF meters, BTPS correction may be accomplished by limiting the environmental operational range for the instrument in terms of barometric pressure (altitude) and ambient temperature. Portable PEF meters must meet the accuracy and precision requirements above, given the range of environmental conditions encountered with typical use. A 10% accuracy requirement, higher than the 5% for other flows, is recommended to allow for potential BTPS correction complications associated with PEF measurements. Besides providing a method of correcting PEF values to BTPS, the instrument's manufacturer must also provide a correction for the effects of altitude or other environmental conditions as appropriate.

A package insert must be provided with each portable PEF meter containing *at least*: (*1*) clear instructions (with illustrations) for use of the instrument in simple terms that are understood by the general public; (*2*) instructions concerning maintenance of the instrument and methods to recognize when it is malfunctioning; and (*3*) appropriate actions to be taken when PEF readings change appreciably (i.e., whom to contact).

Rationale. Concerning the requirement of a flat frequency response up to 12 Hz, Lemen and coworkers (19) have shown that the mean highest frequency (HF) with significant amplitude content was 5.06 Hz in healthy individuals and 6.4 Hz in patients and smokers. They concluded that flow measuring devices should have a frequency response that is flat up to 12 Hz. Peslin and coworkers (20) found a slightly higher HF of about 10 Hz in healthy males and 7.5 Hz in female subjects. In addition, current mechanical waveform-generating equipment generally cannot accurately produce waveforms with frequency content above 12 Hz. The accuracy recommendation is less stringent for PEF than for the FVC and FEV_1 (10% versus 5%) because of the higher within- and between-subject variabilities associated with PEF measurements and because of testing instrument limitations. The PEF instrument precision and intra-instrument variability recommendations are lower (5%) than the accuracy and inter-instrument variability requirements (10%) because of the need for low instrument variability in the routine use of PEF meters for serial measurements. In addition, several studies have shown PEF meters to be much more precise than accurate (21–23). These recommendations are also similar to those of the NAEP (5). The range recommendations are made with the understanding that PEF measurements are often made using portable PEF meters. With these meters, reading resolution (number of graduations) must be balanced against the range of the meter (upper and lower meter limits). Therefore, different instrument ranges for children and adults are appropriate. The range recommendations for children are not intended to preclude the use of an instrument with adult ranges if the instrument meets the resolution requirements (ease of reading) for children.

An instrument's life span and durability are difficult to determine and will be specific to an instrument. However, portable peak flowmeters are often used for extended periods of time. Therefore, the instrument manufacturer must provide information on the typical life span of their instrument as well as cleaning and other maintenance instructions. The package insert requirements recommended by the NAEP (5) are similar to those recommended in this statement.

Recommendation: $FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal mid-expiratory flow (MMEF), expressed in liters/second (BTPS).

The $FEF_{25-75\%}$ must be measured with an accuracy of *at least* ± 5% of reading or ± 0.200 L/s, whichever is greater, over a range of up to 7 L/s. The $FEF_{25-75\%}$ must be measured on a system that meets diagnostic FVC recommendations.

Recommendation: Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow (except for PEF), expressed in liters/second (BTPS).

Flow may be measured electronically or manually from a flow–volume display with adequate size for hand measuring. Where flow–volume loops or other uses of flow are made, with flow in the range of −14 to 14 L/s, the flow must be measurable to within ± 5% of reading or ± 0.200 L/s, whichever is greater.

Recommendation: Forced Expiratory Time (FET%)

FET% = Time from the back-extrapolated "time zero" until a specified percentage of a maneuver's FVC is exhaled, expressed in seconds. For example, FET95% would be the time required to reach 95% of a maneuver's FVC. See APPENDIX A for FET% examples. FET100% would be defined as the time required to reach the FVC or the time at which the volume was observed to be at its highest level. For maneuver quality assessment purposes, the reporting of the FET99% (24) or FET100% is encouraged but not mandated. Also, the FET25–75% (mid-expiratory time) may be a useful indicator of diminished flow when VC is decreased and may be less dependent on body or lung size than other flow parameters (25).

Recommendation: Forced Inspiratory Vital Capacity Maneuvers

These maneuvers are inspiratory vital capacity maneuvers per-

formed with maximally forced effort from a position of maximal expiration to a position of maximal inspiration. Both volume and flow parameters are measured, which roughly correspond (except for direction) to those from the FVC maneuver. Volume measurements are expressed in liters (BTPS), flow measurements in liters/second (BTPS).

Rationale. Forced inspiratory maneuvers are useful in diagnosing and monitoring upper airway obstruction. They are usually performed either preceding or following the FVC maneuver but may be performed separately. Elderly or ill patients often have difficulty performing forced inspiratory and expiratory maneuvers as part of the same effort. Forced inspiratory maneuvers require the use of one of the closed circuit techniques.

For measurements of forced inspiratory spirometric parameters diagnostic spirometers must meet the corresponding range, accuracy, and precision recommendations specified for diagnostic spirometry systems (Table 2).

Recommendation: Maximal Voluntary Ventilation (MVV)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory efforts, expressed in liters/minute (BTPS).

When a spirometer is used for measuring MVV, it must have an amplitude-frequency response that is flat within ± 10% from zero to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording must be no less than 12 s nor more than 15 s (26). The indicated time must be accurate to within ± 3%. The MVV must be measured with an accuracy of ± 10% of reading or ± 15 L/min, whichever is greater.

General Background: Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are *required* and are used for:

1. Diagnostic function—when waveforms are to be used for quality control or review of the forced expiratory maneuver to determine if the maneuver was performed properly, so that unacceptable maneuvers can be eliminated.
2. Validation function—when waveforms are to be used to validate the spirometer system hardware and software for accuracy and reliability through the use of manual measurements (for example, measurement of FEV_1 using back extrapolation by comparing computer- and manually determined FEV_1).
3. Manual measurement function—when waveforms are to be manually measured for spirometric parameters (FVC, FEV_1, etc.) in the absence or failure of a computer.

With the continued advances in computer technology, there are many different ways to display and record spirometric waveforms. The committee continues to encourage use of computer technology.

Paper recorder requirements are the same regardless of the purpose, diagnostic, validation, or manual measurement. If no paper recorder or printer is available, then proof of validation of the accuracy and stability of the spirometer by an independent laboratory *must* be provided by the manufacturer. For these computer methods, any new software releases *must* also be validated.

Recommendation: Display of VC Maneuver

Either "open" or "closed" circuit technique may be used to measure the VC maneuver. Although the open circuit technique may be preferred because of hygiene concerns, this technique does not allow the monitoring (display) of the inhalation to TLC and therefore is less than optimum. Regardless of whether the open or closed circuit technique is used, a display of the entire VC maneuver must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. Subjects with airways obstruction usually exhibit different shaped curves at the end of their expiratory maneuver—a slope showing the nonhomogeneous emptying of lung units. Some patients with severe airways obstruction are not able to return to the level of FRC due to gas trapping (*see* APPENDIX A, VC maneuvers). In addition, important differences between inspiratory (IVC) and expiratory (EVC) maneuvers may be observed in patients with airways obstruction (27). For systems using a closed circuit with carbon dioxide absorption, a volume–time display is needed to verify baseline end-expiratory level (functional residual capacity or FRC). The graph should indicate the starting volume to evaluate the correct positioning of FRC.

Recommendation: Display of FVC Maneuver

Displays using flow versus volume instead of volume versus time expand the initial portions (first 1–2 s) of the forced vital capacity maneuver. Since this portion of the maneuver, particularly the peak expiratory flow, is correlated with the pleural pressure during the maneuver, the flow–volume display is useful to assess the magnitude of effort during the initial portions of the maneuver. Overlaying a series of flow–volume curves registered at apparent TLC (maximal inhalation, which may not be true TLC) is helpful in detecting a submaximal effort that may result in a large though nonreproducible FEV_1 as a consequence of negative effort dependence (28).

Unlike the flow–volume curve display, display of the FVC maneuver as a volume–time graph expands the terminal portions of the maneuver. Therefore, the volume–time display is useful in assessing the duration of effort and whether a plateau is achieved. Where spirometry may need to be reviewed by independent agencies, a volume–time tracing of sufficient size allows independent measurement and calculation of parameters from the FVC maneuvers. Overlaying a series of volume–time curves aligned at back-extrapolated time zero or flow–volume curves aligned at TLC is useful in evaluating reproducibility and submaximal efforts. For optimal quality control, both flow–volume and volume–time displays are useful and strongly encouraged. See APPENDIX A for illustrations of volume–time and flow–volume displays.

Recommendation: VC and FVC Maneuver Volume and Time Scales

Volume scale: When a volume–time curve is plotted or displayed, the volume scale must be *at least*: 10 mm/L (BTPS).

Time scale: *at least* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when manual measurements are to be made (1, 29, 30). When the volume–time plot is used in conjunction with a flow–volume curve (both display methods are provided for interpretations and no hand-measurements are performed), the time scale requirement is reduced to 1 cm/s from the usually required minimum of 2 cm/s. This exception is allowed because, in these circumstances, the flow–volume curve can provide the means for quality assessment during the initial portion of the FVC maneuver. The volume–time curve can be used to evaluate the terminal portion of the FVC maneuver, and the time scale is less critical. For display of the slow VC, the volume scale may also be reduced to 1 cm/L and the time scale to 0.5 cm/s.

Recommendation: Flow–Volume Curves

When a flow–volume curve is plotted or displayed, exhaled flow must be plotted upwards and exhaled volume towards the right.

TABLE 4

MINIMUM REQUIRED SCALE FACTORS FOR TIME, VOLUME, AND FLOW GRAPHICS

Parameter	Resolution Required	Scale Factor
Volume	0.025 L	10 mm/L
Flow	0.100 L/s	5 mm/L/s
Time	0.20 s	2 cm/s

A 2:1 ratio must be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales must be *at least* as shown in Table 4.

Rationale. It was the committee's unanimous opinion that the previous diagnostic recorder requirements of 5 mm/L and 1 cm/s have proven inadequate for judging the quality of an expiratory effort, e.g., terminal events are not detectable (APPENDIX A). For certain applications (for example, for disability determination and legal cases), diagnostic size displays are clearly *not* adequate (26, 30). The U.S. Cotton Dust standard requires ". . . tracings must be stored and available for recall and must be of sufficient size that manual measurements may be made . . ." (31). Also, users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

Recommendation: Correction to BTPS

This statement recommends that diagnostic spirometric studies not be conducted with ambient temperatures less than 17° C or more than 40° C. In part, the rationale for this recommendation is based on problems with finite cooling times of gases in volume-type spirometers (32–34) and the problems of estimating BTPS correction factors for flow devices (35–37). When a subject performs an FVC maneuver, the air leaving the lungs and entering the spirometer is at approximately 33 to 35° C (38, 39) and is saturated with water vapor. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. However, this is not always the case, and an error in FEV can occur due to the incorrect assumption of instantaneous cooling of the air. For capillary and screen pneumotachometers, the gain is dependent on gas viscosity and increases with increasing temperature. Therefore, a different correction factor is needed between patients and a calibrating syringe and between inspiratory and expiratory maneuvers. In addition, the assumption is usually made that no cooling of the air occurs as the air passes through the flow sensor. This may not be the case, particularly with unheated flow sensors (35). If the expired gas is assumed to be BTPS, an error of about 1% will result. The error will increase if the flow sensor is located further from the mouth and more cooling occurs. In addition, water condensation within or on the surface of a flow sensor may alter its calibration. Depending on environmental temperature, the BTPS correction factor may be as large as 10%. Therefore, the method used to calculate or estimate the BTPS factor can potentially introduce significant errors by the application of an erroneous BTPS correction factor.

Changes in spirometer temperature can be a source of variability; therefore, spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. Johnson and colleagues (40) found that if ambient temperature was used in BTPS correction and applied to all maneuvers, FEV_1 and FVC measurement errors of up to 6% may occur. When using volume spirometers, they recommend that the temperature of air inside the spirometer should be measured accurately during each breathing maneuver.

Recommendation (Monitoring): Correction to BTPS

For operating simplicity, monitoring devices may use one BTPS correction factor for a range of barometric pressures (altitude) and environmental temperatures. However, the use of a single BTPS correction factor or direct readings at BTPS does not eliminate the requirement to meet the accuracy specifications under BTPS conditions. Therefore, manufacturers must provide appropriate labeling concerning the environmental conditions (ambient temperature and pressure) under which their device will meet the accuracy requirements. If necessary or appropriate, the manufacturer may provide several BTPS correction factors to meet the accuracy requirements over a range of environmental conditions (altitude and temperature).

EQUIPMENT VALIDATION

Recommendation: FVC Validation

The diversity of FVC maneuvers encountered in clinical practice are currently best simulated by the use of the 24 standard waveforms developed by Hankinson and Gardner (17, 41). These waveforms can be used to drive a computer-controlled mechanical syringe or its equivalent for testing actual hardware and software (42, 43) or they can be put into a system in digital form to evaluate *only* the software. It is strongly recommended that spirometry systems be evaluated using a computer-driven mechanical syringe or its equivalent and that the digital forms only be used for evaluating changes in software. APPENDIX C shows the measured values for each of the 24 standard waveforms. The American Thoracic Society also provides these waveforms on floppy disks for an IBM-PC.* Appropriate corrections for using gas at ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations. In addition, precision criteria have been added, and testing of spirometry systems using heated and humidified test gas is recommended.

The accuracy validation limits (tolerance for simulator systems is included in these limits) for volume are: volume (FVC, FEV_t) ± 3.5% of reading or ± 0.070 L, whichever is greater; and average flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range is expanded from the earlier ATS spirometry recommendation to allow for errors associated with mechanical syringes (42). The precision validation limits are: volume (FVC and FEV_1) 3.5% (range percent) or 0.100 L, whichever is greater; and flow ($FEF_{25-75\%}$) 5.5% or 0.250 L/s, whichever is greater. Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and FEV_1 and ± 0.100 L/s for $FEF_{25-75\%}$.

Rationale. Testing of spirometry systems using heated and humidified test gas has been added to the validation criteria because of potential problems associated with BTPS correction (32–37). See APPENDIX B for further details.

Recommendation: PEF Validation

PEF instrument designs must be validated using a mechanically driven syringe or its equivalent, using the flow–time waveforms described in APPENDIX D. These waveforms are available on digital media from the ATS. In addition, the mechanically driven syringe must be validated (APPENDIX B) to ensure that it accurately produces these waveforms and corresponding PEFs within ± 2% of reading. The flow–time waveforms in APPENDIX D were chosen to represent a range of peak flows and flow–time signals with various times-to-PEF (time required to go from 0.200 L/s to PEF). The accuracy validation limit for PEF is ± 12% of reading or ± 25 L/min, whichever is greater.

* Available from the American Thoracic Society.

The precision (range deviation) validation limit for PEF is 6% or 15 L/min, whichever is greater.

Rationale. The NAEP (5) recommended the use of a mechanically driven syringe to test and validate the accuracy of peak flow measuring instruments and to assess intra- and inter-device precision. Their recommendations included the use of ATS waveform 24 with various multipliers to achieve different PEFs. One problem with using only waveform 24 is a lack of variability in the shape or rise-time in the waveforms used to test PEF meters. Therefore, the use of several waveforms in the testing and validation of PEF meters to provide a range of PEFs and times-to-PEF (rise-times) is recommended. The waveforms in APPENDIX D are flow-time waveforms and, therefore, the definition of peak flow obtained from these waveforms is simple to derive. In addition, a volume-time curve for use by the mechanically driven syringe can be obtained from a flow-time curve by simply summing the flow-time values (integrating the flow signal).

The accuracy of the mechanically driven syringe for PEF, ± 2% of reading, was chosen based on current technical feasibility. Current technology of mechanically driven syringes is not sufficient to provide greater accuracies. This is due to the dynamic aspect of peak flow—high frequency content and PEF occurs at a point in the flow-time signal where the acceleration is changing, resulting in potential "overshoot" by a mechanical syringe. In addition, insufficient data are available concerning the accuracy of PEF meters using waveforms with higher frequency content (shorter times-to-PEF). Additional detailed information concerning spirometer testing procedures is contained in APPENDICES B, C, and D.

Recommendation: MVV Validation

When tested with a pump producing a sinusoidal waveform, the accuracy validation limits of the spirometer used for MVV for flows up to 250 L/min, produced with stroke volumes up to 2 L, are ± 10.5% of reading or ± 20 L/min, whichever is greater. During the testing, the pressure at the mouthpiece must not exceed ± 10 cm H_2O. For volume spirometers, these requirements apply throughout their volume range.

QUALITY CONTROL

Routine equipment preventive maintenance—cleaning, calibration checks, verification, and quality control—is essential to assure accurate spirometry results (44). A spirometry procedure manual is an important base for a quality assurance program. The manual should contain a quality control plan, guidelines for ordering spirometry, guidelines for performing spirometry, and guidelines for reporting spirometry results. See the document, "ATS Quality Assurance for Pulmonary Laboratories," for more details (44).

Recommendation: Technician's Role in Quality Control

Quality control is important to ensure that the laboratory is consistently meeting appropriate standards. In any quality control program, an important element is a procedures manual containing: calibration procedures, test performance procedures, calculations, criteria, reference values source, and action to be taken when "panic" values are observed. A notebook should be maintained that documents daily instrument calibration as well as problems encountered with the system, corrective action required, and system hardware and software upgrades. Records of anomalous events involving either patients/subjects or the technician should be documented, with the results of subsequent evaluation and responses to the event. The technician should also maintain records of continuing education and the results of evaluation and feedback provided by the medical director. Perhaps the most important component in successful spirometry is a well-motivated, enthusiastic technician. A recent study has clearly demonstrated the importance of a quality control program with feedback to technicians in obtaining adequate spirometry results (8). A quality control program that continuously monitors technician performance is critical to the collection of high-quality spirometry data. Feedback to the technicians concerning their performance should be provided on a routine basis. This feedback should include, at a minimum: (*1*) information concerning the nature and extent of unacceptable FVC maneuvers and non-reproducible tests; (*2*) corrective action the technician can take to improve the quality and number of acceptable maneuvers; and (*3*) recognition for superior performance by the technician in obtaining good maneuvers from challenging patients/subjects.

Manufacturers are encouraged to include quality control aids in their software packages for spirometers. For example, a calibration logging program may be provided that stores the time and results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

Recommendation: Hygiene and Infection Control

This section has been reviewed by the Microbiology Assembly.

The major goal of infection control is to prevent infection transmission to patients/subjects and staff during pulmonary function testing. Two major types of infection transmission are:

1. Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
2. Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.

Prevention:

1. Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing should always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have been reviewed by Tablan and coworkers (45).
2. To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves, and manifolds should be disinfected or sterilized regularly. Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or discarded (i.e., disposable mouthpieces, nose clips, etc.) after each use. The optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established. However, any equipment surface with visible condensation from expired air should be disinfected or sterilized before reuse. Since the use of cold sterilizing agents is not without risk, laboratory staff should take care to follow all manufacturer's recommendations regarding proper handling of these products.
3. Between subjects, spirometers using the closed circuit tech-

nique should be flushed at least five times over the entire volume range to facilitate clearance of droplet nuclei. Also, the breathing tube and mouthpiece should be decontaminated between patients. When the open circuit technique is used, only that portion of the circuit through which rebreathing occurs needs to be decontaminated between patients. For example, when a pneumotachometer system is used, either inspiration from the device should be avoided or the resistive element and tubing should be decontaminated between subjects. A disposable sensor is another alternative. When an open circuit technique is used for measurement of only the forced exhalation, without inspiration from the measuring system (either volume- or flow-type spirometers), only the mouthpiece needs to be changed or decontaminated between subjects.

It should be noted that disassembling, cleaning, and/or sensor replacement requires recalibration. If patients do not inspire through the device, there is the disadvantage that test acceptability may be more difficult to assess in the absence of an inspiratory tracing. On the other hand, disassembly, cleaning, or sensor replacement has the disadvantage that recalibration is required. Alternatively, in-line filters may be effective in preventing equipment contamination (46). However, if an in-line filter is used, the measuring system should meet the minimal recommendations for range, accuracy, flow resistance, and back pressure with the filter installed. The influence of commercially available in-line filters on forced expiratory measures, such as the FVC and FEV_1, has not been well characterized.

4. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, should be used to prevent disease transmission.
5. Special precautions should be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves should be decontaminated before reuse and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.
6. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (*a*) Reserving equipment for the sole purpose of testing infected patients; (*b*) testing patients at the end of the day to allow time for spirometer disassembly and disinfection; and (*c*) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
7. In the absence of evidence for infection transmission during pulmonary function testing, the regular use of in-line filters is not mandated when the precautions described above are followed. However, some spirometric equipment, particularly those incorporated in multi-purpose testing systems, employ valve manifolds that are situated proximal to breathing tubes. These valving arrangements provide internal surfaces on which deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition, presumably as aerosol nuclei on spirometer surfaces (46), their use may be indicated in this setting. The economy of using in-line filters compared with tubing and valve changes depends on the PFT equipment in use. The extent to which measures such as maximum expiratory flow or other instantaneous flows are influenced by the use of in-line filters is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices, such as the forced vital capacity and the FEV_1 (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and FEV_1 (e.g., PEF) should allow for the possibility that the filter might affect spirometer performance. The mechanical characteristics of the combined measuring device and filter should meet the minimal recommendations outlined in Table 2. Furthermore, if in-line filters are used, it is recommended that equipment be calibrated with the filter installed. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment.
8. Manufacturers of spirometric equipment are encouraged to design instrumentation that can be easily disassembled for disinfection.

Rationale. Spirometric equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing (PFT). Organisms from the respiratory tract of test subjects can be recovered from PFT mouthpieces and from the proximal surfaces of tubing through which the subjects breathe (48, 49). There is one case report of a tuberculosis skin-test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (50). Likewise, there is circumstantial evidence that contaminated PFT equipment may be implicated in the increasing prevalence of *Pseudomonas* infections among cystic fibrosis patients at one center (51). There is some evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers (52). Finally, it is well documented that community hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms (53–55). Thus, the potential exists for both patients/subjects and health care workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients. This does not seem to pose an appreciable threat to patients/subjects with competent immune systems.

It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens. Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade, has led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection. There is no direct evidence that routine spirometry testing poses an increased risk of infection to immunocompromised patients.

Recommendation: Equipment Quality Control

The recommendations that follow are primarily aimed at diagnostic devices.

Attention to good equipment quality control and calibration is an important part of good laboratory practice. Log books of calibration results must be maintained. Documentation of repairs or other alterations that return the equipment to acceptable operation need to be maintained. Dates of computer software and hardware updates or changes must also be maintained.

Volume. The spirometer's ability to accurately measure volume must be checked *at least* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other studies in which a large number of subject maneuvers are done, the equipment's calibration must be checked daily, before testing, and every 4 h during use (44). In circumstances where the temperature is changing (e.g., field studies), more frequent temperature corrections may be needed. Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be de-

termined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. It is recommended that the calibration syringe be stored and used in such a way as to maintain the exact temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer. In the case of flow-type spirometers where a volume syringe is used to check the instrument, volume calibration checks using different flow rates are recommended. At least three trials where the flow rates are varied between 2 and 12 L/s must be performed (3-L injection times of approximately 1 s, 6 s, and somewhere in between 2 and 6 s).

Syringe Accuracy. The syringe used to check the volume calibration of spirometers must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate syringe calibration intervals. If the syringe has an adjustable variable stop, the syringe may be out of calibration if the stop is reset. Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

Leak Test. Volumetric spirometer systems must be evaluated for leaks on a daily basis (15, 56). The Intermountain Thoracic Society Manual (15) suggests that leaks can be detected by applying a constant positive pressure of 3 cm H_2O or more with the spirometer outlet occluded. Any observed volume change of greater than 10 ml after 1 min is indicative of a leak (15) and needs to be corrected.

Linearity. At least quarterly, volume spirometers must have their calibration checked over their entire volume range (in 1-L increments) using a calibrated syringe (42) or an equivalent volume standard. Flow spirometers must have their linearity determined *at least* weekly and given the current software capabilities, daily linearity checks are reasonable. Flow spirometer linearity can be checked by injecting the volume from a 3-L syringe with several different flows. The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all flows and/or volumes tested.

Time. Assessing mechanical recorder time scale accuracy with a stopwatch must be performed *at least* quarterly. An accuracy of within 1% must be achieved. If equipment is changed or relocated (e.g., industrial surveys), calibration checks and quality control procedures must be repeated before initiating further testing.

PEF Meters. Since it is difficult to perform a calibration check of portable peak flow monitoring meters, it is particularly important that the instructions from the manufacturer include information concerning typical instrument lifetimes and methods of recognizing when an instrument is malfunctioning.

Other Quality Assurance Procedures. In addition to calibration with physical standards, the practice of using laboratory personnel as "known subjects" and performing intralaboratory and interlaboratory testing is recommended (44). The ATS has published guidelines for quality assurance in pulmonary function laboratories (44), which can be consulted for specific details.

The use of computers to analyze spirometry has accelerated in the past 10 yr, and this trend is advantageous to obtain accurate spirometry (10, 30). However, testing of commercially available spirometers consistently shows that a major source of errors is in computer software (42). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (42, 57), the ATS has published computer guidelines for pulmonary laboratories (58), which should be followed. Computer software must adhere to ATS recommendations, especially procedural recommendations, contained in this statement. Because of the tremendous improvement in the power and speed of computers and their extensive use in hospitals and clinics, manufacturers should attempt to integrate computers into their spirometry systems. Primary data should be available, allowing independent manipulation of uncorrected values by the user. Listings or descriptions of ATS algorithms should be available (end of test, back-extrapolation, etc.). In addition, some program flexibility should be available to the user, for example, allowing user selection of appropriate reference equations, including the use of user-derived reference equations.

TABLE 5

EQUIPMENT QUALITY CONTROL SUMMARY

Test	Minimum Interval	Action
Volume	Daily	3-L syringe check
Leak	Daily	3 cm H_2O constant pressure for 1 min
Linearity	Quarterly	1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges)
	Weekly (flow spirometers)	
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

MANEUVER PERFORMANCE RECOMMENDATIONS

Personnel Qualifications

The ATS has made recommendations for laboratory personnel conducting pulmonary function tests (59). High school training was recommended. In addition, the ATS encouraged but did not mandate one or more years of college or equivalent training and a strong background in mathematics. For pulmonary function laboratories, 6 mo of supervised training time is recommended for conducting spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 yr is recommended. The ATS recommends that the medical directors must have appropriate training and be responsible for all pulmonary function testing (60).

For industrial/occupational testing, there are training requirements mandated by the National Institute for Occupational Safety and Health (NIOSH), industry, and the ACCP (16, 31, 61). Several excellent training manuals have been prepared for performance of spirometry (15, 16, 31, 62, 63). NIOSH approves the content of spirometry training courses under the U.S. Cotton Dust Standard (16).

Recommendation: VC—Subject Instruction and Maneuver Performance

The VC maneuver may be considered either as an inspiratory vital capacity (IVC), where the subject inhales completely from a position of full expiration, or as an expiratory vital capacity (EVC), where the subject exhales completely from a position of full inspiration. In addition, several spirometer setups are possible using either open or closed circuit techniques with or without rebreathing.

1. A closed circuit technique *without* CO_2 absorption (i.e., using a rolling-sealed or water-sealed spirometer) may be used. Subjects may also rebreathe from the spirometer circuit. Rebreathing is preferable because it allows technicians to better monitor the entire vital capacity maneuver. In the absence of CO_2 absorption and the addition of supplemental oxygen, the maneuver should be brief – fewer tidal volumes before and after the VC maneuver.
2. A closed circuit technique *with* CO_2 absorption and the addition of supplemental oxygen may be used. This system allows

the subject to rebreathe for a longer period of time and establish a better FRC baseline. However, it requires precise replacement of oxygen to avoid shifting the baseline.

3. A modified closed circuit technique (i.e., flow-sensor-based systems where the subject can breathe in and out through the sensor without the need for CO_2 absorption) may be used.
4. An open circuit technique where the subjects may inhale completely before inserting the mouthpiece and exhaling into the spirometer may be used. This may be preferable when hygiene concerns are present.

For all systems, it is important to instruct the subject in the VC maneuver and demonstrate the appropriate technique. It is important that subjects understand they must *completely* fill and empty their lungs.

Standard Procedure Open Circuit Technique. The subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until a clear plateau is seen at maximal exhalation or until end-of-test criteria (see sections on FVC and end-of-test criteria) are met. The technician must observe the subject's inhalation to ensure that it is complete and that air is not exhaled while the mouthpiece is being inserted. During the exhalation, the technician should monitor the spirometer volume-time display to ensure that a relatively constant expiratory flow and an adequate end-expiratory plateau is achieved (*see* APPENDIX A for examples of the VC maneuver).

Closed Circuit Techniques. The following procedure should be used when testing is conducted *without* CO_2 absorption (limited oxygen reserve available for test performance). A two-way valve may be useful, allowing the initial tidal volumes to be performed with room air before the subject is connected to the spirometer. The test is begun with quiet breathing, preferably with the subject breathing room air. No more than five tidal volumes should be recorded with the subject rebreathing from the spirometer. The subject should then perform the VC maneuver described below. When CO_2 absorption is not used, returning to FRC after the VC maneuver followed by three tidal volumes may be helpful but is not required.

The following procedure should be used when testing is conducted with CO_2 absorption and oxygen supplementation. The test is begun with quiet breathing. Several tidal volumes should be recorded (minimum of five or until a stable end-expiratory level is observed). The subject should then perform the VC maneuver described below. The end of test is reached when the subject returns to the level of FRC and performs at least three more tidal volumes.

For both procedures, the maneuver is not forced; it is performed in a relaxed manner with the subject using a mouthpiece and a nose clip. The VC maneuver is composed of the subject exhaling completely to residual volume (RV), and completely inhaling to total lung capacity (TLC), and then exhaling to residual volume again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. Technicians should observe the subject to be certain his/her lips are sealed, that nothing obstructs the mouthpiece, that no leaks occur, and that TLC and RV are reached. The technician should check the volume display to ensure relatively linear inspiratory and expiratory volume curves and adequate maximal inspiratory and expiratory level plateaus. Oxygen should be added to the circuit to precisely counterbalance the absorption of CO_2.

For all techniques, a minimum of two acceptable VC maneuvers should be obtained, with a maximum of four attempts. The largest VC should be reported. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects (64).

TABLE 6

PERFORMANCE OF FVC MANEUVER

- Check spirometer calibration
- Explain test
- Prepare subject
  - Ask about smoking, recent illness, medication use, etc.
- Instruct and demonstrate test to subject
  - Correct posture with head elevated
  - Inhale completely
  - Position mouthpiece (open circuit)
  - Exhale with maximal force
- Perform maneuver
  - Have subject assume correct posture
  - Attach nose clip
  - Inhale completely; the inhalation should be rapid but not forced
  - Place mouthpiece in mouth and close lips around mouthpiece
  - Exhale maximally as soon as lips are sealed around mouthpiece*
  - Repeat instructions as necessary, coaching vigorously
  - Repeat for a minimum of three maneuvers; no more than eight are usually required
  - Check test reproducibility and perform more maneuvers as necessary

* D'Angelo and coworkers (65) have reported that PEF and FEV_1 for 13 normal subjects measured in a body plethysmograph are reduced (4% and 5%, respectively) when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. Therefore, an excessive pause at TLC should be avoided.

Recommendation: FVC—Subject Instruction and Maneuver Performance

Instruct the subject in the FVC maneuver. The technician should demonstrate the appropriate technique (Table 6). Have the subject inhale from FRC and then, if using the open circuit method, insert the breathing tube into his/her mouth, making sure his/her lips are sealed around the mouthpiece, and begin the FVC maneuver with minimal hesitation (65). It is *imperative* that the subject have a complete inhalation before beginning the forced exhalation. Prompt the subject to "blast," not just "blow," the air from their lungs, then continue to encourage him/her to fully exhale. Throughout the maneuver, enthusiastically coach the subject by word and body language. It is particularly helpful to observe the subject and the chart recorder or computer display during the test to better ensure maximal effort. Perform a *minimum* of three acceptable FVC maneuvers. If a subject shows large variability (FVC and/or FEV_1) between expiratory maneuvers (> 0.2 L), reproducibility criteria may require that up to but usually no more than eight maneuvers be performed. Volume-time or flow-volume curves from the best three FVC maneuvers must be retained. See Figure 3 and the section on acceptability and reproducibility for further clarification.

Recommendation (Monitoring): PEF—Subject Instruction and Test Performance

Since PEF is both effort- and volume-dependent, maximum subject cooperation is essential. Since an optimal peak flow is usually reached in about one-tenth of a second, patients must be encouraged to perform the expiratory maneuver as vigorously as possible. The subject should not cough and a prolonged exhalation is unnecessary (1 to 2 s is adequate).

When implementing unobserved self-administered PEF measurements, it is essential that:

1. The subject should be taught how to use the peak flow meter properly by someone skilled with the procedure. Trained personnel should observe the subject's performance both initially and on repeat visits.
2. The subject should be taught how and when to record PEF measurements, along with other pertinent information, such as symptoms.
3. The subject should be instructed about what action to take if PEF falls.

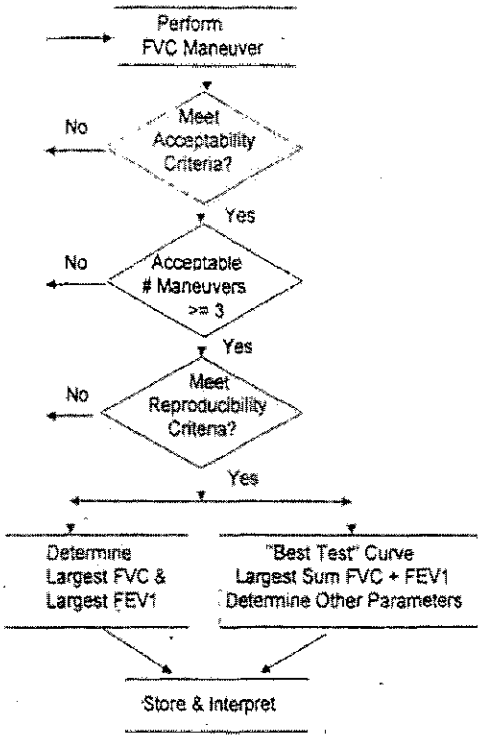


Figure 3. Flow-chart diagram of FVC spirometry testing.

TABLE 7

PERFORMANCE OF PEAK FLOW MANEUVER

Explain and demonstrate the test*
Zero the PEF monitor, if necessary
Stand up straight
Inhale completely; the inhalation should be rapid but not forced
Place PEF monitor in mouth and close lips around mouthpiece†
Exhale with maximal force‡ as soon as lips are sealed around mouthpiece§
Write down results
Repeat two more times (three total)
Record all three values

* Not necessary if at home.
† Nose clips are not necessary.
‡ Make sure subject understands to make full use of respiratory muscles, not just use the diaphragm as a "toot" or "mouth" maneuver.
§ D'Angelo and coworkers (65) have reported that PEF is reduced when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. It is not known if similar changes will be observed with portable peak flow meters.

Recommendation: FVC—Satisfactory Start-of-Test Criteria

To achieve accurate "time zero" and ensure that the FEV_t comes from a maximal effort curve, the extrapolated volume must be less than 5% of the FVC or 0.15 L, whichever is greater. See Figure 2 for an example and explanation of back extrapolation. In the example shown, the extrapolated volume is 0.16 L or 8%. In general, back-extrapolated volume should be measured on any curve with a perceptible extrapolated volume. Provisions for rapid computerized feedback to the technician when these criteria are not met are encouraged.

The committee discussed the possible use of time-to-PEF as a measure of the subject's performance early in the FVC maneuver. However, the committee felt there were insufficient data on which to base a clear recommendation, and additional research is needed. When conducting research on assessment of the subjects' correct performance of FVC maneuvers, investigators are encouraged to measure the time-to-PEF or rise-time of peak flow in addition to other quality assessment parameters. The rise-time of peak flow is defined as the time required for expiratory flow to rise from 10% to 90% of the maneuver's peak flow. Although use of other measures of acceptable efforts have been described and may be useful (8, 66), they are not recommended at this time.

Rationale. A very slow start with a low peak flow will result in a greater than allowable extrapolated volume (Figure 2) (1, 67–69). In addition, the FEV_t from a submaximal effort can be either smaller than those obtained when a maximal effort is performed because the subject fails to reach a maximal TLC, or larger due to less dynamic compression of airways in subjects where airways are relatively more collapsible. Recent experience in large epidemiologic studies (8) suggests that use of time-to-PEF and PEF reproducibility may minimize most of these problems in the majority of subjects. However, at this time, it is not recommended that maneuvers be eliminated because of a low PEF or PEF rise-time, but only because of an excessively large extrapolated volume.

Recommendation: FVC—Minimum Exhalation Time

A minimum exhalation time of 6 s (length of maximum expiratory effort), unless there is an obvious plateau in the volume–time curve display, is required to obtain maximal FVC results. There are instances (e.g., the testing of children, young adults, and some restricted patients) where shorter exhalation times are acceptable.

Recommendation: FVC—End-of-Test Criteria

To obtain an optimal effort, it is important that subjects be verbally exhorted to continue to exhale air at the end of the maneuver. End-of-test criteria are used to identify a reasonable FVC effort. Recommended end-of-test criteria are:

1. The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the maneuver on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication the patient is experiencing discomfort and should terminate the test if a patient is becoming uncomfortable.

OR

2. The volume–time curve shows an obvious plateau. This criterion is based on no change in volume for *at least* 1 s after an exhalation time of *at least* 6 s (10 s is optimal). "No change in volume" is defined as the minimal detectable volume of the spirometer. To meet ATS criteria, the minimal detectable volume for spirometers must be 0.030 L or less.

OR

3. The forced exhalation is of reasonable duration. For patients with airways obstruction or older subjects, exhalation times longer than 6 s are frequently needed to reach a plateau. Many would not reach a plateau even with a 20-s exhalation. However, exhalation times greater than 15 s will rarely change clinical decisions. *Multiple* prolonged exhalations (longer than 6 s) are seldom justified and may cause lightheadedness, syncope, undue fatigue, and unnecessary discomfort. In such patients, a slow or unforced VC maneuver (previously described) may provide a more appropriate denominator for calculation

of the $FEV_t/VC\%$. Manufacturers should note that several of the 24 test waveforms have durations longer than 20 s.

Achieving an end-of-test criterion is one measure of maneuver acceptability. Maneuvers that do not meet an end-of-test criterion should not be used to satisfy the requirement of three acceptable maneuvers. However, early termination is not by itself a reason to eliminate a maneuver from further consideration. Information such as FEV_1 and FEV_3 may be valid (depending on the length of exhalation) and should be reported from these early terminated maneuvers. When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g., 4 s) may be used as an approximate surrogate for FVC. In such cases, the volume label should reflect the shorter exhalation time (e.g., FEV_4 for a 4-s exhalation).

Recommendation: VC and FVC—Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight maneuvers is considered a practical upper limit for most subjects. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects, and thus on their spirometric parameters, so additional maneuvers would be of little added value. In addition, some subjects with asthma may exhibit spirometry-induced bronchospasm. Ferris and associates (70) and Kanner and colleagues (71) have reported that for adults and children, eight maneuvers is a practical upper limit. For VC, four is considered a practical upper limit. Because of the potential for muscular fatigue and volume history effects, it is preferable that VC maneuvers be performed before FVC maneuvers.

Recommendation (Monitoring): PEF—Number of Trials

The subject must perform and record a minimum of three trials.

Recommendation: VC and FVC—Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C may pose problems. Ambient temperature must *always* be recorded and reported to an accuracy of ± 1° C. In situations where the ambient air temperature is changing rapidly (> 5° C in less than 30 min), continuous temperature corrections should be made. Spirometer users should be aware of the problems with testing done at lower temperatures, which in some subjects can cause airflow limitation. Due to other technical reasons, 17° C is judged to be an acceptable and reasonable lower limit (32–38, 72) for ambient temperature. Ranges of barometric pressures that are acceptable for the spirometer must be published by the manufacturer.

Rationale. There is evidence that some subjects may develop airflow limitation with the inhalation of very cold air. Therefore, spirometry should not be conducted when the ambient temperature is cold enough to induce airflow limitation.

Studies also point out the problem of finite cooling times of gases in volume-type spirometers and their associated tubing (32–35) when BTPS correction techniques usually assume instantaneous cooling. In one of these studies, it was found that a 7.7 to 14% error in FEV_1 results if the volume-type spirometer is at an ambient temperature of 3° C and the standard BTPS correction is used. This error is less if the spirometer is warmer (nearer body temperature) (32). As a result, 17° C was judged to be an acceptable and reasonable lower limit.

Complexities related to temperature are also encountered with flow-measuring devices (34–38). Air exhaled from the mouth is estimated to be 33 to 35° C (36, 38, 39). If any connecting tubing is used between the mouthpiece and the flow sensor, the exhaled gas will experience a variable amount of cooling if the room temperature is not at approximately 33° C. Details of the cooling pattern for many types of flow spirometers have not been studied, but they may result in errors similar to those for volume devices (34–38).

Because not all spirometers are used at sea level (blood pressure = 760 mm Hg), the range of barometric pressures allowed by the spirometer and its associated computational equipment must be specified by the manufacturer.

Recommendation: VC and FVC—Use of Nose Clips

In most people, not wearing nose clips does not appreciably influence the FVC when using the open circuit technique. However, some people breathe through the nose and the use of nose clips is encouraged, especially when performing a slow VC maneuver. Nose clips must be used if a closed circuit technique with carbon dioxide absorption is used.

Recommendation: VC and FVC—Sitting Versus Standing

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report (1, 73). The standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced maneuvers. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can be quickly and easily eased into a sitting position if he/she becomes light-headed during the maneuver.

Rationale. Studies by Townsend show that for adults there are significantly larger FEVs in the standing position than in the sitting position (73). The earlier ATS recommendation indicates that in children, VC is greater when standing (1).

Recommendation (Monitoring): PEF—Nose Clips and Subject Position

Nose clips are not necessary when using PEF meters. Although the test can be conducted while sitting, the standing position is preferred.

Rationale. Because the PEF is dependent on a complete inhalation and an exhalation with maximal force, the standing position is preferred.

Bronchodilator Testing. Spirometry is often performed before and after inhalation of bronchodilators (or bronchoconstrictors) from a metered dose inhaler (MDI) or nebulizers. Although specific recommendations are beyond the scope of this document, it should be remembered that this is a complex procedure. Factors that can significantly affect a patient's response include: (*1*) activity, dose, and airway deposition of the medication; (*2*) recent prior medication; (*3*) timing of the postmedication maneuver; (*4*) choice and variability of the measurement used to detect a response; and (*5*) the method of calculating the magnitude of change after administering the bronchodilator.

MEASUREMENT PROCEDURES

Measurement

Spirometric variables should be measured from a series of *at least* three acceptable forced expiratory curves.

Recommendation: VC and FVC—Test Result Selection/Reporting of Results

The largest VC should be reported from all acceptable curves, including the forced maneuvers (FVC). The largest FVC and the largest FEV_1 (BTPS) should be recorded after examining the data from all of the acceptable curves, even if they do not come from the same curve. Other measures, such as the $FEF_{25-75\%}$ and the instantaneous expiratory flows, should be obtained from the single curve (1, 2, 15) that meets the acceptability criteria and gives the largest sum of FVC plus FEV_1 (best test).

Recommendation (Monitoring): PEF—Test Result/Reporting of Readings

Although all readings are recorded, the highest reading at any testing session (minimum of three trials) should be used in trend analysis. All readings are recorded to allow the comparison of the trials to evaluate reproducibility and to detect possible maneuver-induced bronchospasm.

Rationale. Since the PEF is effort-dependent, the highest reading should be used. This is consistent with the current recommended selection method for FVC and FEV_1.

ACCEPTABILITY AND REPRODUCIBILITY

Recommendation: VC and FVC—Maneuver Acceptability

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously in the section on performing the FVC test are met. APPENDIX A contains examples of unacceptable volume–time and corresponding flow–volume curves. In review, these acceptability criteria are: (*1*) satisfactory start-of-test; (*2*) minimum FVC exhalation time of 6 s; and (*3*) end-of-test criteria. In addition, the technician should observe that the subject understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and *without*:

1. An unsatisfactory start of expiration, characterized by excessive hesitation, false start, or extrapolated volume of greater than 5% of FVC or 0.15 L, whichever is greater (Figure 2).
2. Coughing during the first second of the maneuver, thereby affecting the measured FEV_1 value, or any other cough that, in the technician's judgment, interferes with measurement of accurate results (APPENDIX A, Figures 2A and 2B).
3. Early termination of expiration. A plateau in the volume–time curve should be observed, as defined by no change in volume for at least 1 s or a reasonable expiratory time. In a *normal* young subject this would be before completion of the breath—*usually* less than a 6-s maneuver. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau (2, 74, 75) (APPENDIX A, Figures 3A and 3B). However, *multiple* prolonged exhalations (longer than 6 s) are seldom justified.
4. Valsalva maneuver (glottis closure) or hesitation during the maneuver that causes a cessation of airflow (APPENDIX A, Figures 4A and 4B).
5. A leak (APPENDIX A, Figures 5A and 5B).
6. An obstructed mouthpiece (e.g., obstruction due to the tongue being placed in front of the mouthpiece or false teeth falling in front of the mouthpiece).

For VC measurements, all of the above requirements should be met with the exception of those related to the forced nature of the effort. In addition, plateaus in the volume–time display should be reached at both the maximal inspiratory and expiratory volumes.

Computer-based systems that provide feedback to the technician when the above conditions are not met are desirable. The reporting format should include qualifiers indicating the acceptability of each maneuver. However, it cannot be overemphasized that failure to meet these criteria does not necessarily invalidate the maneuver, since for some subjects this is their best performance. Further, such maneuvers should be retained, since these maneuvers may contain useful information.

A flow chart outlining how acceptability and reproducibility criteria are to be applied is shown in Figure 3.

Recommendation: VC and FVC—Test Result Reproducibility

As a goal during test result performance, the largest FVC (or VC) and second largest FVC (or VC) from acceptable maneuvers must not vary by more than 0.2 L. In addition for forced exhalations, the largest FEV_1 and the second largest FEV_1 must not vary by more than 0.2 L. The 0.2 L reproducibility criteria are a change from the ATS 1987 Spirometry Statement and are intended to provide an equal assessment of test reproducibility independent of lung size. However, these criteria are only goals during data collection; therefore, an immediate change in spirometry data collection software is not warranted.

The reproducibility criteria are used as a guide to whether more than three acceptable FVC maneuvers are needed; these criteria are *not* to be used for excluding results from reports or for excluding subjects from a study. Labeling results as being derived from data that do not conform to the reproducibility criteria stated above is encouraged (especially when the data suggest that bronchospasm was triggered by the FVC maneuver). In addition, the reproducibility criteria are minimum requirements and many subjects should be able to provide FVC and FEV_1 reproducibility well below 0.2 L. The acceptability criteria must be applied before the reproducibility criteria (Figure 3). Unacceptable maneuvers must be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility. Reproducibility of *results* should be considered at the time of interpretation. Use of data from maneuvers with poor reproducibility is left to the discretion of the interpreter. In addition, use of data from unacceptable maneuvers due to failure to meet the end-of-test requirements is left to the discretion of the interpreter.

Rationale. Several epidemiologic studies (67–69) have shown that the elimination of data from subjects who fail to meet the ATS reproducibility criteria may result in a population bias by excluding data from subjects who have abnormal lung function. Pennock and colleagues (76) have reported that subjects with obstruction have greater coefficients of variation than do normal subjects. Therefore, these subjects are more likely to be unable to meet the ATS minimum reproducibility criteria. The reproducibility criteria have been simplified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, a passive exhalation maneuver will often be labeled as the best test maneuver because it may give the largest sum of FVC and FEV_1.

The calculation of the FVC and FEV_1 reproducibility presents no problem for a computer; however, the need for rapid determination of FEV_1 during the testing session presents a recognized logistics problem if results are hand-measured and calculated. Changing to 0.2-L criterion does simplify this calculation.

Changing the reproducibility criteria to a minimum value of 0.2-L is based on evidence that within subject variability of FVC and FEV_1 is not dependent on body size. The use of a 5% or 100-ml criterion has been shown to result in more individuals of short stature being classified as nonreproducible. In contrast, a 0.2-L fixed volume criterion provides a commensurable level of difficulty for all subjects, regardless of age or height (lung volume) (77). Regardless of the reproducibility criterion for FVC or FEV_1, it should be used as a goal during data collection. Therefore, continued use of the previous criteria (5% or 0.1 L, whichever is greater) during an interim period should have little practical impact on spirometry results.

Recommendation: PEF—Maneuver Acceptability and Reproducibility

PEF values for each maneuver must be recorded in the order in which they occur. This information will be useful in detecting possible test (maneuver)-induced bronchospasms.

TABLE 8

ACCEPTABILITY AND REPRODUCIBILITY CRITERIA: SUMMARY

Acceptability criteria
- Individual spirograms are "acceptable" if:
  - They are free from artifacts (see APPENDIX A for examples)
    - Cough or glottis closure during the first second of exhalation
    - Early termination or cutoff
    - Variable effort
    - Leak
    - Obstructed mouthpiece
  - Have good starts
    - Extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater; OR
    - Time-to-PEF of less than 120 ms (optional until further information is available)
  - Have a satisfactory exhalation
    - 6 s of exhalation and/or a plateau in the volume-time curve; OR
    - Reasonable duration or a plateau in the volume-time curve; OR
    - If the subject cannot or should not continue to exhale

Reproducibility criteria
- After three acceptable spirograms have been obtained, apply the following tests:
  - Are the two largest FVC within 0.2 L of each other?
  - Are the two largest FEV_1 within 0.2 L of each other?
- If both of these criteria are met, the test session may be concluded
- If both of these criteria are not met, continue testing until:
  - Both of the criteria are met with analysis of additional acceptable spirograms; OR
  - A total of eight tests have been performed; OR
  - The patient/subject cannot or should not continue
- Save at a minimum the three best maneuvers

Rationale. Unlike the FEV_1 obtained from routine spirometry, PEF measurements are more variable, and the measurement is often conducted in patients with high variability in their PEF. Although there may be some benefit from using PEF reproducibility to improve a subject effort, no specific reproducibility criterion is recommended at this time.

REFERENCE VALUES, INTERPRETATION STANDARDIZATION, AND CLINICAL ASSESSMENT

Clinical/Epidemiologic Considerations

Whether the spirogram results are to be used for clinical or epidemiologic purposes, the following recommendations apply.

Since the last standards were issued in 1987, a detailed statement on selection of reference values and interpretation of lung function tests has been published (3). The interpretation of spirometry involves two tasks: (*1*) The classification of the derived values with respect to a reference population and assessment of the reliability of the data; and (*2*) The integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient. The first task is ordinarily the responsibility of the laboratory director or a designee and serves not only to communicate information to referring health care providers but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the medical director to develop explicit procedures for interpretation of spirometry and to select appropriate reference values. The procedures for interpretation and reference values may legitimately vary from laboratory to laboratory depending upon geographic location and the characteristics of the population being tested. In a setting where large numbers of healthy individuals are being screened for abnormality and the prevalence of disease is low, it is appropriate to set the threshold for abnormality at a higher level than in a setting where most individuals are referred because of symptoms or disease. In the latter case, where the prevalence of disease is high, an appropriate standard would be set to a more sensitive threshold for abnormality. The interpretative strategy should also take into consideration the consequences of false-positive and false-negative errors. Accordingly, no specific guidelines for interpretative procedures are recommended that would be applicable to all laboratories. More important, however, is that there be a consistent approach to the interpretation of lung function tests within a single laboratory. Therefore, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is the result of a change in the approach of the interpreting physician.

In providing the referring physician with an interpretation of spirometry results, it is also important to comment on deviations of the data from the guidelines for acceptability and reproducibility set forth herein. Although a spirometry session may not meet all of the guidelines, it may provide important clinical information and should be reported with appropriate qualification. Although some individuals display negative effort dependence, submaximal efforts usually lead to underestimation of the maximal effort values (28). Suboptimal efforts may be adequate to assist clinical decisions, where it can be judged that the recorded values underestimate true lung function.

Acknowledgment: The Committee thanks those who have provided input to this update of the Standardization of Spirometry. Special thanks go to the original participants of the Update Workshop, whose valued input was sought and used.

External reviewers: Scott T. Weiss, M.D., M.S., Gary R. Epler, M.D., and James R. Hansen, M.D.

APPENDIX A

Sample Spirograms

The sample spirograms shown in this appendix are from actual individuals and represent a few illustrations of acceptable and unacceptable maneuvers. It is imperative that the technician administering the test be capable of recognizing these anomalies and take appropriate corrective action—proper coaching. During the interpretation process, the reviewer may decide to include a maneuver that may have been considered unacceptable during test performance. As with the reproducibility criteria, some judgment must be made concerning what is an unacceptable maneuver. This decision will be based on the number of curves available, the disease pattern observed or expected for the individual, etc. However, the technician's action taken during the data collection stage of the process should almost always be to obtain additional maneuvers combined with effective coaching of the individual.

Figures A1a and A1b are volume-time and corresponding flow-volume samples that are acceptable spirograms from the draft NIOSH spirometry manual (78). In these spirograms, the individual exhibited a maximal effort for the entire maneuver, exhaling for at least 6 s with a greater than 1 s plateau in the volume-time curve. Figure A1a illustrates the relative expansion of the last portion of the FVC maneuver associated with a volume-time curve display. In contrast, Figure A1b illustrates the relative expansion of the initial portion of the FVC maneuver associated with a flow-volume curve display. Notice in the flow-volume curve (Figure A1b) it is more difficult to determine that the individual produced an acceptable plateau than in the volume-time curve display.

Figures A2a and A2b illustrate an unacceptable spirogram due to a cough during the first second of exhalation. Notice that the cough, which occurs at approximately 3.0 to 3.5 L, is very apparent in the flow-volume curve but is more difficult to detect in the volume-time curve. The anomalies seen in the volume-time curve at approximately 5.0 and 5.5 L could be slight coughs or variable effort, but occurred after the first second of exhalation.

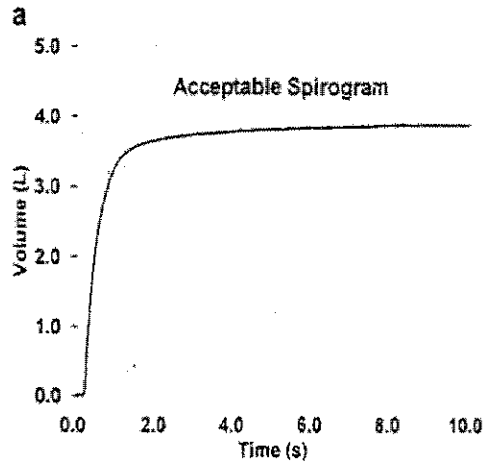


Figure A1a. Acceptable volume–time spirogram.

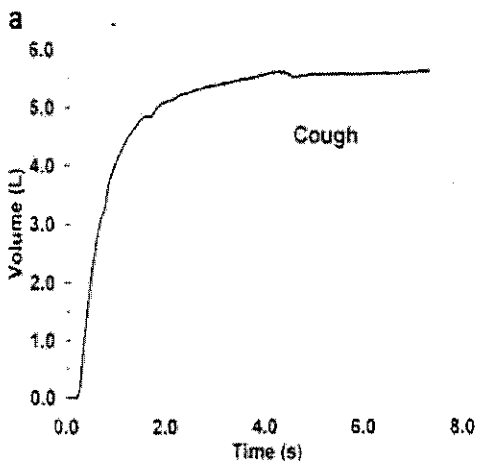


Figure A2a. Volume–time spirogram with a cough during the first second of exhalation.

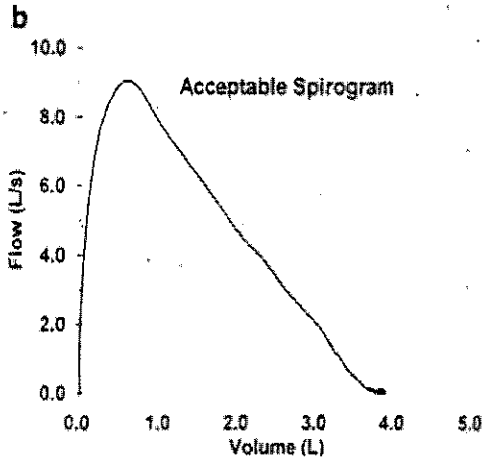


Figure A1b. Acceptable flow–volume spirogram.

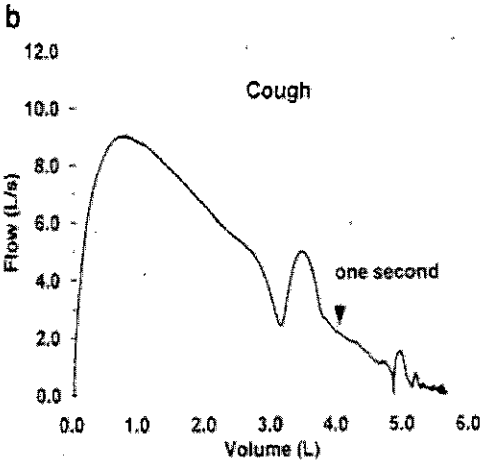


Figure A2b. Flow–volume spirogram with a cough during the first second of exhalation.

Although the fluctuations in flow observed in the flow–volume curve in Figure A2b are reasonably large, they may not result in a significantly different FEV_1. Therefore, the FEV_1 from this curve may be valid, particularly if all other curves are unacceptable. Regardless, when the technician observes the spirograms in Figures A2a and A2b, additional maneuvers should be obtained from the individual.

Figures A3a and A3b illustrate an unacceptable spirogram due to a variable effort or cough during the first second of exhalation and early termination of the maneuver. The anomaly observed at 1 L of exhalation is apparent on both the volume–time and flow–volume curves.

The duration of the anomaly and the fact that the flow immediately following the anomaly does not exceed the expected flow–volume envelope suggest that the anomaly is a variation in effort instead of a cough. The early termination is less apparent on the flow–volume curve. However, on the volume–time curve, it is apparent that the individual failed to exhale for 6 s and there is no 1-s plateau of the volume–time curve.

Figures A4a and A4b illustrate unacceptable sample spirograms due to an abrupt termination of flow at the end of the maneuver, possibly the result of the individual closing his/her glottis. Notice in Figure A4a that the volume–time curve plateau occurs abruptly at approximately 2.2 s where the volume remains constant for the remainder of the maneuver. In Figure A4b, the flow–volume curve exhibits an abrupt decrease in flow at the end of the maneuver.

Figures A5a and A5b illustrate unacceptable sample spirograms due to a leak in the volume-type spirometer or spirometer hose. This leak is approximately 50 ml/s and produces an approximate 300-ml loss in volume over the 6-s exhalation produced by this individual. Notice that the leak is very apparent on the volume–time curve and perhaps less apparent on the flow–volume curve. At the end of the maneuver when the leak is most

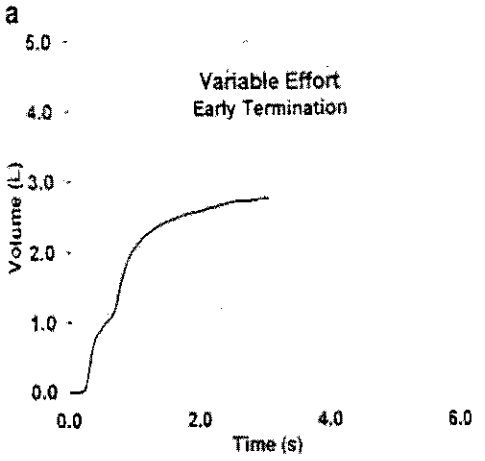


Figure A3a. Unacceptable volume–time spirogram due to variable effort and early termination.

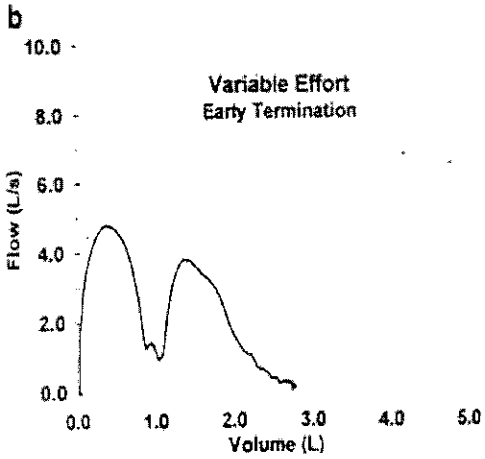


Figure A3b. Unacceptable flow–volume spirogram due to variable effort and early termination.

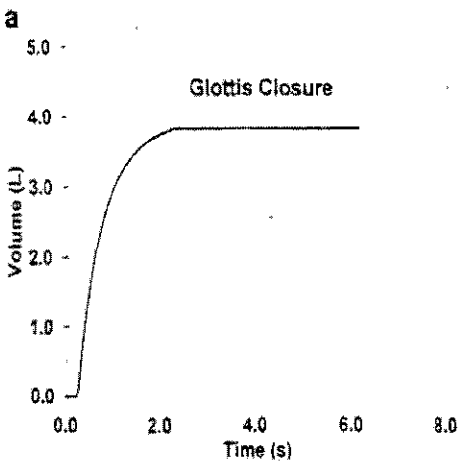


Figure A4a. Unacceptable volume–time spirogram due to possible glottis closure.

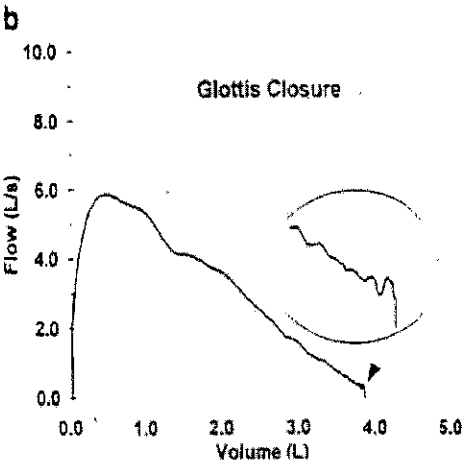


Figure A4b. Unacceptable flow–volume spirogram due to possible glottis closure.

apparent, the flow is slightly negative and volume is decreasing (*see* insert in Figure A5b, short line moving to the left below the zero flow line). If a spirometry system display does not display negative flows, then the leak would be even less apparent on the flow–volume curve.

Figures A6a and A6b illustrate acceptable sample spirograms for an individual with mild airways obstruction ($FEV_1/FVC\%$ = 67%). Notice the relatively small change in volume after 10 s of exhalation (Figure A6a) and the corresponding relative low flow (Figure A6b) at the end of the maneuver.

In addition to requiring three acceptable maneuvers, the reproducibility criteria for FVC and FEV_1 should be met as a goal during test performance. Figure A7a illustrates the volume–time curve and Figure A7b the corresponding flow–volume curve for a 22-yr-old, healthy female. In these figures, the subject did not meet the minimum reproducibility criteria for both the FVC and FEV_1 despite performing three acceptable maneuvers. The second largest FVC was 0.43 L (10%) lower than the largest, and the second largest FEV_1 was 0.37 L (12.1%) lower than the largest FEV_1. Therefore, at least one additional maneuver should be performed by this subject in an attempt to meet the FVC and FEV_1 reproducibility criteria. The most likely cause of this pattern (nonreproducible tracings but good initial effort) is a failure to achieve a maximal inhalation before performing the FVC maneuver.

Figures A8a and A8b illustrate a reproducible test with three acceptable maneuvers. Figure A8a displays the three acceptable volume–time curves, and Figure A8b displays the corresponding flow–volume curves. These maneuvers were obtained from an 80-yr-old male with an $FEV_1/FVC\%$ = 61.7%. Notice that the curves are very reproducible even though the subject required approximately 20 s to reach his final volume or FVC.

Figure A9 shows a sample VC maneuver for a normal subject. This subject starts the test with several tidal volumes through

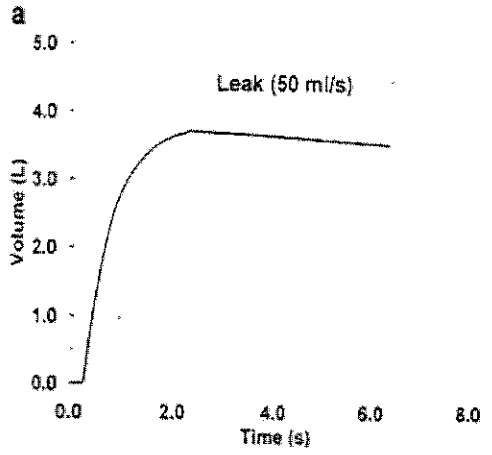


Figure A5a. Unacceptable volume–time spirogram due to a leak.

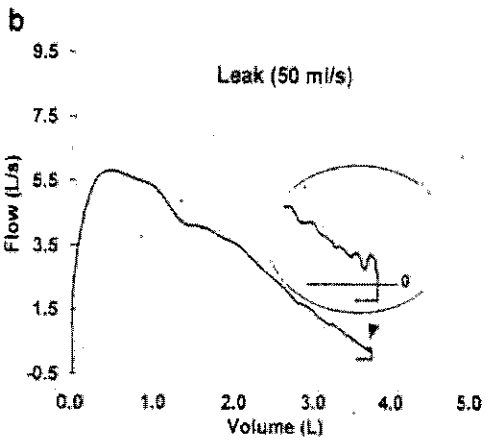


Figure A5b. Unacceptable flow–volume spirogram due to a leak.

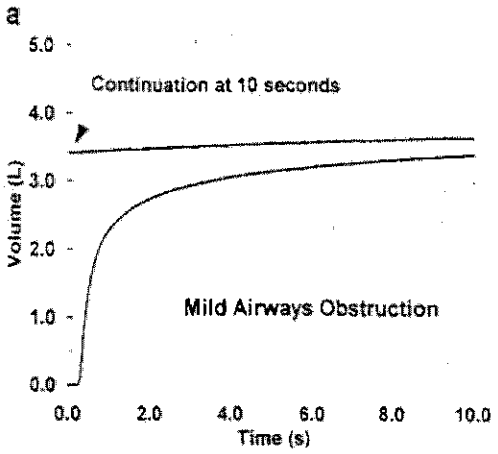


Figure A6a. Acceptable volume–time spirogram for an individual with mild airways obstruction.

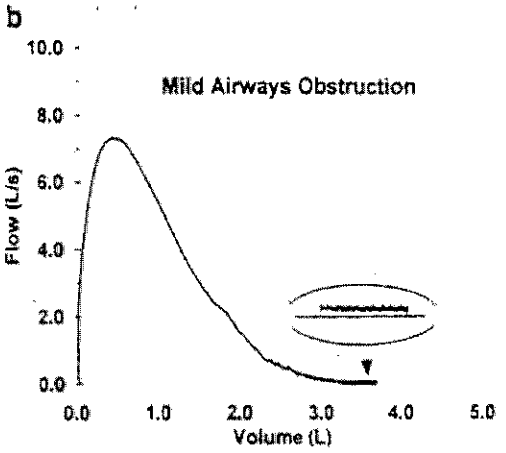


Figure A6b. Acceptable flow–volume spirogram for an individual with mild airways obstruction.

a valve opened to room air to become accustomed to breathing on the mouthpiece. The subject is then connected to the spirometer, where several additional tidal volumes are recorded. The subject then completely inhales to total lung capacity (TLC) and slowly exhales to residual volume (RV), making sure to completely inhale to TLC and exhale to RV. After reaching RV, the subject returns to FRC, where several tidal volumes are again obtained before the subject comes off the mouthpiece. Notice the plateaus at TLC and RV, indicating that the subject has completely inhaled and exhaled.

Figure A10 shows a sample VC maneuver for a subject with severe airways obstruction. The identical maneuver for the normal subject shown in Figure A9 is repeated for this subject with severe airways obstruction. However, the tidal volumes of the subject with severe airways obstruction are much more rapid and the subject requires a longer exhalation time to reach RV, as long as 25 s. Notice that as with the normal subject, a plateau in the volume–time curve is obtained at both TLC and RV. This indicates that the subject has completely inhaled and exhaled. Also notice that the subject has some difficulty in obtaining a stable FRC after the VC maneuver, probably due to gas trapping.

APPENDIX B

Spirometer Testing Guidelines

The following testing guidelines should be used when evaluating new spirometer designs and when changes have been made to spirometer hardware or software. For production testing, the use of a smaller set of test waveforms may be appropriate. The spirometer selected for testing should be a "production" model and not one that was specifically selected because of any extraordinary calibration efforts. Once testing has begun, the device be-

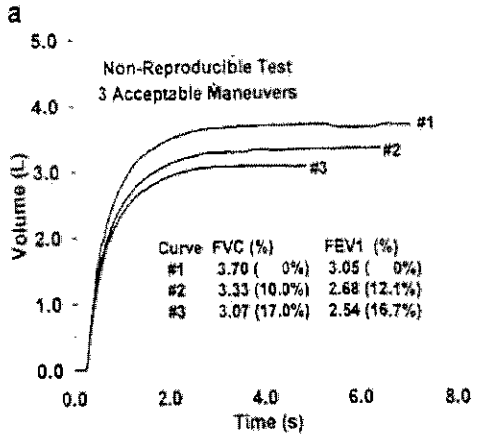


Figure A7a. Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

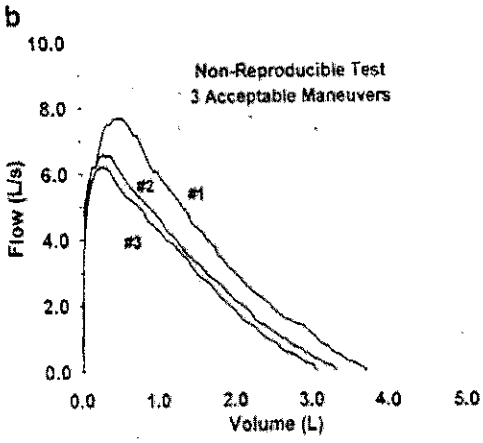


Figure A7b. Nonreproducible test with three acceptable flow–volume curves.

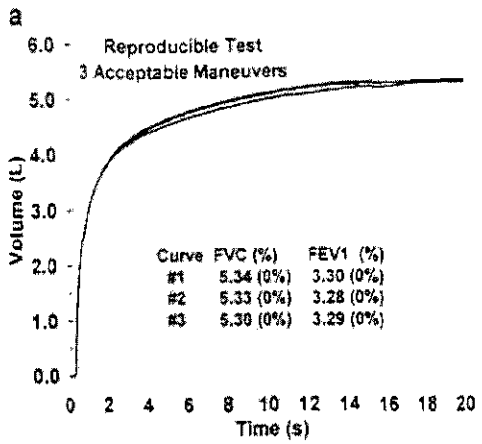


Figure A8a. Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

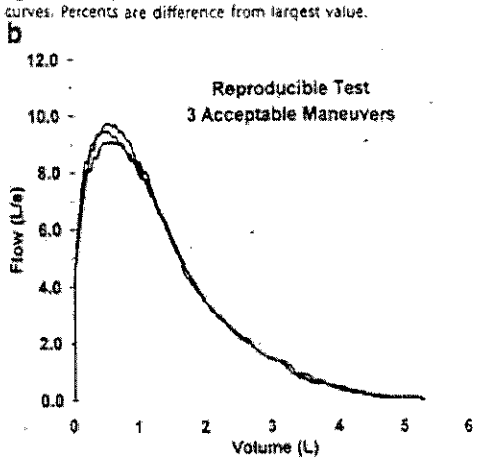


Figure A8b. Reproducible test with three acceptable flow–volume curves.

ing tested should not receive any adjustments or special calibration procedures that are not part of its routine operational procedures.

Volume parameters should be validated using the 24 volume-time standard waveforms described in APPENDIX C. For PEF and other flow parameters *not* based on a percentage of the FVC, the 26 flow-time standard waveforms should be used (APPENDIX D). The validation limits are provided for each parameter in the main sections of this statement. All tests should be conducted using the appropriate waveforms and a computer-controlled mechanical syringe or its equivalent (waveform generator). The accuracy of the waveform generator should be checked at least daily when in use, either using a spirometer for volume waveforms or a pneumotachometer for flow waveforms, or an equivalent method. The desired accuracy of the waveform generator for volume parameters is ± 0.5% (or ± 0.05 L, whichever is greater); ± 2% (or ± 5 L/min, whichever is greater) for flow parameters (e.g., PEF). In comparing results obtained from a particular spirometer, the tolerance limits of the waveform generator are to be considered by adding them to the accuracy requirement for the parameter under test, for example 0.5% (± 0.05 L) for volume parameters and 2% (± 5 L/min) for flow parameters. Therefore, the FVC accuracy requirement for comparisons with observed values would be ± 3.5% (performance accuracy requirement ± 3% plus waveform generator accuracy of ± 0.5%).

The accuracy and precision validation limits contained in this section assume a waveform generator accuracy of 0.5% for volume and 2% for flow parameters. The accuracy of available waveform generators has not been established; therefore, the desired 2% waveform generator accuracy for flow parameters may not be achieved. In this circumstance, the *actual* accuracy limit of the waveform generator should be added to the accuracy require-

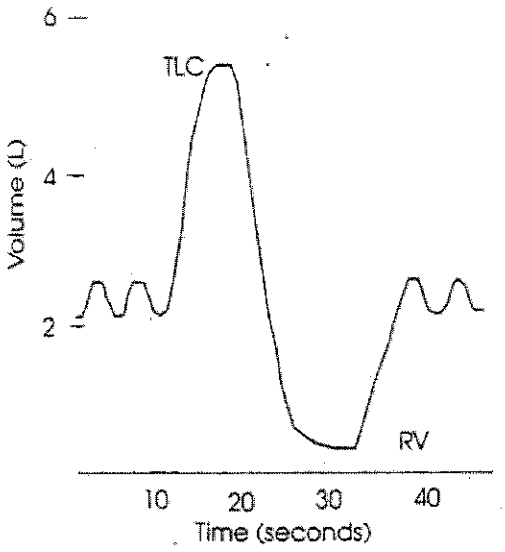


Figure A9. Sample relaxed VC maneuver in a normal subject.

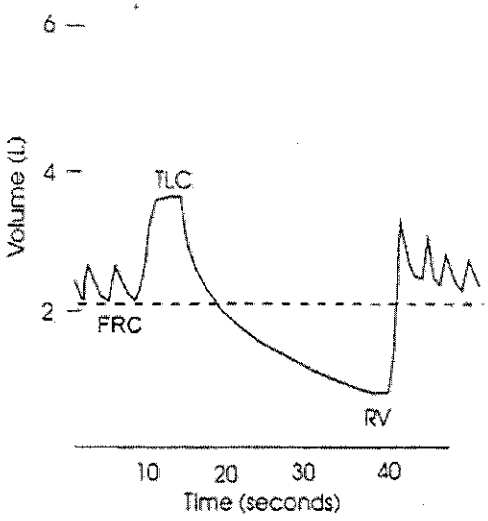


Figure A10. Sample VC maneuver from a subject with severe airways obstruction.

ment of the parameter under test. Every attempt should be made to improve the accuracy of waveform simulators, but in no case should the simulator accuracy limit be considered less than 0.5% for volume and 2% for flow parameters.

Spirometers or peak flow meters should be connected to the waveform generator in the same orientation used in the testing of subjects. Tubing or other connecting material may be used, but the volume associated with the connecting tubing should be less than 300 ml. For handheld devices, full testing should be conducted with the sensor in a horizontal position (the typical position with the patient at TLC about to initiate the maneuver). In addition, handheld devices should be tested with two waveforms (standard volume-time waveforms 1 and 6) at a typical FRC position (instrument at a 30° angle down from horizontal). These devices must meet diagnostic spirometer accuracy criteria for these two waveforms in the 30° down-angle position.

The instruments (diagnostic or monitoring devices) should be tested using the waveform generator under conditions similar to those present when testing human subjects. No special procedures should be followed in testing the instrument. Specifically, each waveform will be injected into the instrument within not less than 5 s or more than 1 min of the instrument being set to the ready condition. In measuring the resistance of the instrument, pressure should be measured in the side of the standard mouthpiece used by the instrument when constant flows are injected into the spirometer. If an in-line filter is to be used as part of routine testing of humans, a filter must be attached during spirometer validation and resistance testing.

Five repeats of each of the 24 waveforms should be injected into the test instrument using room air at ambient temperature. In those circumstances where the flow or volume sensor is changed between subjects (e.g., disposable flow sensor), a different sensor should be used for each of the repeat tests. The average of the five repeat values should be used for comparison with the standard values. The range and percent deviations of values from the five repeated tests should also be computed by:

$$\text{Range} = \text{maximum} - \text{minimum} \quad \text{(B1)}$$

$$\text{Range (\%)} = 100 \cdot \frac{(\text{maximum} - \text{minimum})}{\text{average}} \quad \text{(B2)}$$

$$\text{Deviation} = \text{average} - \text{standard} \quad \text{(B3)}$$

$$\text{Deviation (\%)} = 100 \cdot \frac{(\text{average} - \text{standard})}{\text{standard}} \quad \text{(B4)}$$

Averages are calculated as a simple n weighted average.

The five repeats of 24 waveforms should be considered a rigid testing sequence. The testing of a device should be completed by running all 24 waveforms with five repeated tests. If the device fails to accurately measure a value for a particular waveform, no additional repeats should be conducted for only one waveform.

Diagnostic devices should also be tested by injecting at least four waveforms using heated and humidified air (waveforms 1 through 4) to verify accuracy of volume parameters under BTPS conditions. Using volume-time waveforms 1 through 4, the average FVC and FEV_1 of three trials shall be compared to the standard values. The validation limits for testing under BTPS conditions are ± 4.5% or 200 ml, whichever is greater. Spirometers must meet these accuracy criteria for all four waveforms under BTPS conditions. Using 4.5% allows a 1.5% simulator error, necessary because of the added uncertainty when using heated and humidified air. The time between each of the three trials should be less than 2 min. The temperature of the air injected into the device under test should be within ± 1° C of 37° C and should be measured before the air is injected into the device. Waveform generators are being modified to allow BTPS testing. The BTPS testing requirement will be implemented when BTPS testing services are available.

In addition to testing using the waveform generator, the device should be tested using at least two healthy human subjects.

TABLE B1

STROKE VOLUME, VOLUME IN SPIROMETER AT START OF TEST (FOR VOLUME SPIROMETERS), RATE, AND CORRESPONDING MVV TARGET VALUES

Test Number	Target MVV (L/min)	Stroke Volume (L)	Rate (Strokes/min)	Starting Volume (L)
1	60	1.0	60	2.0
2	100	1.0	100	3.0
3	120	2.0	60	3.0
4	200	2.0	100	3.0

The purpose of the testing using a human subject is to verify that the instrument will function properly under conditions other than those present using a mechanical simulator. To achieve a balanced design, each subject should perform alternating maneuvers between a standard spirometer and the device being tested, performing three maneuvers on each device, for a total of six maneuvers. One subject should be randomly assigned to perform their first maneuver on the standard spirometer while the other subject's first maneuver will be performed on the device being tested, allowing the learning effect to be equally distributed across both instruments. The differences between the largest of the three trials from each device should be within ± 6% or 200 ml, whichever is greater, for FVC and FEV_1, and ± 15% or 30 L/min, whichever is greater, for PEF.

For validating MVV, a mechanical pump should be used with a sinusoidal waveform. The response of the device should be determined using incrementally increased flows up to a maximum of 250 L/min, produced with stroke volumes up to 2 L. The specific minimum patterns and for volume spirometers, the volume in the spirometer, are given in Table B1. The device should read the MVV within ± 10.5% of reading or ± 20 L/min, whichever is greater for all four test patterns specified in Table B1. In addition, the pressure measured at the mouthpiece should not exceed 10 cm H_2O during the entire MVV maneuver. No mechanical pump testing at BTPS is required for MVV.

DIAGNOSTIC DEVICES: TESTING FOR ACCURACY AND PRECISION WITH A WAVEFORM GENERATOR

Accuracy Testing

Accuracy criteria: Deviation ± 3.5% or ± 0.100 L, whichever is greater, for volume measurements; ± 5.5% or ± 0.250 L/s, whichever is greater, for $FEF_{25-75\%}$; ± 12% or ± 25 L/min (± 0.420 L/s), whichever is greater, for PEF. These criteria are increased slightly from those in Table 2 to account for the waveform generator inaccuracy. For MVV testing, deviation must be less than ± 10.5% or 20 L/min, whichever is greater.

Waveforms: Twenty-four standard volume-time waveforms (APPENDIX C) for FVC, FEV_1, and $FEF_{25-75\%}$; 26 standard flow-time waveforms (APPENDIX D) for PEF. For BTPS testing, volume-time waveforms 1 through 4 should be used with heated and humidified air as specified in this appendix. For MVV testing, sinusoidal waveforms should be used with the patterns specified in Table B1.

Spirometer tested: One production spirometer. Spirometers should not be screened or especially calibrated before testing. If an in-line filter is to be used during the testing of humans, it should be attached for this testing. When during clinical testing, if the flow or volume sensor is changed between subjects, the sensors must be changed for each of the five repeat tests described below. The spirometer may not be recalibrated after these sensor changes unless recalibration is required after each sensor change during clinical testing.

Validation: Each spirometric waveform is to be injected into the spirometer five times. MVV patterns will be injected in duplicate. Average values will be calculated for each waveform and, along with individual values, will be used to score the spirometer. See formulas B1-B4.

Acceptable performance: For FVC and FEV_t in each of the volume-time waveforms: deviation (formula B3) must be less than 0.100 L *or* deviation (%) (formula B4) must be less than 3.5%. For $FEF_{25-75\%}$ in each of the volume-time waveforms: deviation must be less than 0.250 L/s *or* deviation (%) must be less than 5.5%. For PEF in each of the flow-time waveforms: deviation must be less than 25 L/min (0.420 L/s) or deviation (%) must be less than 12%. For BTPS testing using waveforms 1-4: deviation must be less than 0.2 L or deviation (%) must be less than 4.5%. For MVV in each of the patterns: deviation must be less than 20 L/min or deviation (%) must be less than 10.5%.

An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. For testing with ambient air, acceptable performance is present if the error rate for each individual parameter (FVC, FEV_t, $FEF_{25-75\%}$, PEF) is less than 5% (one error for each parameter when 24 or 26 waveforms are used). For MVV testing and spirometric testing with BTPS conditions, acceptable performance is present if the error rate is zero.

Precision Testing: Intradevice Testing

Precision criteria: See the acceptable performance criteria listed below.

Waveforms: Use data generated as part of accuracy testing.

Acceptable performance: For FVC and FEV_t, for each of the volume-time waveforms: The range (formula B1) must be less than 0.100 L *or* range (%) (formula B2) must be less than 3.5%. For $FEF_{25-75\%}$ using each of the volume-time waveforms: The range (formula B1) must be less than 0.250 L/s or the range (%) (formula B2) must be less than 5.5%. For PEF using each of the flow-time waveforms: The range must be less than 25 L/min (0.420 L/s) or the range (%) must be less than 7%.

An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if the error rate for each individual parameter (FVC, FEV_t, PEF) is less than 5% (one error for each parameter if 24 or 26 waveforms are used).

MONITORING DEVICES (PEF) TESTING CRITERIA

The range and deviations from the standard PEF values should be calculated using formulas B1 through B4.

Accuracy Testing

Accuracy criterion: ± 12% or ± 25 L/min of target values, whichever is larger. The primary criterion is ± 10%; 2% is added to account for the inaccuracy of the waveform generator.

Waveforms: 26 flow-time curves (APPENDIX D).

Meters tested: Two production meters. Meters should be selected routinely from a production run and not be screened before validation testing.

Validation: Each meter will receive five maneuvers for each of the 26 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance is less than three errors out of the total 52 tests (26 waveforms, 2 meters).

Precision Testing: Intradevice Testing

Criterion: Less than 6% intradevice variability or 15 L/min, whichever is greater. The primary criterion is less than 5%. One per-

TABLE C1

VALUES FOR STANDARD WAVEFORMS

Curve	FVC (L)	FEV_1 (L)	FEV_1 (%FVC)	Vext (L)	Vext (%FVC)	PEF_{max} (L/s)	$FEV_{25-75\%}$ (L/s)
1	6.000	4.262	71.0	0.052	0.9	6.497	3.410
2	4.999	4.574	91.5	0.068	1.4	9.873	5.683
3	3.498	1.188	33.9	0.014	0.4	1.380	0.644
4	3.498	3.371	91.5	0.039	1.3	2.952	1.704
5	5.132	3.868	75.4	0.087	1.7	7.535	3.209
6	4.011	3.027	75.5	0.317	7.9	5.063	2.572
7	3.169	2.519	79.5	0.354	11.2	4.750	2.368
8	1.993	1.615	81.0	0.151	7.6	3.450	1.857
9	4.854	3.772	77.7	0.203	4.2	7.778	3.365
10	3.843	3.031	78.9	0.244	6.3	4.650	2.899
11	2.735	1.811	66.2	0.022	0.8	3.708	1.272
12	2.002	1.623	81.0	0.094	4.7	3.807	1.780
13	4.896	3.834	78.3	0.460	9.4	5.207	3.677
14	3.786	3.053	80.6	0.338	10.2	4.368	3.122
15	5.937	5.304	89.3	0.080	1.3	12.132	6.092
16	5.458	3.896	71.4	0.215	3.9	7.395	2.892
17	5.833	2.597	44.5	0.035	0.6	5.257	1.153
18	4.343	3.155	72.6	0.042	1.0	7.523	2.335
19	3.935	2.512	63.8	0.044	1.1	5.408	1.137
20	2.881	2.563	89.0	0.041	1.4	5.822	2.695
21	4.477	3.549	79.3	0.102	2.3	9.398	3.368
22	3.857	2.813	72.9	0.036	0.9	5.055	2.204
23	3.419	1.360	39.8	0.013	0.4	2.868	0.531
24	1.237	0.922	74.5	0.037	3.0	2.095	0.709

Definition of abbreviations: Vext = extrapolated volume (see Figure 2 for description).

cent or 5 L/min is added to account for the imprecision of the waveform generator.

Waveforms: Four of the 26 standard flow–time waveforms (waveforms 1, 4, 8, and 25).

Meters tested: Ten production meters.

Validation: Three flows for each waveform for each meter. For each waveform and for each meter, calculate range (formula B1) and range (%) (formula B2) for each PEF.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is six or fewer errors (error rate = 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 25 L/min, whichever is greater. This includes 1% or 5 L/min for the imprecision of the waveform generator.

Waveforms: Same as for intradevice testing.

Meters tested: Same as for intradevice testing.

Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each meter, calculate an average PEF for each waveform. For each waveform, combine all data from the 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

TABLE D1

CALCULATED VALUES FOR 26 STANDARD FLOW–TIME WAVEFORMS (0.002-S SAMPLING INTERVAL)*

Waveform Number	Flow PEF (L/s)	Vol-80 PEF (L/s)	Vol-40 PEF (L/s)	Rise-Time (ms)	Vext Time-to-PEF (ms)	Flow Time-to-PEF (ms)	Extr Vol (L)	%Vext (%FVC)	FEV_1 (L)
1	7.445	7.245	7.337	93.5	86.8	151.7	0.108	2.5	3.373
2	10.860	9.905	10.450	55.7	46.5	86.6	0.093	2.2	3.838
3	4.794	4.372	4.630	68.3	53.0	114.7	0.054	3.3	1.302
4	4.401	4.240	4.321	76.0	65.6	116.3	0.051	2.9	1.468
5	3.630	3.564	3.584	159.5	170.6	241.0	0.081	3.0	2.053
6	3.088	2.728	2.949	44.5	36.8	62.7	0.021	1.3	1.110
7	2.509	2.237	2.403	148.0	67.6	173.6	0.057	3.7	1.046
8	2.328	2.048	2.210	42.4	35.6	57.6	0.015	1.0	0.950
9	5.259	4.923	5.109	52.0	47.2	85.4	0.046	1.8	2.182
10	4.733	4.657	4.666	46.7	93.6	122.2	0.035	1.5	2.029
11	6.870	6.472	6.706	81.1	67.4	125.6	0.085	3.1	2.080
12	10.684	10.528	10.558	115.3	139.9	214.1	0.189	3.4	4.618
13	4.804	4.708	4.739	105.3	121.7	194.9	0.080	2.7	2.304
14	3.821	3.756	3.769	124.7	127.7	201.8	0.074	2.5	2.249
15	7.956	7.814	7.852	174.9	152.6	270.4	0.192	5.0	5.219
16	5.251	5.100	5.165	76.3	80.5	123.7	0.060	2.1	2.246
17	5.842	5.721	5.757	165.1	163.4	265.1	0.151	5.0	2.802
18	8.393	8.404	8.465	132.9	126.2	248.7	0.178	3.6	4.303
19	6.953	6.651	6.807	76.5	63.7	120.2	0.083	2.2	3.007
20	7.430	7.274	7.324	120.9	143.3	268.4	0.141	2.5	4.613
21	3.973	3.745	3.880	130.3	88.4	193.1	0.079	6.0	1.096
22	3.377	3.316	3.334	184.2	157.6	259.6	0.094	5.0	1.559
23	8.132	7.954	8.019	84.8	83.1	152.1	0.107	2.4	3.476
24	4.155	4.028	4.086	50.3	52.3	83.7	0.032	1.2	1.833
25	14.194	13.896	13.964	57.9	53.7	100.3	0.126	1.9	5.944
26	11.595	10.446	11.172	69.6	42.2	79.1	0.088	1.7	4.311

Definition of abbreviations: Flow PEF = peak flow determined by obtained highest observed flow value; Vol-80 PEF = peak flow determined from volume–time curve using an 80-ms segment; Vol-40 PEF = Peak flow determined from volume–time curve using a 40-ms segment; Rise-Time = time required for the flow to rise from 10% of PEF to 90% of PEF; Flow Time-to-PEF = time required for flow to rise from 200 ml/s to maximum flow (PEF); Vext Time-to-PEF = time required for flow to rise from Vext time zero to PEF.

* Units: flow (L/s), volumes (L), and time (milliseconds). These waveforms are available on digital media from the American Thoracic Society.

MONITORING DEVICES (FVC AND FEV_1) TESTING CRITERIA

Accuracy Testing

Criterion: Deviation ± 5.5% *or* deviation (%) ± 0.1 L, whichever is larger.

Waveforms: Twenty-four standard volume-time waveforms (APPENDIX C).

Device testing: Two production devices selected routinely from a production run and not screened before testing.

Validation: Each device will receive five maneuvers for each of the 24 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance for each individual parameter is less than three errors out of the total 48 tests (24 waveforms, 2 devices).

Precision Testing: Intradevice Testing

Criterion: Range (%) < 3.5% or range < 0.1 L, whichever is greater.

Waveforms: Four of the 24 standard volume-time waveforms (waveforms 1, 3, 6, and 11).

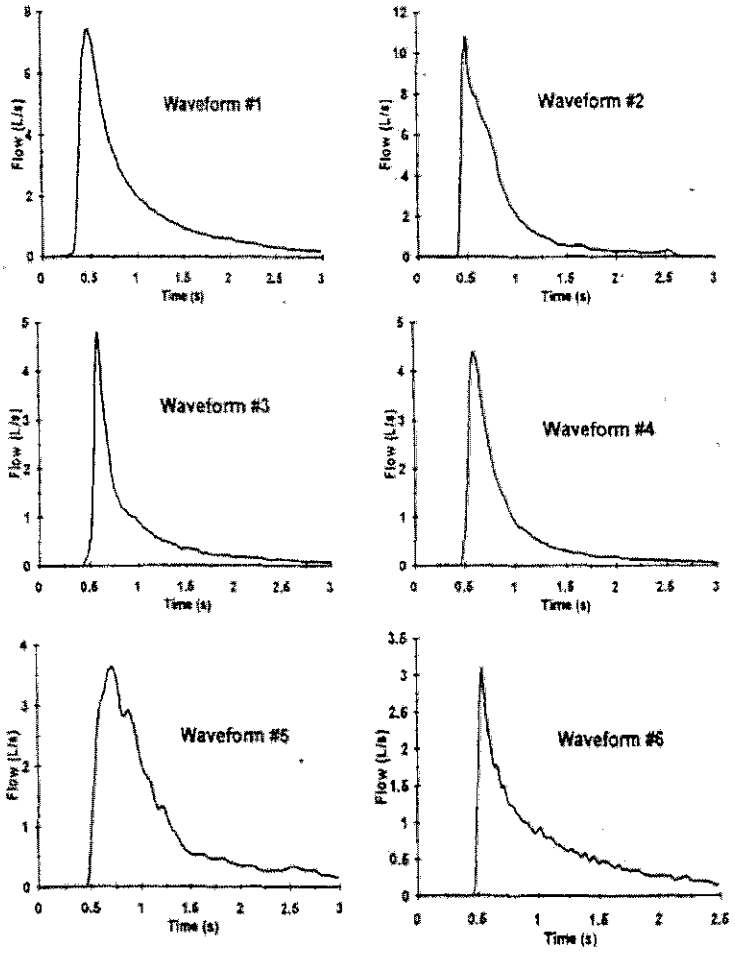
Meters tested: Ten production devices.

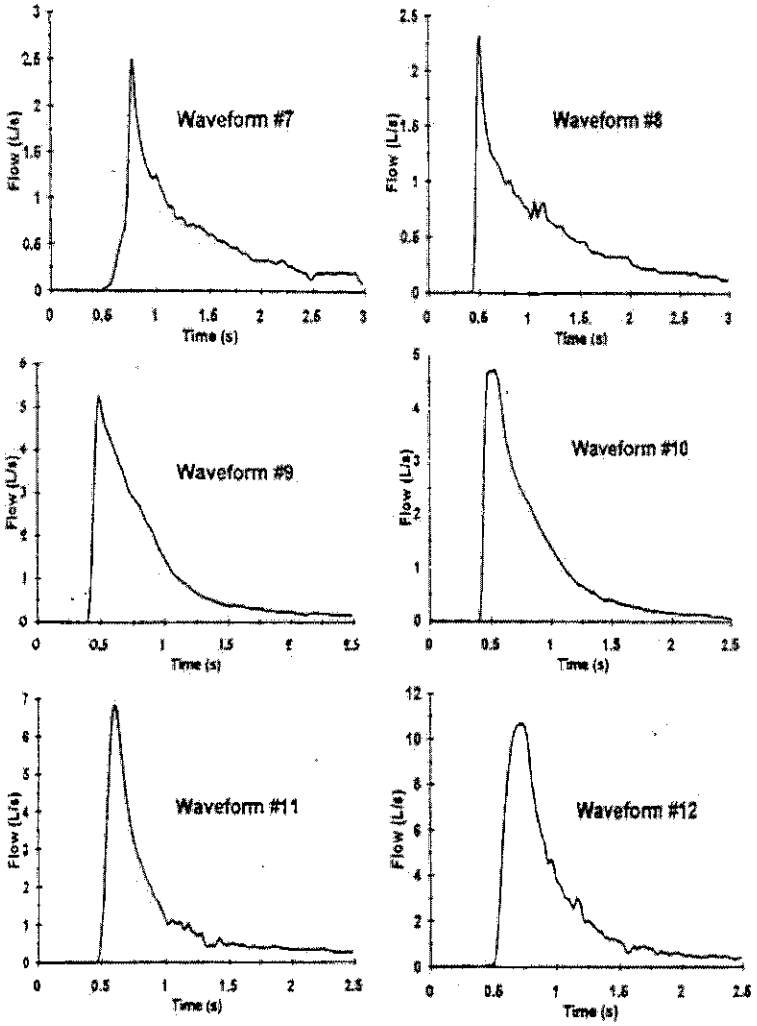
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and FEV_1.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance for each individual parameter is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 0.2 L, whichever is greater.





Waveforms: Same as for intradevice testing.

Devices tested: Same as for intradevice testing.

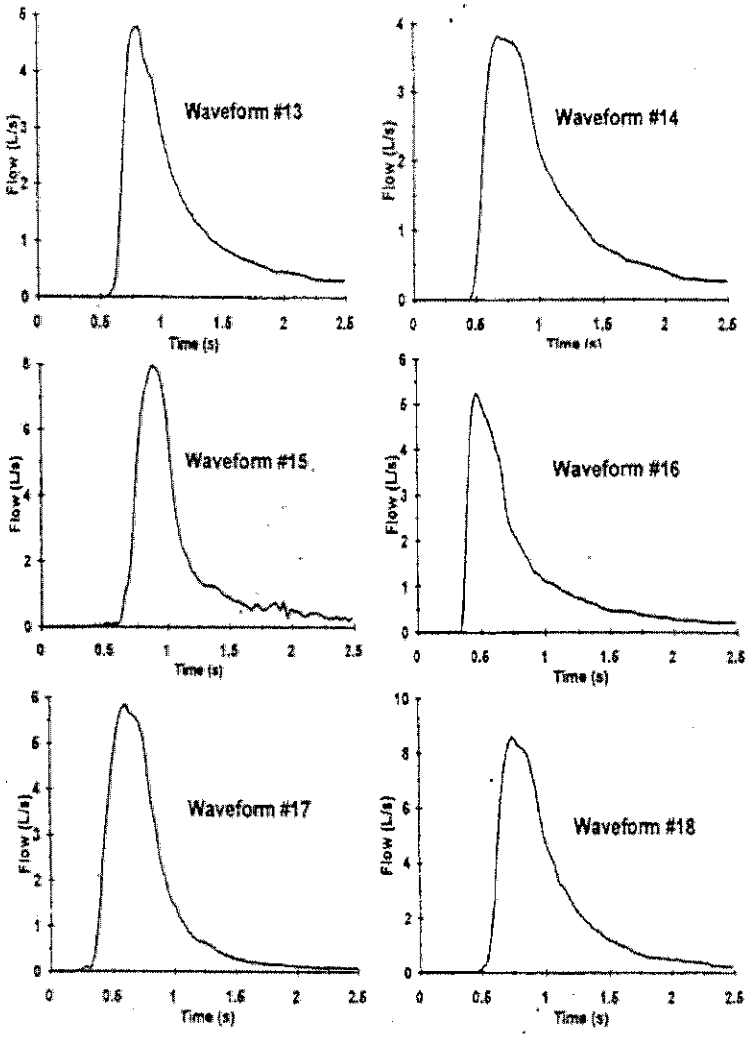
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV, for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

APPENDIX D

Standard Flow-Time Waveforms for Validating PEF

The following flow-time waveforms are intended primarily for testing portable PEF meters but can be used for testing other types of spirometers, especially those measuring PEF, time-to-peak flow, or rise-time. These waveforms were chosen to represent a range of PEFs and efforts (rise-times). The PEF is derived directly from the flow-time waveform-maximal observed value. To calculate the volume-determined PEF, volume is first obtained by integrating (summing) the flow values. Flow is then calculated from the volume-time waveform using the ATS 8-point smoothing function. The resulting volume PEF is usually lower than the PEF obtained from the flow-time waveform. Rise-time is defined as the time required for the flow to rise from 10% of the PEF to 90% of the PEF and is expressed in milliseconds. Other investigators have used the time-to-PEF, using the back-extrapolated technique to determine the zero time-point. Using back-extrapolation to calculate time-to-peak flow sometimes



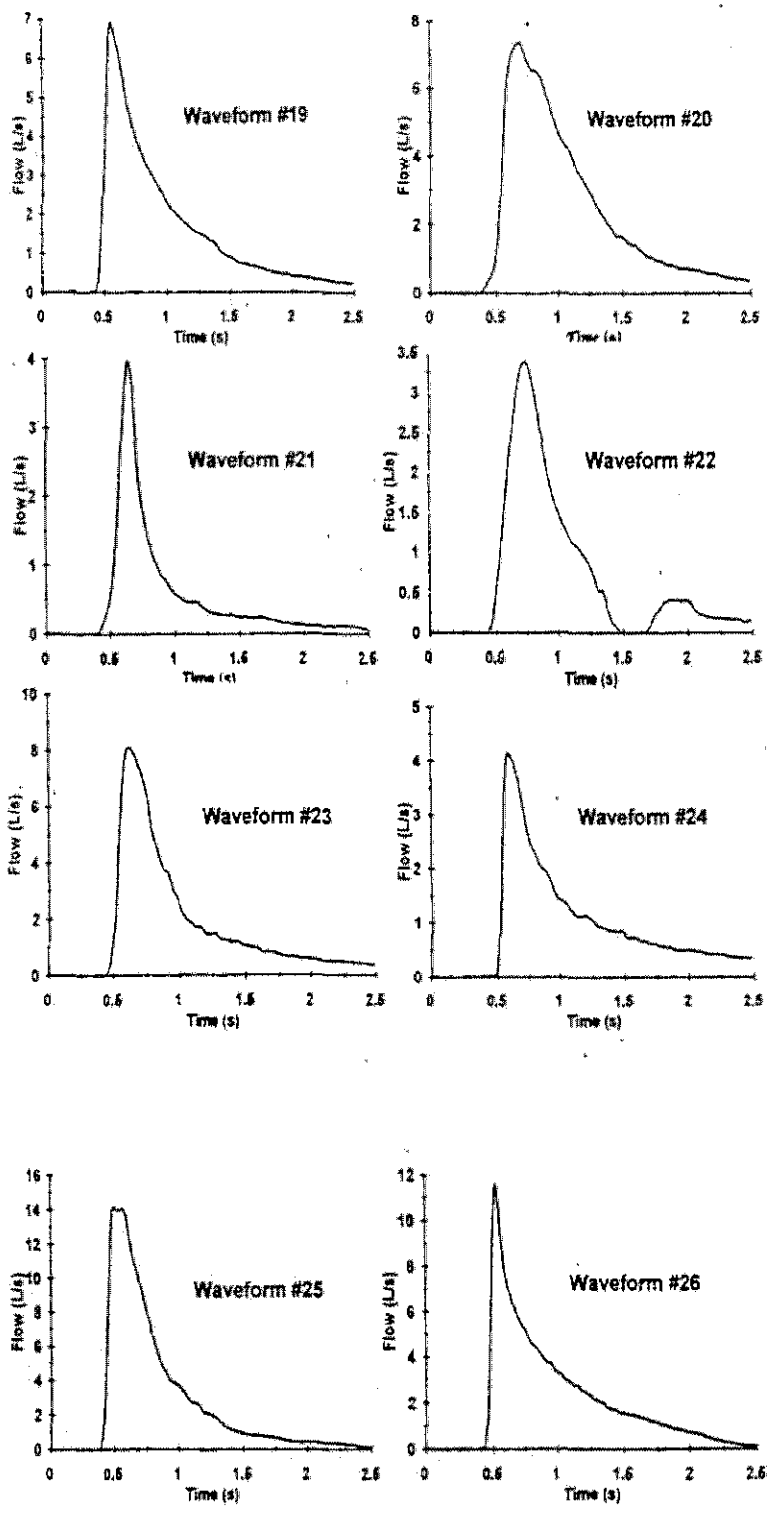
results in artificially lower time-to-PEF, as can be seen in waveform 7.

APPENDIX E

Signal-Processing Tutorial

Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (79), a short tutorial on signal processing is presented (Figure E1).

For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer and the flow device with a flow transducer, the signal is sampled by a computer's analog to digital (A-to-D) converter. The ability of these systems to accurately measure the spirogram depends on the volume or flow transducer's linearity, the accuracy and linearity of the electrical transducer (potentiometer), and the resolution of the A-to-D converter. A resolution of 12 bits (1 part in 4,096, raw resolution from 0.003 to 0.004 L) for the A-to-D converter is recommended, although 10 bits (1 part in 1,024, raw resolution from 0.008 to 0.016 L) may be adequate for sampling volume. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (19) have shown


Waveform #19
Waveform #20
Waveform #21
Waveform #22
Waveform #23
Waveform #24
Waveform #25
Waveform #26
Flow (L/s)
Time (s)

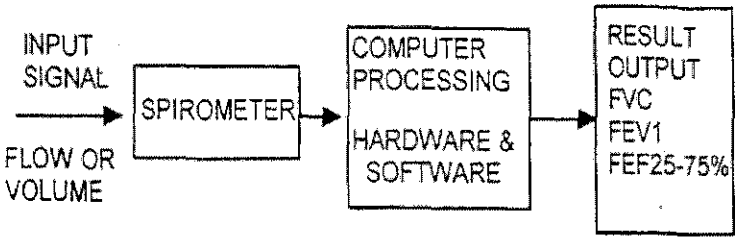


Figure E1. Block diagram of spirometer data acquisition.

that for both infants and adults, 95% of the signal energy in the flow-time spirogram is within a bandwidth of zero to 12 Hz. For the volume-time curve, 95% of the signal energy is contained from zero to 6 Hz. Digital sampling theory requires that samples be taken at least twice the rate of the highest frequency contained in the signal (81). Thus for volume-time spirograms, a 12-Hz sampling rate should be adequate. However, most volume-time spirograms are sampled at a 100-Hz or greater rate to make measurements easier and more accurate. Computer system developers should be aware that even with 100-Hz sampling, it may be necessary to linearly interpolate between sampling points to determine accurate FEV_1, $FEF_{25-75\%}$, and other similar spirometric measures.

Volume sampling techniques with optical and shaft or position encoders of the volume-time signal have been used (80). This approach measures the time interval between uniform volume intervals (for example, 0.010 L). In this case, the resolution of the time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (80). For example, if a resolution of flow to within ± 5% of reading at 12 L/s for a system with 0.010-L resolution is required, then a clock resolution of at least 40 μs is needed (80).

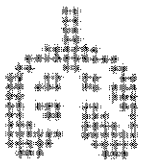
References

1. American Thoracic Society. 1979. Standardization of spirometry. *Am. Rev. Respir. Dis.* 119:831–838.
2. American Thoracic Society. 1987. Standardization of spirometry: 1987 update. *Am. Rev. Respir. Dis.* 136:1286–1296.
3. American Thoracic Society. 1991. Lung function testing: selection of reference values and interpretative strategies. *Am. Rev. Respir. Dis.* 144:1202–1218.
4. Quanjer, P. H., G. J. Tammeling, J. E. Cotes, R. Pedersen, R. Peslin, and J. C. Yernault. 1993. Lung volumes and forced ventilatory flows: report of working party, standardization of lung function tests, European Community for Steel and Coal – official statement of the European Respiratory Society. *Eur. Respir. J.* 6(Suppl. 16):5–40.
5. National Asthma Education Program. October 1992. Expert panel report on diagnosis and management of asthma. U.S. Government Printing Office, Washington, DC. NIH Publication No. 92-2113A.
6. U.S. Department of Health and Human Services. June 1992. International consensus report on the diagnosis and treatment of asthma. U.S. Government Printing Office, Washington, DC. DHHS Publication No. 92-3091.
7. 1993. Guidelines on the management of asthma: statement by the British Thoracic Society, the British Paediatric Association, the Research Unit of the Royal College of Physicians of London, the King's Fund Centre, the National Asthma Campaign, *et al. Thorax* 48(Suppl.): S1–S24.
8. Enright, P. L., L. J. Johnson, J. E. Connett, H. Voelker, and A. S. Buist. 1991. Spirometry in the Lung Health Study: methods and quality control. *Am. Rev. Respir. Dis.* 143:1215–1223.
9. Crapo, R. O. 1994. Pulmonary-function testing. *N. Engl. J. Med.* 331: 25–30.
10. Renzetti, A. D., Jr., E. R. Bleecker, G. R. Epler, R. N. Jones, R. E. Kanner, and L. H. Repsher. 1986. Evaluation of impairment/disability secondary to respiratory disorders. *Am. Rev. Respir. Dis.* 133: 1205–1209.
11. Hankinson, J. L. 1986. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance, and interpretation. *J. Occup. Med.* 28:1081–1092.
12. 1975. Pulmonary terms and symbols: a report of the ACCP-ATS Joint Committee on Pulmonary Nomenclature. *Chest* 67:583–593.
13. 1994 Topical review: guidelines for the measurement of respiratory function – recommendations of the British Thoracic Society and the Association of Respiratory Technicians and Physiologists. *Respir. Med.* 88:165–194.
14. Smith, A. A., and E. A. Gaensler. 1975. Timing of forced expiratory volume in one second. *Am. Rev. Respir. Dis.* 112:882.
15. Morris, A. H., R. E. Kanner, R. O. Crapo, and R. M. Gardner. July 1984. Clinical Pulmonary Function Testing: A Manual of Uniform Laboratory Procedures, 2nd ed. Intermountain Thoracic Society, Salt Lake City.
16. E. P. Horvath, Jr., editor. 1981. Manual of Spirometry in Occupational Medicine. National Institutes for Occupational Safety and Health, Cincinnati.
17. Hankinson, J. L., and R. M. Gardner. 1982. Standard waveforms for spirometer testing. *Am. Rev. Respir. Dis.* 126:362–364.
18. Hankinson, J. L., and R. O. Crapo. 1995. Flow-time standard waveforms for testing PEF. *Am. J. Respir. Crit. Care Med.* 696–701.
19. Lemen, R. J., C. B. Gerdes, M. J. Wegmann, and K. J. Perrin. 1982. Frequency spectra of flow and volume events for forced vital capacity. *J. Appl. Physiol.* 53:977–984.
20. Peslin, R., A. Jardin, A. Bohadana, and B. Hannahard. 1982. Harmonic content of the flow signal during forced expiration in normal man. *Bull. Eur. Physiopath. Respir.* 18:491–500.
21. Jensen, R. L., R. O. Crapo, R. T. Jackson, and S. L. Berlin. 1991. Evaluation of peak flow meter precision using a computerized pump. *Am. Rev. Respir. Dis.* 143:A347.
22. Shapiro, S. M., J. M. Hendler, R. G. Ogirala, T. K. Aldrich, and M. B. Shapiro. 1992. An evaluation of the accuracy of Assess and miniWright peak flow meters. *Chest* 99:358–362.
23. Hankinson, J. L., M. S. Pillos, K. B. Kinsley, and E. L. Petsonk. 1993. Comparison of miniWright and spirometer measurements of peak flow. *Am. Rev. Respir. Dis.* 147:A115.
24. Glindmeyer, H. W., R. N. Jones, H. W. Barkman, and H. Weill. 1987. Spirometry: quantitative test criteria and test acceptability. *Am. Rev. Respir. Dis.* 136:449–452.
25. Brown, L. K., A. Miller, M. Pilipski, and T. S. Lau. 1995. Forced mid-expiratory time: reference values and the effect of smoking. *Lung* (In press)
26. Section of pulmonary function specifications. *Federal Register*, February 12, 1973; 38:4265.
27. Hansen, L. M., O. F. Pedersen, S. Lyager, and N. Naerra. 1983. Differences in vital capacity due to the methods employed (in Danish). *Ugerkr. Laeger* 145:2752–2756.
28. Krowka, M. J., P. L. Enright, J. R. Rodarte, and R. E. Hyatt. 1987. Effect of effort on measurement of forced expiratory volume in one second. *Am. Rev. Respir. Dis.* 136:829–833.
29. Morgan, K. C. 1975. The assessment of ventilatory capacity (committee

recommendations). *Chest* 67:95–97.
50. Gardner, R. M., R. O. Crapo, R. G. Billings, J. W. Shigeoka, and J. L. Hankinson. 1983. Spirometry: what paper speed? *Chest* 84:161–165.
51. Occupational Safety and Health Administration. 1980. Pulmonary function standards for cotton dust: 29 Code of Federal Regulations: 1910. 1043 Cotton Dust. Appendix D: 808–832.
52. Hankinson, J. L., and J. O. Viola. 1983. Dynamic atps correction factors for spirometric data. *J. Appl. Physiol.* 44:1354–1360.
53. Hankinson, J. L., R. M. Castellan, K. B. Kinsley, and D. G. Kemmg. 1986. Effects of spirometer temperature on FEV, shift changes. *J. Occup. Med.* 28:1222–1225.
54. Pincock, A. C., and M. R. Miller. 1983. The effect of temperature on recording spirograms. *Am. Rev. Respir. Dis.* 128:894–898.
55. Hankinson, J. L., J. O. Viola, E. L. Petsonk, and T. R. Ebeling. 1994. BTPS correction for ceramic flow sensors. *Chest* 105:1481–1486.
56. Miller, M. R., and A. C. Pincock. 1986. Linearity and temperature control of the Fleisch pneumotachometer. *J. Appl. Physiol.* 60:710–715.
57. Perks, W. H., T. Sopwith, D. Brown, C. H. Jones, and M. Green. 1983. Effects of temperature on vitalograph spirometer readings. *Thorax* 38:592–594.
58. Cole, P. 1954. Recordings of respiratory air temperature. *J. Laryngol.* 68:295–307.
59. Madan, I., P. Bright, and M. R. Miller. 1993. Expired air temperature at the mouth during a maximal forced expiratory manoevre. *Eur. Respir. J.* 6:1556–1562.
60. Johnson, L. R., P. L. Enright, H. T. Voelker, and D. P. Tashkin. 1994. Volume spirometers need automated internal temperature sensors. *Am. J. Respir. Crit. Care Med.* 150:1575–1580.
61. Association for the Advancement of Medical Instrumentation. October 1980. Standard for Spirometers (draft). AAMI, Arlington, Virginia.
62. Nelson, S. B., R. M. Gardner, R. O. Crapo, and R. L. Jensen. 1990. Performance evaluation of contemporary spirometers. *Chest* 97:288–297.
63. Gardner, R. M., J. L. Hankinson, and B. J. West. 1986. Evaluating commercially available spirometers. *Am. Rev. Respir. Dis.* 134:626–627.
64. Gardner, R. M., J. L. Clausen, R. O. Crapo, G. R. Epler, J. L. Hankinson, R. L. Johnson, Jr., and A. L. Plummer. 1986. Quality assurance in pulmonary function laboratories. *Am. Rev. Respir. Dis.* 134:626–627.
65. Tablan, O. C., W. W. Williams, and W. J. Martone. 1985. Infection control in pulmonary function laboratories. *Infect. Control* 6:442–444.
66. Kirk, Y. L., K. Kenday, H. A. Ashworth, and P. R. Hunter. 1992. Laboratory evaluation of a filter for the control of cross-infection during pulmonary function testing. *J. Hosp. Infect.* 20:193–198.
67. Denison, D. M., D. S. Cramer, and P. J. V. Hanson. 1989. Lung function testing and AIDS. *Respir. Med.* 83:133–138.
68. Rutala, D. R., W. A. Rutala, D. J. Weber, and C. A. Thomann. 1991. Infection risks associated with spirometry. *Infect. Control Hosp. Epidemiol.* 12:89–92.
69. Leeming, J. P., A. H. Kendrick, D. Pryce-Roberts, D. Smith, and E. C. Smith. 1993. Use of filters for the control of cross-infection during pulmonary function testing. *J. Hosp. Infect.* 23:245–246.
70. Hazaleus, R. E., J. Cole, and M. Berdischewsk. 1981. Tuberculin skin test conversion from exposure to contaminated pulmonary function testing apparatus. *Respir. Care* 26:53–55.
71. Isles, A., I. Maclusky, M. Corey, R. Gold, C. Prober, P. Fleming, and H. Levison. 1984. *Pseudomonas cepacia* in cystic fibrosis: an emerging problem. *J. Pediatr.* 104:206–210.
72. Burgos, F., C. Martinez, and J. Torres. 1993. *Am. Rev. Respir. Dis.* 147:A400.
73. du Moulin, G. C., K. D. Stottmeier, P. A. Pelletier, A. Y. Tsang, and J. Hedley-White. 1988. Concentration of *Mycobacterium avium* by hospital hot water systems. *J.A.M.A.* 260:1599–1601.
74. von Reyn, C. F., R. D. Waddell, T. Eaton, R. D. Arbeit, J. N. Maslow, T. W. Barber, R. J. Brindle, C. F. Gilks, J. Lumio, J. Ladevinta, A. Ranki, D. Dawson, and J. D. Falkinham III. 1993. Isolation of *Mycobacterium avium* complex from water in the United States, Finland, Zaire, and Kenya. *J. Clin. Microbiol.* 31:3227–3230.
75. Eichorn, J. H., M. L. Bancroff, H. Laasberg, G. C. du Moulin, and A. J. Saubermann. 1977. Contamination of medical gas and water pipelines in a new hospital building. *Anesthesiology* 46:286–289.
76. Townsend, M. C. 1984. The effects of leaks in spirometers on measurement of pulmonary function. *J. Occup. Med.* 26:835–841.
77. Crapo, R. O., R. M. Gardner, S. L. Berlin, and A. H. Morris. 1986. Automation of pulmonary function equipment: user beware! *Chest* 90:1–2.
78. Gardner, R. M., J. L. Clausen, D. J. Cotton, R. D. Crapo, G. R. Epler, J. L. Hankinson, and R. L. Johnson. 1986. Computer guidelines for pulmonary laboratories. *Am. Rev. Respir. Dis.* 134: 628–629.
79. Gardner, R. M., J. L. Clausen, G. Epler, J. L. Hankinson, S. Permutt, and A. L. Plummer. 1986. Pulmonary function laboratory personnel qualifications. *Am. Rev. Respir. Dis.* 134:623–624.
80. American Thoracic Society. 1978. ATS respiratory care committee position paper: director of pulmonary function laboratory. *ATS News* 4:6.
81. Make, B. 1979. Minimum criteria for training course in spirometric testing in industry. *Bull. Am. Coll. Chest Phys.* 18:24–26.
82. Enright, P. L., and R. D. Hyatt. 1987. Office Spirometry. Lea & Febiger, Philadelphia.
83. Wanger, J. 1992. Pulmonary Function Testing: A Practical Approach. Williams & Wilkins, Baltimore.
84. Paoletti, P., G. Pistelli, P. Fazzi, G. Viegi, F. DiPede, Prediletto, L. Carrozzi, R. Polato, M. Saetta, R. Zambon, T. Sagiani, M. D. Lebowitz, and C. Giuntini. 1986. Reference values for vital capacity and flow-volume curves from a general population study. *Bull. Eur. Physiopathol. Respir.* 22:451–459.
85. D'Angelo, E., E. Prandi, and J. Milic-Emili. 1993. Dependence of maximal flow-volume curves on time course of preceding inspiration. *J. Appl. Physiol.* 75:1155–1159.
86. Hankinson, J. L. 1993. Instrumentation for spirometry. *In* E. A. Eisen, editor. Occupational Medicine: State of the Art Reviews, Vol. 8, Hanley and Belfus, Philadelphia. 397–407.
87. Eisen, E. A., J. M. Robins, I. A. Greaves, and D. H. Wegman. 1984. Selection effects of repeatability criteria applied to lung spirometry. *Am. J. Epidemiol.* 120:734.
88. Eisen, E. A., L. C. Oliver, D. C. Christiani, J. M. Robins, and D. H. Wegman. 1985. Effects of spirometry standards in two occupational cohorts. *Am. Rev. Respir. Dis.* 132:120.
89. Kellie, S. E., M. D. Attfield, J. L. Hankinson, and R. M. Castellan. 1987. The ATS spirometry variability criteria: associations with morbidity and mortality in an occupational cohort of coal miners. *Am. J. Epidemiol.* 125:437–444.
90. Ferris, B. G., Jr., F. E. Speizer, Y. Bishop, G. Prang, and J. Weenet. 1978. Spirometry for an epidemiologic study: deriving optimum summary statistics for each subject. *Bull. Eur. Physiopathol. Respir.* 14:146–166.
91. Kanner, R. E., M. B. Schenker, A. Munoz, and F. E. Speizer. 1983. Spirometry in children: methodology for obtaining optimal results for clinical and epidemiological studies. *Am. Rev. Respir. Dis.* 127:720–724.
92. Liese, W., W. J. Warwick, and G. Cumming. 1974. Water vapour pressure in expired air. *Respiration* 31:252–261.
93. Townsend, M. C. 1984. Spirometric forced expiratory volumes measured in the standing versus the sitting position. *Am. Rev. Respir. Dis.* 103:123–124.
94. Ferris, B. G. 1978. Epidemiology standardization project: recommended standardized procedures for pulmonary function testing. *Am. Rev. Respir. Dis.* 118(part 2):55–88.
95. Townsend, M. C., A. G. DuChene, and R. J. Fallat. 1982. The effects of underrecording forced expirations on spirometric lung function indexes. *Am. Rev. Respir. Dis.* 126:734–737.
96. Pennock, B. E., R. M. Rogers, and D. R. McCaffree. 1981. Changes in measured spirometric indices: what is significant? *Chest* 80:97.
97. Hankinson, J. L., and K. M. Bang. 1991. Acceptability and reproducibility criteria of the American Thoracic Society as observed in a sample of the general population. *Am. Rev. Respir. Dis.* 143:516–521.
98. National Institute for Occupational Safety and Health. August 1991. Draft Spirometry Training Guide. National Institute for Occupational Safety and Health and the Universities Occupational Safety and Health Educational Resource Center, Continuing Education and Outreach Program, University of Medicine and Dentistry of New Jersey.
99. Nelson, S. B. 1987. Commercially Available Spirometers: Performance Evaluation. University of Utah. Thesis.
100. Ostler, D. V., R. M. Gardner, and R. O. Crapo. 1984. A computer system for analysis and transmission of spirometry waveforms using volume sampling. *Comput. Biomed. Res.* 17:229–240.
101. Jerri, A. J. 1977. The Shannon sampling theorem: its various extension and applications—a tutorial review. *Proc. IEEE* 65:1565–1596.

Appendix G—ATS-ERS Interpretative Strategies for Lung Function Tests

Eur Respir J 2005; 26: 948–968
DOI: 10.1183/09031936.05.00035205



SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING"
Edited by V. Brusasco, R. Crapo and G. Viegi
Number 5 in this Series

Interpretative strategies for lung function tests

R. Pellegrino, G. Viegi, V. Brusasco, R.O. Crapo, F. Burgos, R. Casaburi, A. Coates, C.P.M. van der Grinten, P. Gustafsson, J. Hankinson, R. Jensen, D.C. Johnson, N. MacIntyre, R. McKay, M.R. Miller, D. Navajas, O.F. Pedersen and J. Wanger

CONTENTS

AFFILIATIONS
For affiliations, please see Acknowledgements section.

CORRESPONDENCE
V. Brusasco
Internal Medicine
University of Genoa
V.le Benedetto XV, 6
Genova I-16132
Italy
Fax: 39 0103537690
E-mail: vito.brusasco@unige.it

Received:
March 24 2005
Accepted:
April 05 2005

KEYWORDS: **Bronchodilator, diffusing capacity, lung volume measurements, spirometry, reference values, ventilatory defects**

BACKGROUND

This section is written to provide guidance in interpreting pulmonary function tests (PFTs) to medical directors of hospital-based laboratories that perform PFTs, and physicians who are responsible for interpreting the results of PFTs most commonly ordered for clinical purposes. Specifically, this section addresses the interpretation of spirometry, bronchodilator response, carbon monoxide diffusing capacity (*D*L,CO) and lung volumes.

The sources of variation in lung function testing and technical aspects of spirometry, lung volume measurements and *D*L,CO measurement have been considered in other documents published in this series of Task Force reports [1–4] and in the American Thoracic Society (ATS) interpretative strategies document [5].

An interpretation begins with a review and comment on test quality. Tests that are less than optimal may still contain useful information, but interpreters should identify the problems and the

Previous articles in this series: No. 1: Miller MR, Crapo R, Hankinson J, *et al.* General considerations for lung function testing. *Eur Respir J* 2005; 26: 153–161. **No. 2:** Miller MR, Hankinson J, Brusasco V, *et al.* Standardisation of spirometry. *Eur Respir J* 2005; 26: 319–338. **No. 3:** Wanger J, Clausen JL, Coates A, *et al.* Standardisation of the measurement of lung volumes. *Eur Respir J* 2005; 26: 511–522. **No. 4:** MacIntyre N, Crapo RO, Viegi G, *et al.* Standardisation of the single-breath determination of carbon monoxide uptake in the lung. *Eur Respir J* 2005; 26: 720–735.

European Respiratory Journal
Print ISSN 0903-1936
Online ISSN 1399-3003

direction and magnitude of the potential errors. Omitting the quality review and relying only on numerical results for clinical decision making is a common mistake, which is more easily made by those who are dependent upon computer interpretations.

Once quality has been assured, the next steps involve a series of comparisons [6] that include comparisons of test results with reference values based on healthy subjects [5], comparisons with known disease or abnormal physiological patterns (*i.e.* obstruction and restriction), and comparisons with self, a rather formal term for evaluating change in an individual patient. A final step in the lung function report is to answer the clinical question that prompted the test.

Poor choices made during these preparatory steps increase the risk of misclassification, *i.e.* a falsely negative or falsely positive interpretation for a lung function abnormality or a change in lung function. Patients whose results are near the thresholds of abnormality are at a greatest risk of misclassification.

REFERENCE EQUATIONS

General issues

Interpretation of PFTs is usually based on comparisons of data measured in an individual patient or subject with reference (predicted) values based on healthy subjects. Predicted values should be obtained from studies of "normal" or "healthy" subjects with the same anthropometric (*e.g.* sex, age and height) and, where relevant, ethnic characteristics of the patient being tested. Ideally, reference values are calculated with equations derived from measurements observed in a representative sample of healthy subjects in a general population. Reference equations can also be derived from large groups of volunteers, provided that criteria for normal selection and proper distribution of anthropometric characteristics are satisfied. Criteria to define subjects as "normal" or healthy have been discussed in previous ATS and European Respiratory Society (ERS) statements [5, 7, 8].

Height and weight should be measured for each patient at the time of testing; technicians should not rely on stated height or weight. Height should be measured with a stadiometer, with shoes off, using standard techniques (patient standing erect with the head in the Frankfort horizontal plane) [9]. When height cannot be measured, options include using stated height or estimating height from arm span, as indicated in a previous document from this series and other publications [1, 10, 11].

Specific recommendations for selecting reference values to be used in any lung function laboratory have also been discussed [3]. These include the following: matching age-range, anthropometric, race/ethnic, socio-economic and environmental characteristics between subjects investigated by the laboratory and the reference population from which the prediction equations have been drawn; using similar instruments and lung function protocols in the reference population as in the laboratory; and using reference values derived by valid and biologically meaningful statistical models, taking into account the dependence of lung function with age. If possible, all parameters should be taken from the same reference source. For example, forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and FEV_1/FVC should come from the same reference source.

The subjects being tested should be asked to identify their own race/ethnic group, and race/ethnic-specific reference equations should be used whenever possible. If such equations are not available or are unsuitable for a particular setting, a race/ethnic adjustment factor based on published data may be used for lung volumes. The use of adjustment factors is not as good as specific race/ethnic equations [12]. An example of adjustment factors is the finding that populations using standing height as the measure of size tend to overpredict values measured in Black subjects by ~12% for total lung capacity (TLC), FEV_1 and FVC, and by ~7% for functional residual capacity (FRC) and residual volume (RV) [5]. A race/ethnic adjustment factor of 0.94 is also recommended for Asian Americans based on two recent publications [13, 14]. Such adjustment factors should not be applied to the FEV_1/FVC or FEV_1/vital capacity (VC) ratios. The use of sitting height does not completely account for race/ethnic differences in pulmonary function [15]. If a race adjustment factor is used, a statement should be included in the report, along with the race adjustment value used.

Differences in the evaluation of lung function using different sets of reference equations have been documented [16, 17]. Ideally, spirometric reference values should be derived from a population similar to the individual subject using the same kind of instrument and testing procedure.

There have been recommendations to compare selected reference equations with measurements performed on a representative sample of healthy subjects tested in each laboratory. The reference equation that provides the sum of residuals (observed – predicted computed for each adult subject, or log observed – log predicted for each subject in the paediatric age range) closest to zero will be the most appropriate for that laboratory [7]. However, for spirometry, a relatively large number of subjects (*i.e.* n=100) is necessary to be confident that a significant difference between the published reference equations and the values from the local community does not exist [18]. Therefore, the suggestion is impractical for most laboratories.

When using a set of reference equations, extrapolation beyond the size and age of investigated subjects should be avoided [7]. If a patient's age or height is outside the limits of the reference population, a statement in the interpretation should indicate that an extrapolation has been made.

Publications on reference equations should include explicit definitions of the upper and lower limits of the normal range, or provide information to allow the reader to calculate a lower range [5]. For each lung function index, values below the 5th percentile of the frequency distribution of values measured in the reference population are considered to be below the expected "normal range" [5]. If the reference data have a normal distribution, the lower 5th percentile can be estimated as the 95% confidence interval using Gaussian statistics. If the distribution is skewed, the lower limit should be estimated with a nonparametric technique, such as the 95th percentile. The practice of using 80% predicted as a fixed value for the lower limit of normal may be acceptable in children, but can lead to important errors when interpreting lung function in adults [5]. The practice of using 0.70 as a lower limit of the

FEV1/FVC ratio results in a significant number of false-positive results in males aged >40 yrs and females >50 yrs [12], as well as in a risk of overdiagnosis of chronic obstructive pulmonary diseases (COPD) in asymptomatic elderly never-smokers [19]. This discussion has been focused on the lower limit of the reference range. Upper limits are appropriate where the variable can be either too high or too low. Such variables include TLC, RV/TLC and $D_{L,CO}$. As equipment and techniques for lung function testing improve, advanced mathematical models to describe lung function data are implemented. Furthermore, the characteristics of the populations of "normal" subjects, with respect to nutrition, health status, environmental conditions and other factors, evolve (a phenomenon also described as "cohort effect"). Consideration should be given to updating reference equations on a regular basis, *e.g.* every 10 yrs, taking into account the applicability of the newer reference equations and the effect on interpretation of longitudinal patient follow-up.

Manufacturers should also provide software that allows users to easily select among a panel of reference equations. They should also allow easy insertion of new equations. The reference values used should be documented on every pulmonary function report with the first author's last name (or organisation) and the date of publication.

Spirometry

The European Community for Coal and Steel (ECCS) [8, 20] and the ATS [5, 21] have both published comprehensive listings of published reference equations for spirometry. A number of additional studies on lung function reference values, dealing with a variety of ethnic/race groups and age ranges, have been published in the last 10 yrs [12, 14, 17, 22, 23].

Spirometric reference equations are usually derived from cross-sectional studies and are subject to "cohort effect". Few authors have published longitudinal equations covering ages from childhood to the elderly [24–26], and there are few published sets of equations that cover volume and flow indices over a wide range of ages [27, 28]. Table 1 includes reference equations published from 1995 to August 2004. The table was created from known equations and a MEDLINE search using the keywords "reference equations" and "spirometry". Its purpose is to recognise and encourage the continuing interest of world-wide researchers in deriving and using reference equations.

In the USA, ethnically appropriate National Health and Nutrition Examination Survey (NHANES) III reference equations are recommended for those aged 8–80 yrs [12]. For children aged <8 yrs, the equations of WANG *et al.* [29] are recommended. Other prediction equations may be used if there are valid reasons for the choice. In Europe, the combined reference equations published in the 1993 ERS statement [8] are often used for people aged 18–70 yrs, with a height range of 155–195 cm in males, and 145–180 cm in females, and those from QUANJER *et al.* [30] in paediatric ages. Currently, this committe does not recommend any specific set of equations for use in Europe, but suggests the need for a new Europe-wide study to derive updated reference equations for lung function.

Lung volumes

Lung volumes are related to body size, and standing height is the most important correlating variable. In children and adolescents, lung growth appears to lag behind the increase in standing height during the growth spurt, and there is a shift in the relationship between lung volume and height during adolescence [31, 32]. Height growth in young males between 12.5 and 18 yrs of age peaks ~1 yr before the growth rate of weight and FVC, and ~1.5 yrs before the growth rate of maximum flow at 50% FVC. In young females, growth rates of all spirometric indices decrease over the same age range. Using simple allometric relationships between stature and lung volumes, volume predictions are too high in the youngest age group and too low in the oldest adolescents.

Furthermore, for the same standing height, young males have greater lung function values than young females, and Whites have greater values than Blacks. Lung function increases linearly with age until the adolescent growth spurt at age ~10 yrs in females and 12 yrs in males. The pulmonary function *versus* height relationship shifts with age during adolescence. Thus, a single equation or the pulmonary function–height growth chart alone does not completely describe growth during the complex adolescent period. Nevertheless, race- and sex-specific growth curves of pulmonary function *versus* height make it easy to display and evaluate repeated measures of pulmonary function for an individual child [29].

Details of reference populations and regression equations for children and adolescents are summarised by QUANJER *et al.* [30]. Lung volume reference equations have been frequently derived from relatively small populations (<200 children) over a 6–12-yr age range when growth and developmental changes are extremely rapid. Relatively few studies have taken puberty or age into account.

A comprehensive listing of published reference equations for lung volumes was published in 1983 by the ECCS [20] and updated in 1993 [8]. A set of equations was created by combining the equations in this list with the intent to use the combined equations for adults aged 18–70 yrs with a height range of 155–195 cm in males, and 145–180 cm in females.

A report on an ATS workshop on lung volume measurements [7] reviewed published reference values in infants, pre-school children, children, adolescents and adults, and gave recommendations for selecting reference values, expressing results, measuring ancillary variables and designing future studies. Most reference equations for children are derived from Caucasian populations.

Differences due to ethnicity are not well defined [33–36]. These differences may be explained, in part, by differences in trunk length relative to standing height, but there are also differences in fat-free mass, chest dimensions and strength of respiratory muscles. Until better information is available, correction factors for Black and Asian children could be the same as those recommended for adults [7]. Reference values for RV, VC and TLC are, on average, 12% lower in Blacks than in Whites [35]; this difference may be smaller in elderly persons than in young adults [36]. Reference values for absolute lung volumes for adults of Asian ethnicity are generally considered to be lower than for Whites, but the magnitude of the differences is not well defined, and the difference may be less in Asians raised on "Western" diets during childhood [37]. According to the

Special attention must be paid when FEV1 and FVC are concomitantly decreased and the FEV1/FVC ratio is normal or almost normal. This pattern most frequently reflects failure of the patient to inhale or exhale completely. It may also occur when the flow is so slow that the subject cannot exhale long enough to empty the lungs to RV. In this circumstance, the flow–volume curve should appear concave toward the end of the manoeuvre. TLC will be normal and FEF_{75} will be low. Measurement of slow VC (inspiratory or expiratory) may then give a more correct estimate of the FEV1/VC ratio. Another possible cause of this pattern is patchy collapse of small airways early in exhalation [8, 49–52]. Under these conditions, TLC may be normal, but RV is ordinarily increased. A typical example is shown in figure 1b. When this pattern is observed in a patient performing a maximal, sustained effort, it may be useful to repeat spirometry after treatment with an inhaled bronchodilator. Significant improvement in the FEV1, FVC or both would suggest the presence of reversible airflow obstruction.

Apart from this unusual circumstance, measurement of lung volumes is not mandatory to identify an obstructive defect. It may, however, help to disclose underlying disease and its functional consequences. For example, an increase in TLC, RV or the RV/TLC ratio above the upper limits of natural variability may suggest the presence of emphysema, bronchial asthma or other obstructive diseases [47], as well as the degree of lung hyperinflation.

Airflow resistance is rarely used to identify airflow obstruction in clinical practice. It is more sensitive for detecting narrowing of extrathoracic or large central intrathoracic airways than of more peripheral intrathoracic airways [47]. It may be useful in patients who are unable to perform a maximal forced expiratory manoeuvre.

Restrictive abnormalities

A restrictive ventilatory defect is characterised by a reduction in TLC below the 5th percentile of the predicted value, and a normal FEV1/VC. A typical example is shown in figure 1c. The presence of a restrictive ventilatory defect may be suspected when VC is reduced, the FEV1/VC is increased (>85–90%) and the flow–volume curve shows a convex pattern. Once again, the pattern of a reduced VC and a normal or even slightly increased FEV1/VC is often caused by submaximal inspiratory or expiratory efforts and/or patchy peripheral airflow obstruction, and a reduced VC by itself does not prove a restrictive ventilatory defect. It is associated with a low TLC no more than half the time [53, 54].

Pneumothorax and noncommunicating bullae are special cases characterised by a normal FEV1/VC and TLC measured in a body plethysmograph, but low FEV1 and VC values. In these conditions, TLC assessed by gas dilution techniques will be low.

A low TLC from a single-breath test (such as V_A from the $D_{L,CO}$ test) should not be interpreted as demonstrating restriction, since such measurements systematically underestimate TLC [55]. The degree of underestimation increases as airflow obstruction worsens. In the presence of severe airflow obstruction, TLC can be underestimated by as much as 3 L, greatly increasing the risk of misclassification of the type of PFT abnormality [55, 56]. A method of adjusting the single-breath V_A for the effect of airway obstruction has been published, but needs further validation [57].

Mixed abnormalities

A mixed ventilatory defect is characterised by the coexistence of obstruction and restriction, and is defined physiologically when both FEV1/VC and TLC are below the 5th percentiles of their relevant predicted values. Since VC may be equally reduced in both obstruction and restriction, the presence of a restrictive component in an obstructed patient cannot be inferred from simple measurements of FEV1 and VC. A typical example is presented in figure 1d. If FEV1/VC is low and the largest measured VC (pre- or post-bronchodilator VC or V_I in the $D_{L,CO}$ test) is below its lower limits of normal (LLN), and there is no measurement of TLC by body plethysmography, one can state that the VC was also reduced, probably due to hyperinflation, but that a superimposed restriction of lung volumes cannot be ruled out [58]. Conversely, when FEV1/VC is low and VC is normal, a superimposed restriction of lung volumes can be ruled out [53, 54].

Table 5 shows a summary of the types of ventilatory defects and their diagnoses.

COMMENTS ON INTERPRETATION AND PATTERNS OF DYSFUNCTION

The definition of an obstructive pulmonary defect given in the present document is consistent with the 1991 ATS statement on interpretation [5], but contrasts with the definitions suggested by both Global Initiative for Chronic Obstructive Lung Disease (GOLD) [59] and ATS/ERS guidelines on COPD [60], in that FEV1 is referred to VC rather than just FVC and the cut-off value of this ratio is set at the 5th percentile of the normal distribution rather than at a fixed value of 0.7. This committee feels that the advantage of using VC in place of FVC is that the ratio of FEV1 to VC is capable of accurately identifying more obstructive patterns than its ratio to FVC, because FVC is more dependent on flow and volume histories [61]. In contrast with a fixed value of 0.7, the use of the 5th percentile does not lead to an overestimation of the ventilatory defect in older people with no history of exposure to noxious particles or gases [62].

The assumption that a decrease in major spirometric parameters, such as FEV1, VC, FEV1/VC and TLC, below their relevant 5th percentiles is consistent with a pulmonary defect is a useful simple approach in clinical practice. Problems arise, however, when some or all of these variables lie near their upper limits of normal or LLN. In these cases, a literal interpretation of the functional pattern is too simplistic and could fail to properly describe the functional status.

The current authors suggest that additional studies should be done in these circumstances if they are indicated by the clinical problem being addressed. Such tests could include bronchodilator response, $D_{L,CO}$, gas-exchange evaluation, measurement of respiratory muscle strength or exercise testing.

Caution is also recommended when TLC is at the LLN and coexists with a disease expected to lead to lung restriction. A typical example is lung resection. The expected restrictive defect would be difficult to prove on the simple basis of TLC as per cent of predicted if the latter remains above the 5th

TABLE 5 Types of ventilatory defects and their diagnoses

Abnormality	Diagnosis
Obstruction	FEV1/VC <5th percentile of predicted
	A decrease in flow at low lung volume is not specific for small airway disease in individual patients
	A concomitant decrease in FEV1 and VC is most commonly caused by poor effort, but may rarely reflect airflow obstruction. Confirmation of airway obstruction requires measurement of lung volumes
	Measurement of absolute lung volumes may assist in the diagnosis of emphysema, bronchial asthma and chronic bronchitis. It may also be useful in assessing lung hyperinflation
	Measurements of airflow resistance may be helpful in patients who are unable to perform spirometric manoeuvres
Restriction	TLC <5th percentile of predicted
	A reduced VC does not prove a restrictive pulmonary defect. It may be suggestive of lung restriction when FEV1/VC is normal or increased
	A low T_LC from a single-breath test should not be seen as evidence of restriction
Mixed defect	FEV1/VC and TLC <5th percentile of predicted

FEV1: forced expiratory volume in one second; VC: vital capacity; TLC: total lung capacity.

percentile of predicted as a result of subsequent lung growth or of a large TLC before surgery. Similar care must be taken in cases where diseases with opposing effects on TLC coexist, such as interstitial lung disease (ILD) and emphysema.

While patterns of physiological abnormalities can be recognised, they are seldom pathognomonic for a specific disease entity. The types of clinical illness most likely to produce an observed set of physiological disturbances can be pointed out. Regardless of the extent of testing, it is important to be conservative in suggesting a specific diagnosis for an underlying disease process based only on pulmonary function abnormalities.

The VC, FEV1, FEV1/VC ratio and TLC are the basic parameters used to properly interpret lung function (fig. 2). Although FVC is often used in place of VC, it is preferable to use the largest available VC, whether obtained on inspiration (IVC), slow expiration (SVC) or forced expiration (*i.e.* FVC). The FVC is usually reduced more than IVC or SVC in airflow obstruction [61]. The FEV6 may be substituted for VC if the appropriate LLN for the FEV1/FEV6 is used (from the NHANES III equations) [12, 63]. Limiting primary interpretation of spirograms to VC, FEV1 and FEV1/VC avoids the problem of simultaneously examining a multitude of measurements to see if any abnormalities are present, a procedure leading to an inordinate number of "abnormal" tests, even among the healthiest groups in a population [64, 65]. When the rate of abnormality for any single test is only 5%, the frequency of at least one abnormal test was shown to be 10% in 251 healthy subjects when the FEV1, FVC and FEV1/FVC ratio were examined and increased to 24% when a battery of 14 different spirometric measurements were analysed [23]. It should be noted, however, that additional parameters, such as the peak expiratory flow (PEF) and maximum inspiratory flows, may assist in diagnosing extrathoracic airway obstruction.

The most important parameter for identifying an obstructive impairment in patients is the FEV1/VC ratio. In patients with respiratory diseases, a low FEV1/VC, even when FEV1 is within the normal range, predicts morbidity and mortality [66]. For healthy subjects, the meaning of a low FEV1/FVC ratio accompanied by an FEV1 within the normal range is unclear. This pattern is probably due to "dysanaptic" or unequal growth of the airways and lung parenchyma [67] (referred to in a previous ATS document as a possible physiological variant when FEV1 was ⩾100% pred [5]). Whether this pattern represents airflow obstruction will depend on the prior

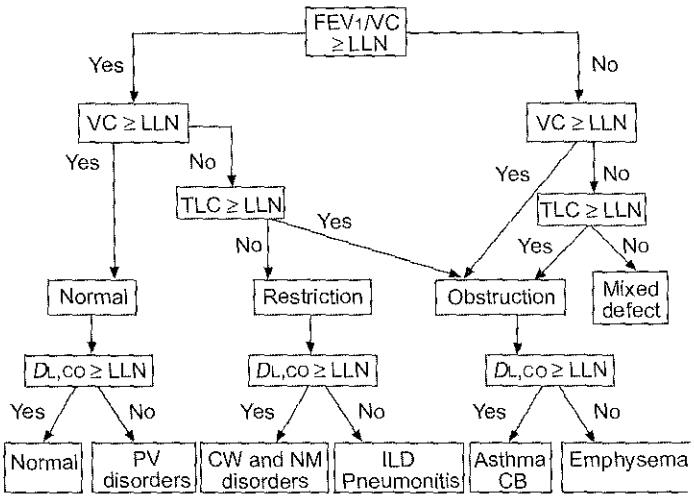


FIGURE 2. A simplified algorithm that may be used to assess lung function in clinical practice. It presents classic patterns for various pulmonary disorders. As in any such diagram, patients may or may not present with the classic patterns, depending on their illnesses, severity and lung function prior to the disease onset (e.g. did they start with a vital capacity (VC) close to the upper or lower limits of normal (LLN)). The decisions about how far to follow this diagram are clinical, and will vary depending on the questions being asked and the clinical information available at the time of testing. The forced expiratory volume in one second (FEV1)/VC ratio and VC should be considered first. Total lung capacity (TLC) is necessary to confirm or exclude the presence of a restrictive defect when VC is below the LLN. The algorithm also includes diffusing capacity for carbon monoxide (D_LCO) measurement with the predicted value adjusted for haemoglobin. In the mixed defect group, the D_LCO patterns are the same as those for restriction and obstruction. This flow chart is not suitable for assessing the severity of upper airway obstruction. PV: pulmonary vascular; CW: chest wall; NM: neuromuscular; ILD interstitial lung diseases; CB: chronic bronchitis.

probability of obstructive disease and possibly on the results of additional tests, such as bronchodilator response, $D_{L,CO}$, gas-exchange evaluation, and measurement of muscle strength or exercise testing. Expiratory flow measurements other than the FEV_1 and FEV_1/VC should be considered only after determining the presence and clinical severity of obstructive impairment using the basic values mentioned previously. When the FEV_1 and FEV_1/VC are within the expected range, the clinical significance of abnormalities in flow occurring late in the maximal expiratory flow–volume curve is limited. In the presence of a borderline value of FEV_1/VC, however, these tests may suggest the presence of airway obstruction. The same is true for average flows, such as mid-expiratory flow ($MEF_{25-75\%}$), especially in children with cystic fibrosis [68, 69]. Even with this limited use, the wide variability of these tests in healthy subjects must be taken into account in their interpretation.

The maximal voluntary ventilation (MVV) is not generally included in the set of lung function parameters necessary for diagnosis or follow-up of the pulmonary abnormalities because of its good correlation with FEV_1 [70]. However, it may be of some help in clinical practice. For example, a disproportionate decrease in MVV relative to FEV_1 has been reported in neuromuscular disorders [71, 72] and UAO [73]. In addition, it is also used in estimating breathing reserve during maximal exercise [74], although its application may be of limited value in mild-to-moderate COPD [75, 76]. For these purposes, the current authors suggest that MVV should be measured rather than estimated by multiplying FEV_1 by a constant value, as is often done in practice.

SEVERITY CLASSIFICATION

A method of categorising the severity of lung function impairment based on the FEV_1 % pred is given in table 6. It is similar to several previous documents, including GOLD [59], ATS 1986 [77], ATS 1991 [5], and the American Medical Association (AMA) [78]. The number of categories and the exact cut-off points are arbitrary.

Severity scores are most appropriately derived from studies that relate pulmonary function test values to independent indices of performance, such as ability to work and function in daily life, morbidity and prognosis [79–82]. In general, the ability to work and function in daily life is related to pulmonary function, and pulmonary function is used to rate impairment in several published systems [77–79, 83]. Pulmonary function level is also associated with morbidity, and the patients with lower function have more respiratory complaints [82].

Lung function level is also associated with prognosis, including a fatal outcome from heart as well as lung disease [84, 85], even in patients who have never smoked [86]. In the Framingham study, VC was a major independent predictor of cardiovascular morbidity and mortality [84, 85]. In several occupational cohorts, FEV_1 and FEV_1/FVC were independent predictors of all-cause or respiratory disease mortality [87–89]. In addition, a meta-analysis of mortality in six surveys in various UK working populations showed that the risk of dying from COPD was related to the FEV_1 level. In comparison to those whose FEV_1 at an initial examination was within 1 SD of average, those whose FEV_1 was >2 SD below average were 12 times more likely to die of COPD, more than 10 times as likely to die of non-neoplastic respiratory disease, and more than twice as likely to die of vascular disease over a 20-yr follow-up period [90]. Although there is good evidence that FEV_1 correlates with the severity of symptoms and prognosis in many circumstances [79, 82, 90], the correlations do not allow one to accurately predict symptoms or prognosis for individual patients.

The $D_{L,CO}$ is also an important predictor of mortality both in the general population [91] and in patients after pulmonary resection [92].

Though the FEV_1 % pred is generally used to grade severity in patients with obstructive, restrictive and mixed pulmonary defects, it has little applicability to patients with UAO, such as tracheal stenosis, where obstruction could be life-threatening and yet be classified as mildly reduced by this scheme. In addition, there is little data documenting the performance of other functional indexes, such as FRC in airflow obstruction or TLC in lung restriction as indices to categorise severity of impairment.

VC is reduced in relation to the extent of loss of functioning lung parenchyma in many nonobstructive lung disorders. It is also of some use in assessing respiratory muscle involvement in certain neuromuscular diseases. VC may be only slightly impaired in diffuse interstitial diseases of sufficient severity to lead to marked loss of diffusing capacity and severe blood gas abnormalities [63]. The onset of a severe respiratory problem in patients with a rapidly progressive neuromuscular disease may be associated with only a small decrement in VC [47, 93].

FEV_1 and FVC may sometimes fail to properly identify the severity of ventilatory defects, especially at the very severe stage for multiple reasons. Among them are the volume history effects of the deep breath preceding the forced expiratory manoeuvre on the bronchial tone and, thus, calibre [94–98], and the inability of these parameters to detect whether tidal breathing is flow limited or not [99–102]. The FEV_1/VC ratio should not be used to determine the severity of an obstructive disorder, until new research data are available. Both the FEV_1 and VC may decline with the progression of disease, and an FEV_1/VC of 0.5/1.0 indicates more impairment than one of 2.0/4.0, although the ratio of both is 50%. While the FEV_1/VC ratio should not routinely be used to determine the severity of an obstructive disorder, it may be of value when persons having genetically large lungs develop obstructive disease. In

TABLE 6 Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV_1)

Degree of severity	FEV_1 % pred
Mild	>70
Moderate	60–69
Moderately severe	50–59
Severe	35–49
Very severe	<35

% pred: % predicted.

these cases, the FEV1/VC ratio may be very low (60%), when the FEV1 alone is within the mild category of obstruction (*i.e.* >70% pred).

Recent studies have stressed the importance of additional measurements in assessing the severity of the disease. For example, when airflow obstruction becomes severe, FRC, RV, TLC and RV/TLC tend to increase as a result of decreased lung elastic recoil and/or dynamic mechanisms [47, 103, 104]. The degree of hyperinflation parallels the severity of airway obstruction [58]. On one hand, lung hyperinflation is of benefit because it modulates airflow obstruction, but, on the other hand, it causes dyspnoea because of the increased elastic load on inspiratory muscles [47]. In a recent investigation, resting lung hyperinflation, measured as inspiratory capacity (IC)/TLC, was an independent predictor of respiratory and all-cause mortality in COPD patients [105]. In addition, in either severe obstructive or restrictive diseases, tidal expiratory flow often impinges on maximum flow [98, 99, 102]. This condition, denoted as expiratory flow limitation during tidal breathing (EFL), is relatively easy to measure in practice by comparing tidal and forced expiratory flow–volume loops. Its clinical importance is that it contributes to increased dyspnoea [100], puts the inspiratory muscles at a mechanical disadvantage [43] and causes cardiovascular side-effects [106]. Although there currently isn't sufficient evidence to recommend the routine use of measurements of hyperinflation or EFL to score the severity of lung function impairment, they may be helpful in patients with disproportionate differences between spirometric impairment and dyspnoea.

Finally, the reported increase in RV in obstruction is deemed to be a marker of airway closure [47, 103]. Although its clinical relevance remains uncertain, especially with regard to assessment of severity, RV may be useful in special conditions, including predicting the likelihood of lung function improvement after lung volume-reduction surgery [104].

Table 7 shows the summary of the considerations for severity classification.

TABLE 7 Summary of the considerations for severity classification

The severity of pulmonary function abnormalities is based on FEV1 % pred. This does not apply to upper airway obstruction. In addition, it might not be suitable for comparing different pulmonary diseases or conditions
FEV1 may sometimes fail to properly identify the severity of a defect, especially at the very severe stages of the diseases
FEV1 % pred correlates poorly with symptoms and may not, by itself, accurately predict clinical severity or prognosis for individual patients
Lung hyperinflation and the presence of expiratory flow limitation during tidal breathing may be useful in categorising the severity of lung function impairment

FEV1: forced expiratory volume in one second; % pred: % predicted.

BRONCHODILATOR RESPONSE

Bronchial responsiveness to bronchodilator medications is an integrated physiological response involving airway epithelium, nerves, mediators and bronchial smooth muscle. Since the within-individual difference in response to a bronchodilator is variable, the assumption that a single test of bronchodilator response is adequate to assess both the underlying airway responsiveness and the potential for therapeutic benefits of bronchodilator therapy is overly simplistic [107]. Therefore, the current authors feel that the response to a bronchodilator agent can be tested either after a single dose of a bronchodilator agent in the PFT laboratory or after a clinical trial conducted over 2–8 weeks.

The correlation between bronchoconstriction and bronchodilator response is imperfect, and it is not possible to infer with certainty the presence of one from the other.

There is no consensus about the drug, dose or mode of administering a bronchodilator in the laboratory. However, when a metered dose inhaler is used, the following procedures are suggested in order to minimise differences within and between laboratories. Short-acting β_2-agonists, such as salbutamol, are recommended. Four separate doses of 100 μg should be used when given by metered dose inhaler using a spacer. Tests should be repeated after a 15-min delay. If a bronchodilator test is performed to assess the potential therapeutic benefits of a specific drug, it should be administered in the same dose and by the same route as used in clinical practice, and the delay between administration and repeated spirometric measurements should reflect the reported time of onset for that drug.

The first step in interpreting any bronchodilator test is to determine if any change greater than random variation has occurred. The per cent change in FVC and FEV1 after bronchodilator administration in general population studies [108–110] and patient populations [101, 111–113] are summarised in table 8. Studies show a tendency for the calculated bronchodilator response to increase with decreasing baseline VC or FEV1, regardless of whether the response was considered as an absolute change or as a per cent of the initial value. Bronchodilator responses in patient-based studies are, therefore somewhat higher than those in general population studies.

There is no clear consensus about what constitutes reversibility in subjects with airflow obstruction [111, 114]. In part, this is because there is no consensus on how a bronchodilator response should be expressed, the variables to be used, and, finally, the kind, dose and inhalation mode of bronchodilator agent. The three most common methods of expressing bronchodilator response are per cent of the initial spirometric value, per cent of the predicted value, and absolute change.

Expressing the change in FEV1 and/or FVC as a per cent of predicted values has been reported to have advantages over per cent change from baseline [115]. When using per cent change from baseline as the criterion, most authorities require a 12–15% increase in FEV1 and/or FVC as necessary to define a meaningful response. Increments of <8% (or <150 mL) are likely to be within measurement variability [107, 115]. The current authors recommend using the per cent change from baseline and absolute changes in FEV1 and/or FVC in an individual subject to identify a positive bronchodilator response. Values >12% and 200 mL compared with baseline during a single testing session suggest a "significant" bronchodilatation. If the change in FEV1 is not significant,

TABLE 8 Selected studies of bronchodilator response

Population	Agent/mode of delivery	FVC	FEV1	$MEF_{25-75\%}$ or $MEF_{50\%}$	Comments
Selected population studies					
1063 subjects 8–75 yrs of age; general population [108]	IP 2 puffs *via* MDI	10.7% (0.40 L)	7.7% (0.31 L)	20%	95th percentile for per cent change from baseline
2609 subjects; random sample of 3 areas in Alberta, Canada [109]	TB 500 μg *via* spacer		Males 9% (0.34 L); females 9% (0.22 L)		95th percentile for per cent change from baseline in asymptomatic never-smokers with FEV1 >80% pred
75 selected normal subjects [110]	Two puffs *via* MDI	5.1% (0.23 L)	10.1% (0.36 L)	48.3%	Upper 95% CL (two-tailed) for per cent change from baseline
Selected patient studies					
40 patients referred to PFT laboratory [112]	Placebo	14.9% (0.34 L)	12.3% (0.18 L)	45.1%	Upper 95% CI change after placebo
985 COPD patients in the IPPB trial [111]	IP 250 μg *via* air nebuliser		15%		Per cent change from baseline
150 patients with airway obstruction [113]	SB 200 μg or TB 500 μg *via* MDI	15% (0.33 L)	10% (0.16 L)		95% CI for absolute change
78 patients with COPD/asthma [101]	SB 200 μg *via* MDI	14% (0.51 L)	15% (0.25 L)		95% CL per cent change of baseline

FVC: forced vital capacity; FEV1: forced expiratory volume in one second; $MEF_{25-75\%}$: mean flow between 25% and 75% of FVC; $MEF_{50\%}$: flow at 50% of FVC; IP: isoproterenol; MDI: metered dose inhaler; TB: terbutaline; % pred: % predicted; SB: salbutamol; CL: confidence limits; PFT: pulmonary function tests; CI: confidence interval; COPD: chronic obstructive pulmonary disease; IPPB: intermittent positive pressure breathing. Other variables as in table 6.

decrease in lung hyperinflation may indicate a significant response [101]. The lack of a response to bronchodilator testing in a laboratory does not preclude a clinical response to bronchodilator therapy.

The $MEF_{25-75\%}$ is a highly variable spirometric test, in part because it depends on FVC, which increases with expiratory time in obstructed subjects. If FVC changes, post-bronchodilator $MEF_{25-75\%}$ is not comparable with that measured before the bronchodilator. Volume adjustment of $MEF_{25-75\%}$ has been proposed to solve this problem [116, 117]. At least two studies have assessed the utility of $MEF_{25-75\%}$. The results were disappointing; only 8% of asthmatics [117] and 7% of patients with COPD were identified as outside the expected range by $MEF_{25-75\%}$ criteria alone. Tests such as the FEV1/VC ratio and instantaneous flows measured at some fraction of the VC may also be misleading in assessing bronchodilator response if expiratory time changes are not considered and if flows are not measured at the same volume below TLC.

If the change is above the threshold of natural variability, then the next step is to determine if this change is clinically important. This aspect of the interpretation is harder to define and depends on the reasons for undertaking the test. For instance, even if asthmatics tend to show a larger increase in flow and volume after inhaling a dilator agent than COPD patients, the response to a bronchodilator has never been shown to be capable of clearly separating the two classes of patients [101, 109, 111, 114]. In addition, it must be also acknowledged that responses well below the significant thresholds may be associated with symptom improvement and patient performance [118]. The possible reasons are discussed as follows.

Quite often, responses to bronchodilator therapy are unpredictably underestimated by FEV1 and/or FVC in comparison to airway resistance or flow measured during forced expiratory manoeuvres initiated from a volume below TLC (partial expiratory flow–volume manoeuvres) in both healthy subjects and patients with chronic airflow obstruction [8, 101, 102, 119–122]. These findings are probably due to the fact that deep inhalations tend to reduce airway calibre, especially after a bronchodilator [101, 120]. In patients with airflow obstruction, the increase in expiratory flow after bronchodilation is often associated with a decrease in FRC or an increase in IC of similar extent at rest and during exercise [101, 123]. The improvement of the lung function parameters in the tidal breathing range and not following a deep breath may explain the decrease in shortness of breath after inhaling a bronchodilator, despite no or minimal changes in FEV1 and/or FVC. Short-term intra-individual variabilities for partial flows and IC have been reported [101]. Therefore, the lack of increase of FEV1 and/or FVC after a bronchodilator is not a good reason to avoid 1–8-week clinical trial with bronchoactive medication.

An isolated increase in FVC (>12% of control and >200 mL) not due to increased expiratory time after salbutamol is a sign of

TABLE 9 Summary of the procedures relating to bronchodilator response

Procedures suggested to minimise differences within and between laboratories
Assess lung function at baseline
Administer salbutamol in four separate doses of 100 μg through a spacer
Re-assess lung function after 15 min. If you want to assess the potential benefits of a different bronchodilator, use the same dose and the same route as used in clinical practice. The wait time may be increased for some bronchodilators
An increase in FEV1 and/or FVC ≥12% of control and ≥200 mL constitutes a positive bronchodilator response
In the absence of a significant increase in FEV1 and/or FVC, an improvement in lung function parameters within the tidal breathing range, such as increased partial flows and decrease of lung hyperinflation, may explain a decrease in dyspnoea
The lack of a bronchodilator response in the laboratory does not preclude a clinical response to bronchodilator therapy

FEV1: forced expiratory volume in one second; FVC: forced vital capacity.

bronchodilation [124]. This may, in part, be related to the fact that deep inhalations tend to reduce airway calibre and/or airway wall stiffness, especially after a bronchodilator [101, 120].

Table 9 shows a summary of the suggested procedures for laboratories relating to bronchodilator response.

CENTRAL AND UPPER AIRWAY OBSTRUCTION

Central airway obstruction and UAO may occur in the extrathoracic (pharynx, larynx, and extrathoracic portion of the trachea) and intrathoracic airways (intrathoracic trachea and main bronchi). This condition does not usually lead to a decrease in FEV1 and/or VC, but PEF can be severely affected. Therefore, an increased ratio of FEV1 divided by PEF ($mL \cdot L^{-1} \cdot min^{-1}$) can alert the clinician to the need for an inspiratory and expiratory flow–volume loop [125]. A value >8 suggests central or upper airway obstruction may be present [126]. Poor initial effort can also affect this ratio.

At least three maximal and repeatable forced inspiratory and forced expiratory flow–volume curves are necessary to evaluate for central or upper airway obstruction. It is critical that the patient's inspiratory and expiratory efforts are near maximal and the technician should confirm this in the quality notes. When patient effort is good, the pattern of a repeatable plateau of forced inspiratory flow, with or without a forced expiratory plateau, suggests a variable extrathoracic central or upper airway obstruction (fig. 3). Conversely, the pattern of a repeatable plateau of forced expiratory flow, along with the lack of a forced inspiratory plateau suggests a variable, intrathoracic central or upper airway obstruction. The pattern of a repeatable plateau at a similar flow in both forced inspiratory and expiratory flows suggests a fixed central or upper airway obstruction (fig. 3).

In general, maximum inspiratory flow is largely decreased with an extrathoracic airway obstruction, because the pressure surrounding the airways (which is almost equal to atmospheric) cannot oppose the negative intraluminal pressure generated with the inspiratory effort. In contrast, it is little affected by an intrathoracic airway obstruction, for the pressure surrounding the intrathoracic airways (which is close to pleural pressure) strongly opposes the negative intraluminal pressure on inspiration, thus limiting the effects of the obstruction on flow. With unilateral main bronchus obstruction, a rare event, maximum inspiratory flow tends to be higher at the beginning than towards the end of the forced inspiration because of a delay in gas filling (fig. 4).

Maximum expiratory flow at high lung volume (especially peak flow) is generally decreased in both intrathoracic and extrathoracic lesions [126–129]. In contrast, maximum flows may be normal in the presence of a variable lesion, such as vocal cord paralysis. Flow oscillations (saw-tooth pattern) may be occasionally observed on the either inspiratory or expiratory phase, and probably represent a mechanical instability of the airway wall.

The effects of anatomical or functional lesions on maximum flows depend on the site of the obstruction, kind of lesion (variable or fixed) and the extent of anatomical obstruction [61, 127, 130]. Typical cases of extra- and intrathoracic central or upper airway obstruction are reported in figures 3 and 4. The absence of classic spirometric patterns for central airway

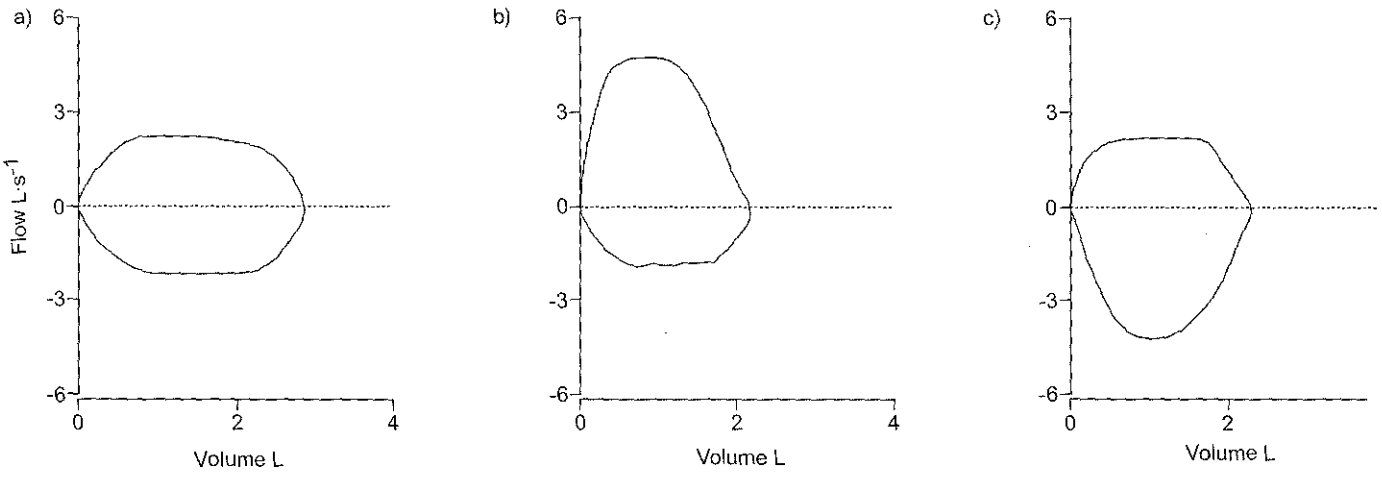


FIGURE 3. Idealised examples of a) fixed, b) variable extrathoracic, and c) variable intrathoracic airway obstruction.

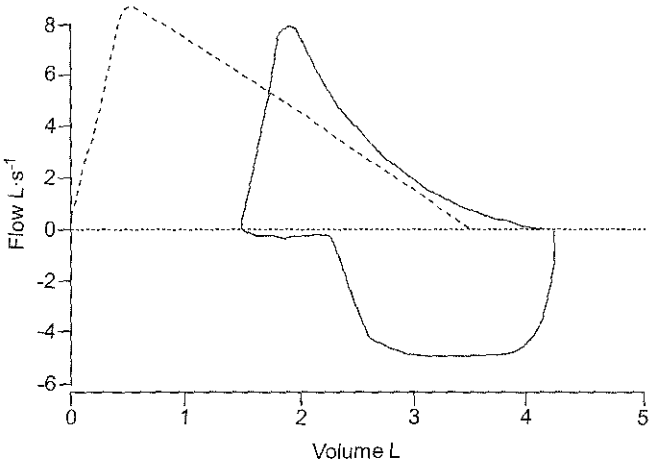


FIGURE 4. Example of unilateral main bronchus obstruction due to a valve-like mechanism occluding the main left stem bronchus during inspiration as a result of a surgical scar. There is a delay in gas filling towards the end of the forced inspiration as evidence of the variable unilateral main bronchus obstruction (forced expiratory volume in one second (FEV_1): 76%; FEV_1/vital capacity: 70%; peak expiratory flow: 93%; total lung capacity: 80%). ----: predicted expiratory flow–volume loop; ——: recorded maximum inspiratory and expiratory flow–volume loops.

obstruction does not accurately predict the absence of pathology. As a result, clinicians need to maintain a high degree of suspicion for this problem, and refer suspected cases for visual inspection of the airways. The authors feel that, although maximum inspiratory and expiratory flow–volume loops are of great help to alert clinicians to the possibility of central or upper airway obstruction, endoscopic and radiological techniques are the next step to confirm the dysfunction.

The parameters presented in table 10 may help to distinguish intrathoracic from extrathoracic airway obstructions.

Table 11 gives a summary of the relevant issues concerning UAO.

INTERPRETATION OF CHANGE IN LUNG FUNCTION

Evaluation of an individual's change in lung function following an intervention or over time is often more clinically valuable than a single comparison with external reference (predicted) values. It is not easy to determine whether a measured change reflects a true change in pulmonary status or

TABLE 10 Lung function parameters capable of differentiating extrathoracic from intrathoracic obstruction

	Extrathoracic obstruction		Intrathoracic obstruction
	Fixed	Variable	
PEF	Decreased	Normal or decreased	Decreased
MIF_{50}	Decreased	Decreased	Normal or decreased
MIF_{50}/MEF_{50}	~1	<1	>1

PEF: peak expiratory flow; MIF_{50}: maximum inspiratory flow at 50% of forced vital capacity (FVC); MEF_{50}: maximum expiratory flow at 50% of FVC.

TABLE 11 Summary of the issues concerning central or upper airway obstruction

Special attention should be paid by the technicians to obtain maximal and repeatable PEFs and forced inspiratory manoeuvres if there is a clinical or spirometric reason to suspect upper airway obstruction

Be aware of how to distinguish intrathoracic from extrathoracic airway obstruction (table 10)

Confirm the presence of central and upper airway obstruction with imaging and/or endoscopic techniques

PEF: peak expiratory flow

is only a result of test variability. All lung function measurements tend to be more variable when made weeks to months apart than when repeated at the same test session or even daily [25, 131]. The short-term repeatability of tracked parameters should be measured using biological controls. This is especially important for the $D_{L,CO}$ [132, 133], since small errors in measurements of inspiratory flows or exhaled gas concentrations translate into large $D_{L,CO}$ errors. The variability of lung volume measurements has recently been reviewed [134].

The optimal method of expressing the short-term variability (measurement noise) is to calculate the coefficient of repeatability (CR) instead of the more popular coefficient of variation [135]. Change measured for an individual patient that falls outside the CR for a given parameter may be considered significant. The CR may be expressed as an absolute value (such as 0.33 L for FEV_1 or 5 units for $D_{L,CO}$) [136] or as a percentage of the mean value (such as 11% for FEV_1) [137].

It is more likely that a real change has occurred when more than two measurements are performed over time. As shown in table 12, significant changes, whether statistical or biological,

TABLE 12 Reported significant changes in forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), mid-expiratory flow ($MEF_{25-75\%}$) and carbon monoxide diffusing capacity ($D_{L,CO}$) over time

	FVC	FEV_1	$MEF_{25-75\%}$	$D_{L,CO}$
Within a day				
Normal subjects	≥5	≥5	≥13	≥7%
COPD patients	≥11	≥13	≥23	
Week to week				
Normal subjects	≥11	≥12	≥21	>6 units
COPD patients	≥20	≥20	≥30	>4 units
Year to year	≥15	≥15		>10%

The variables are the same as in tables 6 and 8. Results for spirometry are rounded to the nearest integer [25, 128]. The within-day $D_{L,CO}$ variability is from a study of diurnal variation in healthy nonsmokers [133]. The week-to-week coefficient of repeatability (CR) is given for $D_{L,CO}$ in units of $mL \cdot min^{-1} \cdot mmHg^{-1}$ as calculated from CRs originally stated in units of $mmol \cdot min^{-1} \cdot kPa^{-1}$ [138]. The year-to-year variability of healthy adults is given using a 95% confidence interval [139]. CRs from repeatability testing performed in your own laboratory should be substituted for the values in this table. COPD: chronic obstructive pulmonary disease.

vary by parameter, time period and the type of patient. When there are only two tests available to evaluate change, the large variability necessitates relatively large changes to be confident that a significant change has in fact occurred. Thus, in subjects with relatively "normal" lung function, year-to-year changes in FEV1 over 1 yr should exceed 15% before confidence can be given to the opinion that a clinically meaningful change has occurred [5].

For tracking change, FEV1 has the advantage of being the most repeatable lung function parameter and one that measures changes in both obstructive and restrictive types of lung disease. Two-point, short-term changes of >12% and >0.2 L in the FEV1 are usually statistically significant and may be clinically important. Changes slightly less than these may, perhaps, be equally significant, depending on the reproducibility of the pre- and post-bronchodilator results. Other parameters such as VC, IC, TLC and $D_{L,CO}$ may also be tracked in patients with ILD or severe COPD [138, 140–142]. Tests like VC and FVC may be relevant to COPD because they may increase when FEV1 does not, and changes in $D_{L,CO}$, in the absence of change in spirometry variables, may be clinically important. Again, when too many indices of lung function are tracked simultaneously, the risk of false-positive indications of change increases.

The clinician seeing the patient can often interpret results of serial tests in a useful manner, which is not reproducible by any simple algorithm. Depending on the clinical situation, statistically insignificant trends in lung function may be meaningful to the clinician. For example, seemingly stable test results may provide reassurance in a patient receiving therapy for a disease that is otherwise rapidly progressive. The same test may be very disappointing if one is treating a disorder that is expected to improve dramatically with the therapy prescribed. Conversely, a statistically significant change may be of no clinical importance to the patient. The largest errors occur in attempting to interpret serial changes in subjects without disease, because test variability will usually far exceed the true annual decline, and reliable rates of change for an individual subject cannot be calculated without prolonged follow-up [143].

Test variability can be reduced when lung function standards and guidelines are followed strictly. Simple plots (*i.e.* trending) of lung function with time can provide additional information to help differentiate true change in lung function from noise. Measuring decline in lung function as a means of identifying individuals (such as smokers) who are losing function at excessive rates has been proposed. However, establishing an accelerated rate of loss in an individual is very difficult, and requires many measurements over several years with meticulous quality control of the measurements.

Table 13 shows a summary of the considerations involved in interpreting lung function changes.

TABLE 13 Summary of the considerations for the interpretation of change in lung function

- Be aware of possible significant changes in lung function parameters over time (table 12)
- Multiple measurements over time are more likely to signal a real change in lung function than two measurements
- When too many indices of lung function are tracked simultaneously, the risk of false-positive indications of change increases
- Clinical interpretation of serial tests should not be based solely on the coefficient of repeatability, but also on the clinical findings

TABLE 14 Degree of severity of decrease in diffusing capacity for carbon monoxide ($D_{L,CO}$)

Degree of severity	$D_{L,CO}$ % pred
Mild	>60% and <LLN
Moderate	40–60%
Severe	<40

% pred: % predicted; LLN: lower limits of normal.

$D_{L,CO}$ INTERPRETATION

The lower 5th percentile of the reference population should be used as LLN for $D_{L,CO}$ and K_{CO} (if the latter is used). Table 14 presents a scheme to grade the severity of reductions in $D_{L,CO}$.

The pathophysiological importance of this test has been recently reviewed [144, 145].

Interpreting the $D_{L,CO}$, in conjunction with spirometry and lung volumes assessment, may assist in diagnosing the underlying disease (fig. 2). For instance, normal spirometry and lung volumes associated with decreased $D_{L,CO}$ may suggest anaemia, pulmonary vascular disorders, early ILD or early emphysema. In the presence of restriction, a normal $D_{L,CO}$ may be consistent with chest wall or neuromuscular disorders, whereas a decrease suggests ILDs. In the presence of airflow obstruction, a decreased $D_{L,CO}$ suggests emphysema [146], but airway obstruction and a low $D_{L,CO}$ are also seen in lymphangioleiomyomatosis [147]. Patients with ILD, sarcoidosis and pulmonary fibrosis usually have a low $D_{L,CO}$ [135–137, 140]. A low $D_{L,CO}$ is also seen in patients with chronic pulmonary embolism, primary pulmonary hypertension [148], and other pulmonary vascular diseases. These patients may or may not also have restriction of lung volumes [149].

A high $D_{L,CO}$ is associated with asthma [150], obesity [151] and intrapulmonary haemorrhage [152].

Adjustments of $D_{L,CO}$ for changes in haemoglobin and carboxyhaemoglobin are important, especially in situations where patients are being monitored for possible drug toxicity and where haemoglobin is subject to large shifts (*e.g.* chemotherapy for cancer).

Adjusting $D_{L,CO}$ for lung volume using $D_{L,CO}/V_A$ or $D_{L,CO}$/TLC is controversial [153, 154]. Conceptually, a loss of $D_{L,CO}$ that is much less than a loss of volume (low $D_{L,CO}$ but high $D_{L,CO}/V_A$) might suggest an extraparenchymal abnormality such as a pneumonectomy or chest wall restriction, whereas loss of $D_{L,CO}$ that is much greater than a loss of volume (low $D_{L,CO}$ and low $D_{L,CO}/V_A$) might suggest parenchymal abnormalities. The relationship between $D_{L,CO}$ and lung

TABLE 15 Summary of the considerations for diffusing capacity for carbon monoxide ($D_{L,CO}$) interpretation

Refer to a scheme to grade the severity of reductions in $D_{L,CO}$ (table 14)
Interpreting $D_{L,CO}$ in conjunction with spirometry and lung volumes may assist in diagnosing the underlying disease (fig. 2)
Adjustments of $D_{L,CO}$ for changes in haemoglobin and carboxyhaemoglobin are important
The relationship between $D_{L,CO}$ and lung volume is not linear, so $D_{L,CO}/V_A$ or $D_{L,CO}/TLC$ do not provide an appropriate way to normalise $D_{L,CO}$ for lung volume
Nonlinear adjustments may be considered, but their clinical utility must be established before they can be recommended

V_A: alveolar volume; TLC: total lung capacity

volume, however, is not linear and markedly less than 1:1, so these simple ratios as traditionally reported do not provide an appropriate way to normalise $D_{L,CO}$ for lung volume [154-159]. Nonlinear adjustments may be considered, but their clinical utility must be established before they can be recommended. Meanwhile, it is advisable to keep examining $D_{L,CO}/V_A$ and V_A separately [153], in so far as it may provide information on disease pathophysiology that cannot be obtained from their product, the $D_{L,CO}$.

Table 15 shows a summary on the considerations for $D_{L,CO}$ interpretation.

ABBREVIATIONS

Table 16 contains a list of abbreviations and their meanings, which have been used in this series of Task Force reports.

TABLE 16 List of abbreviations and meanings

ATPD	Ambient temperature, ambient pressure, and dry
ATPS	Ambient temperature and pressure saturated with water vapour
BTPS	Body temperature (*i.e.* 37°C), ambient pressure, saturated with water vapour
C	Centigrade
CFC	Chlorofluorocarbons
cm	Centimetres
COHb	Carboxyhaemoglobin
$D_{L,CO}$	Diffusing capacity for the lungs measured using carbon monoxide, also known as transfer factor
$D_{L,CO}/V_A$	Diffusing capacity for carbon monoxide per unit of alveolar volume, also known as K_{CO}
D_M	Membrane-diffusing capacity
DT	Dwell time of flow >90% of PEF
EFL	Expiratory flow limitation
ERV	Expiratory reserve volume
EV	Back extrapolated volume
EVC	Expiratory vital capacity
$F_{A,X}$	Fraction of gas X in the alveolar gas
$F_{A,X,t}$	Alveolar fraction of gas X at time t
$FEF_{25-75\%}$	Mean forced expiratory flow between 25% and 75% of FVC
$FEF_{X\%}$	Instantaneous forced expiratory flow when X% of the FVC has been expired
FEV_1	Forced expiratory volume in one second
FEV_t	Forced expiratory volume in t seconds
$F_{E,X}$	Fraction of expired gas X
$FIF_{X\%}$	Instantaneous forced inspiratory flow at the point where X% of the FVC has been inspired
$F_{I,X}$	Fraction of inspired gas X
FIVC	Forced inspiratory vital capacity
FRC	Functional residual capacity
FVC	Forced vital capacity
H_2O	Water
Hb	Haemoglobin
Hg	Mercury
Hz	Hertz, cycles per second
IC	Inspiratory capacity
IRV	Inspiratory reserve volume
IVC	Inspiratory vital capacity
K_{CO}	Transfer coefficient of the lung (*i.e.* $D_{L,CO}/V_A$)
kg	Kilograms
kPa	Kilopascals
L	Litres
$L \cdot min^{-1}$	Litres per minute
$L \cdot s^{-1}$	Litres per second
lb	Pounds
$MEF_{X\%}$	Maximal instantaneous forced expiratory flow where X% of the FVC remains to be expired
MFVL	Maximum flow-volume loop
mg	Milligrams
MIF	Maximal inspiratory flow
mL	Millilitres
mm	Millimetres
MMEF	Maximum mid-expiratory flow
ms	Milliseconds
MVV	Maximum voluntary ventilation
P_{A,O_2}	Alveolar oxygen partial pressure
PB	Barometric pressure
PEF	Peak expiratory flow
P_{H_2O}	Water vapour partial pressure
P_{I,O_2}	Inspired oxygen partial pressure
θ (theta)	Specific uptake of CO by the blood
RT	Rise time from 10% to 90% of PEF
RV	Residual volume
s	Seconds
STPD	Standard temperature (273 K, 0°C), pressure (101.3 kPa, 760 mmHg) and dry
TB	Tuberculosis
TGV (or V_{TG})	Thoracic gas volume
t_I	Time taken for inspiration
TLC	Total lung capacity
Tr	Tracer gas
t_{tot}	Total time of respiratory cycle
TV (or VT)	Tidal volume
V_A	Alveolar volume
$V_{A,eff}$	Effective alveolar volume
VC	Vital capacity
V_c	Pulmonary capillary blood volume
V_D	Dead space volume
V_I	Inspired volume
V_S	Volume of the expired sample gas
μg	Micrograms

ACKNOWLEDGEMENTS

R. Pellegrino: Azienda Ospedaliera S. Croce e Carle, Cuneo, Italy; G. Viegi: CNR Institute of Clinical Physiology, Pisa, Italy; V. Brusasco: Università degli Studi di Genova, Genova, Italy; R.O. Crapo and R. Jensen: LDS Hospital, Salt Lake City, UT, USA; F. Burgos: Hospital Clinic Villarroel, Barcelona, Spain; R. Casaburi: Harbor UCLA Medical Center, Torrance, CA, USA; A. Coates: Hospital for Sick Children, Toronto, ON, Canada; C.P.M. van der Grinten: University Hospital of Maastrict, Maastrict, the Netherlands; P. Gustafsson: Queen Silvias Children's Hospital, Gothenburg, Sweden; J. Hankinson: Hankinson Consulting, Inc., Valdosta, GA, USA; D.C. Johnson: Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA; N. MacIntyre: Duke University Medical Center, Durham, NC, USA; R. McKay: Occupational Medicine, Cincinnati, OH, USA; M.R. Miller: University Hospital Birmingham NHS Trust, Birmingham, UK; D. Navajas: Lab Biofisica I Bioenginyeria, Barcelona, Spain; O.F. Pedersen: University of Aarhus, Aarhus, Denmark; J. Wanger: Pharmaceutical Research Associates, Inc., Lenexa, KS, USA.

REFERENCES

1 Miller MR, Crapo R, Hankinson J, *et al*. General considerations for lung function testing. *Eur Respir J* 2005; 26: 153–161.
2 Miller MR, Hankinson J, Brusasco V, *et al*. Standardisation of spirometry. *Eur Respir J* 2005; 26: 319–338.
3 Wanger J, Clausen JL, Coates A, *et al*. Standardisation of the measurement of lung volumes. *Eur Respir J* 2005; 26: 511–522.
4 MacIntyre N, Crapo RO, Viegi G, *et al*. Standardisation of the single-breath determination of carbon monoxide uptake in the lung. *Eur Respir J* 2005; 26: 720–735.
5 American Thoracic Society. Lung Function Testing: Selection of Reference Values and Interpretative Strategies. *Am Rev Respir Dis* 1991; 144: 1202–1218.
6 Solberg HE, Grasbeck R. Reference values. *Adv Clin Chem* 1989; 27: 1–79.
7 Stocks J, Quanjer PH. Reference values for residual volume, functional residual capacity and total lung capacity. *Eur Respir J* 1995; 8: 492–506.
8 Quanjer PH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault JC. Lung volumes and forced ventilatory flows. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. *Eur Respir J* 1993; 6: Suppl. 16, 5–40.
9 Lohman TG, Roche AF, Martorell R, eds. Anthropometric standardization reference manual. Human Kinetics Books 1988; pp. 1–55.
10 Aggarwal AN, Gupta D, Jindal SK. Interpreting spirometric data: impact of substitution of arm span for standing height in adults from North India. *Chest* 1999; 115: 557–562.
11 Parker JM, Dillard TA, Phillips YY. Arm span-height relationships in patients referred for spirometry. *Am J Respir Crit Care Med* 1996; 154: 533–536.
12 Hankinson JL, Odencratz JR, Fedan KB. Spirometric reference values from a sample of the general US population. *Am J Respir Crit Care Med* 1999; 159: 179–187.
13 Korotzer B, Ong S, Hansen JE. Ethnic differences in pulmonary function in healthy nonsmoking Asian-Americans and European-Americans. *Am J Respir Crit Care Med* 2000; 161: 1101–1108.
14 Sharp DS, Enright PL, Chiu D, Burchfiel CM, Rodriguez BL, Curb JD. Reference values for pulmonary function tests of Japanese-American men aged 71–90 years. *Am J Respir Crit Care Med* 1996; 153: 805–811.
15 Harik-Khan RI, Fleg JL, Muller DC, Wise RA. The effect of anthropometric and socioeconomic factors on the racial difference in lung function. *Am J Respir Crit Care Med* 2002; 164: 1647–1654.
16 Roca J, Burgos F, Sunyer J, *et al*. References values for forced spirometry. Group of the European Community Respiratory Health Survey. *Eur Respir J* 1998; 11: 1354–1362.
17 Langhammer A, Johnsen R, Gulsvik A, Holmen TL, Bjermer L. Forced spirometry reference values for Norwegian adults: the Bronchial Obstruction in Nord-Trondelag study. *Eur Respir J* 2001; 18: 770–779.
18 Jensen RL, Crapo RO, Flint AK, Howell HM. Problems in selecting representative reference values for spirometry. *Am J Respir Crit Care Med* 2002; 165: A200.
19 Hardie JA, Buist AS, Vollmer WM, Ellingsen I, Bakke PS, Morkve O. Risk of over-diagnosis of COPD in asymptomatic elderly never-smokers. *Eur Respir J* 2002; 20: 1117–1122.
20 Quanjer PH. Standardized Lung Function Testing. *Bull Eur Physiopathol* 1983; 19: Suppl. 5, 22–27.
21 American Thoracic Society. Standardization of Spirometry: 1994 update. *Am J Respir Crit Care Med* 1995; 152: 1107–1136.
22 Enright PL, Kronmal RA, Higgins M, Schenker M Haponik EF. Spirometry reference values for women and men 65 to 85 years of age. Cardiovascular healt study. *Am Rev Respir Dis* 1993; 147: 125–133.
23 Glindmeyer HW, Lefante JJ, McColloster C, Jones RN Weill H. Blue-collar normative spirometric values f Caucasian and African-American men and women ag 18 to 65. *Am J Respir Crit Care Med* 1995; 151: 412–422.
24 Sherrill DL, Lebowitz MD, Knudson RJ, Burrows Methodology for generating continuous prediction eq tions for pulmonary function measures. *Comput Bio Res* 1991; 24: 249–260.
25 Burrows B, Lebowitz MD, Camilli AE, Knudson Longitudinal changes in forced expiratory volume in second in adults. Methodologic considerations findings in healthy nonsmokers. *Am Rev Respir* 1986; 133: 974–980.
26 Ware JH, Dockery DW, Louis TA, Xu XP, Ferris B Speizer FE. Longitudinal and cross-sectional estima pulmonary function decline in never-smoking adult *J Epidemiol* 1990; 132: 685–700.
27 Sherrill DL, Lebowitz MD, Knudson RJ, Burro Continuous longitudinal regression equation pulmonary function measures. *Eur Respir J* 19 452–462.

28 Pistelli F, Bottai M, Viegi G, *et al*. Smooth reference equations for slow vital capacity and flow-volume curve indexes. *Am J Respir Crit Care Med* 2000; 161: 899–905.

29 Wang X, Dockery DW, Wypij D, Fay ME, Ferris BG Jr. Pulmonary function between 6 and 18 years of age. *Pediatr Pulmonol* 1993; 15: 75–88.

30 Quanjer PH, Stocks J, Polgar G, Wise M, Karlberg J, Borsboom G. Compilation of reference values for lung function measurements in children. *Eur Respir J* 1989; 1: Suppl. 4, 184S–261S.

31 Degroodt EG, Quanjer PH, Wise ME, Van Zomeren BC. Changing relationships between stature and lung volumes during puberty. *Respir Physiol* 1986; 65: 139–153.

32 Borsboom GJ, van Pelt W, Quanjer PH. Pubertal growth curves of ventilatory function: Relationship with childhood respiratory symptoms. *Am Rev Respir Dis* 1993; 147: 372–378.

33 Cotes JE. Lung Function. *In:* Cotes JE, ed. Differences between Ethnic Groups: Assessment and Application in Medicine. 5th Edn. Oxford, Blackwell Scientific Publications, 1993; 474–482.

34 Yang TS, Peat J, Keena V, Donnelly PM, Unger W, Woolcock A. A review of the racial differences in the lung function of normal Caucasian, Chinese and Indian subjects. *Eur Respir J* 1991; 4: 872–880.

35 Lapp NL, Amandus HE, Hall R, Morgan WK. Lung volumes and flow rates in black and white subjects. *Thorax* 1974; 29: 185–188.

36 Lanese RR, Keller MD, Foley MF, Underwood EH. Differences in pulmonary function tests among whites, blacks, and American Indians in a textile company. *J Occup Med* 1978; 20: 39–44.

37 Gaultier C, Crapo RO. Effects of nutrition, growth hormone disturbances, training, altitude, and sleep on lung volumes. *Eur Respir J* 1997; 10: 2913–2919.

38 Cotes JE, Chinn DJ, Quanjer PhH, Roca J, Yernault JC. Standardization of the measurement of transfer factor (diffusing capacity). Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. *Eur Respir J* 1993; 6: Suppl. 16, 41–52.

39 American Thoracic Society. Single breath carbon monoxide diffusing capacity (transfer factor). Recommendations for a standard technique – 1995 Update. *Am J Respir Crit Care Med* 1995; 152: 2185–2198.

) Crapo RO, Morris AH. Standardized single-breath normal values for carbon monoxide diffusing capacity. *Am Rev Respir Dis* 1981; 123: 185–189.

Cotes JE, Hall AM. The transfer factor for the lung: normal values in adults. *In*: Arcangeli P, Cotes JE, Cournand A, eds. Introduction to the definition of normal values for respiratory function in man. Panminerva Medica, Torino, 1970; pp. 327–343.

Paoletti P, Viegi G, Pistelli G, *et al*. Reference equations for the single-breath diffusing capacity. A cross-sectional analysis and effect of body size and age. *Am Rev Respir Dis* 1985; 132: 806–813.

Roca J, Rodriguez-Roisin R, Cobo E, Burgos F, Perez J, Clausen JL. Single-breath carbon monoxide diffusing capacity prediction equations from a Mediterranean population. *Am Rev Respir Dis* 1990; 141: 1026–1032.

44 Griner PF, Mayewsky RJ, Mushlin AI, Greenland P. Selection and interpretation of diagnostic tests and procedures: principles and applications. *Ann Intern Med* 1981; 94 (part 2): 557–592.

45 Bates DV. Respiratory Function in Disease. 3rd edn. Philadelphia, WB Saunders, 1989.

46 Wilson AF, ed. Pulmonary Function Testing, Indications and Interpretations. Orlando, Grune & Stratton, 1985.

47 Pride NB, Macklem PT. Lung mechanics in disease. *In*: Macklem PT, Mead J, eds. Handbook of Physiology. The Respiratory System. Mechanics of Breathing. Section 3, Vol. III, part 2. Bethesda, American Physiological Society, 1986; pp 659–692.

48 Flenley DC. Chronic obstructive pulmonary disease. *Dis Mon* 1988; 34: 537–599.

49 Olive JT, Hyatt RE. Maximal expiratory flow and total respiratory resistance during induced bronchoconstriction in asthmatic subjects. *Am Rev Respir Dis* 1972; 106: 366–376.

50 Hyatt RE, Okeson GC, Rodarte JR. Influence of expiratory flow limitation on the pattern of lung emptying in man. *J Appl Physiol* 1973; 35: 411–419.

51 Rodarte JR, Hyatt RE, Cortese DA. Influence of expiratory flow on closing capacity at low expiratory flow rates. *J Appl Physiol* 1975; 39: 60–65.

52 Guerry-Force ML, Müller NL, Wright JL, Wiggs B, Coppin C, Paré PD, Hogg JC. A comparison of bronchitis obliterans with organizing pneumonia, usual interstitial pneumonia, and small airways disease. *Am Rev Respir Dis* 1987; 135: 705–712.

53 Aaron SD, Dales RE, Cardinal P. How accurate is spirometry at predicting restrictive impairment. *Chest* 1999; 115: 869–873.

54 Glady CA, Aaron SD, Lunau M, Clinch J, Dales RE. A spirometry-based algorithm to direct lung function testing in the pulmonary function laboratory. *Chest* 2003; 123: 1939–1946.

55 Rodenstein DO, Stanescu DC. Reassessment of lung volume measurement by helium dilution and body plethysmography in COPD. *Am Rev Respir Dis* 1983; 128: 54–59.

56 Ferris BG. Epidemiology standardization project (American Thoracic Society). *Am Rev Respir Dis* 1978; 118: 1–120.

57 Punjabi NM, Shade D, Wise RA. Correction of single-breath helium lung volumes in patients with airflow obstruction. *Chest* 1998; 114: 907–918.

58 Dykstra BJ, Scanlon PD, Kester MM, Beck KC, Enright PL. Lung volumes in 4774 patients with obstructive lung disease. *Chest* 1999; 115: 68–74.

59 Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS, GOLD Scientific Committee. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. *Am J Respir Crit Care Med* 2001; 163: 1256–1276.

60 Celli BR, MacNee W, and committe members. Standard for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. *Eur Respir J* 2004; 23: 932–946.

61 Brusasco V, Pellegrino R, Rodarte JR. Vital capacities in acute and chronic airway obstruction. Dependence on flow and volume histories. *Eur Respir J* 1997; 10: 1316–1320.

62 Celli BR, Halbert RJ, Isonaka S, Schau B. Population impact of different definition of airway obstruction. *Eur Respir J* 2003; 22: 268–273.

63 American Thoracic Society. Idiopathic pulmonary fibrosis: diagnosis and treatment. International consensus statement. *Am J Respir Crit Care Med* 2000; 161: 646–664.

64 Vedal S, Crapo RO. False positive rates of multiple pulmonary function tests in healthy subjects. *Bull Eur Physiopathol Respir* 1983; 19: 263–266.

65 Knudson RJ, Burrows B, Lebowitz MD. The maximal expiratory flow-volume curve: its use in the detection of ventilatory abnormalities in a population study. *Am Rev Respir Dis* 1976; 114: 871–879.

66 Mannino DM, Buist AS, Petty TL, Enright PL, Redd SC. Lung function and mortality in the United States: data from the first National Health and Nutrition Examination Survey follow-up. *Thorax* 2003; 58: 388–393.

67 Hyatt RE. Forced expiration. *In*: Macklem PT, Mead J, eds. Handbook of Physiology. The Respiratory System. Mechanics of breathing. Section 3, Vol. III, part 2. Bethesda, American Physiological Society, 1986; pp. 295–314.

68 Coates AL, Boyce P, Shaw DG, Godfrey S, Mearns M. The relationship between the chest radiograph, regional lung function studies, exercise tolerance, and clinical condition in children with cystic fibrosis. *Arch Dis Child* 1981; 56: 106–111.

69 Kerem E, Reisman JJ, Corey ML, Canny GJ, Levison H. Prediction of mortality in patients with cystic fibrosis. *N Engl J Med* 1992; 326: 1187–1191.

70 Anthonisen NR. Tests of mechanical function. *In*: Macklem PT, Mead J, eds. Handbook of Physiology. The Respiratory System. Mechanics of breathing. Section 3, Vol. III, part 2. Bethesda, American Physiological Society, 1986; pp. 753–784.

71 Braun NMT, Arora NS, Rochester DF. Respiratory muscle and pulmonary function in polymyositis and other proximal myopathies. *Thorax* 1983; 38: 616–623.

72 Serisier DE, Mastaglia FL, Gibson GJ. Respiratory muscle function and ventilatory control, I in patients with motor neurone disease, II in patients with myotonic dystrophy. *Q J Med* 1982; 51: 205–226.

73 Engstrom H, Grimby G, Soderholm B. Dynamic spirometry in patients with tracheal stenosis. *Acta Med Scand* 1964; 176: 329–334.

74 Wasserman K, Hansen JE, Sue DY, Whipp BJ. Principles of Exercise Testing and Interpretation. Philadephia, Lea & Fabiger, 1987; pp. 72–86.

75 Babb TG, Viggiano R, Hurley B, Staats B, Rodarte JR. Effect of mild-to-moderate airflow limitation on exercise capacity. *J Appl Physiol* 1991; 70: 223–230.

76 Pellegrino R, Villosio C, Milanese U, Garelli G, Rodarte JR, Brusasco V. Breathing during exercise in subjects with mild to moderate airflow obstruction. *J Appl Physiol* 1999; 87: 1697–1704.

77 American Thoracic Society. Evaluation of impairment/disability secondary to respiratory disorders. *Am Rev Respir Dis* 1986; 133: 1205–1209.

78 American Medical Association. Guides to the Evaluation of Permanent Impairment. Edn 4. Chicago (IL), USA, American Medical Association, 1995.

79 Becklake MR, Kalica AR. NHLBI workshop summary. Scientific issues in the assessment of respiratory impairment. *Am Rev Respir Dis* 1988; 137: 1505–1510.

80 Kanner RE, Renzetti AD, Stanish WM, Barkman HW, Klauber MR. Predictors of survival in subjects with chronic airflow limitation. *Am J Med* 1983; 74: 249–255.

81 Traver GA, Cline MG, Burrows B. Predictors of mortality in chronic obstructive pulmonary disease. *Am Rev Respir Dis* 1979; 119: 895–902.

82 Anthonisen NR, Wright EC, Hodgkin JE. Prognosis in chronic obstructive pulmonary disease. *Am Rev Respir Dis* 1986; 133: 14–20.

83 American Thoracic Society. Guidelines for the evaluation of impairment/disability in patients with asthma. *Am Rev Respir Dis* 1993; 147: 1056–1061.

84 Kannel WB, Lew EA. Vital capacity as a predictor of cardiovascular disease: the Framingham study. *Am Hearth J* 1983; 105: 311–315.

85 Kannel WB, Lew EA, Hubert HB, Castelli WP. The value of measuring vital capacity for prognostic purposes. *Trans Assoc Life Insur Med Dir Am* 1981; 64: 66–83.

86 Tockman MS, Comstock GW. Respiratory risk factors and mortality: longitudinal studies in Washington county, Maryland. *Am Rev Respir Dis* 1989; 140: S56–S63.

87 Foxman B, Higgins ITT, Oh MS. The effects of occupation and smoking on respiratory disease mortality. *Am Rev Respir Dis* 1986; 134: 649–652.

88 Annesi I, Kauffmann F. Is respiratory mucus hypersecretion really an innocent disorder? *Am Rev Respir Dis* 1986; 134: 688–693.

89 Ortmeyer CE, Costello J, Morgan WKC, Swecker S, Peterson M. The mortality of Appalachian coal miners 1963 to 1971. *Arch Environ Health* 1974; 29: 67–72.

90 Peto R, Speizer FE, Cochrane AL, *et al.* The relevance in adults of air-flow obstruction, but not of mucus hypersecretion, to mortality from chronic lung disease; results from 20 years of prospective observation. *Am Rev Respir Dis* 1983; 128: 491–500.

91 Neas LM, Schwartz J. Pulmonary function levels as predictors of mortality in a national sample of US adults. *Am J Epidemiol* 1998; 147: 1011–1018.

92 Ferguson MK, Little L, Rizzo L, *et al.* Diffusing capacity predicts morbidity and mortality after pulmonary resection. *J Thorac Cardiovasc Surg* 1988; 96: 894–900.

93 Black LF, Hyatt RE. Maximal static respiratory pressures in generalized neuromuscular disease. *Am Rev Respir Dis* 1971; 103: 641–650.

94 Fairshter RD. Airway hysteresis in normal subjects and individuals with chronic airflow obstruction. *J Appl Physiol* 1985; 58: 1505–1510.

95 Zamel N, Hughes D, Levison H, Fairshter RD, Gelb A. Partial and complete maximum expiratory flow-volume curves in asthmatic patients with spontaneous bronchospasm. *Chest* 1983; 83: 35–39.

96 Burns CB, Taylor WR, Ingram RH Jr. Effects of deep inhalation in asthma: relative airway and parenchymal hysteresis. *J Appl Physiol* 1985; 59: 1590–1596.

97 Brusasco V, Pellegrino R, Violante B, Crimi E. Relationship between quasi-static pulmonary hysteresis and maximal airway narrowing in humans. *J Appl Physiol* 1992; 72: 2075–2080.

98 Pellegrino R, Wilson O, Jenouri G, Rodarte JR. Lung mechanics during bronchoconstriction. *J Appl Physiol* 1996; 81: 964–975.

99 Koulouris NG, Valta P, Lavoie A, Corbeil C, Chasse M, Braidy J, Milic-Emili J. A simple method to detect expiratory flow limitation during spontaneous breathing. *Eur Respir J* 1995; 8: 306–313.

100 Eltayara L, Becklake MR, Volta CA, Milic-Emili J. Relationship between chronic dyspnea and expiratory flow limitation in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1996; 154: 1726–1734.

101 Pellegrino R, Rodarte JR, Brusasco V. Assessing the reversibility of airway obstruction. *Chest* 1998; 114: 1607–1612.

102 Pellegrino R, Brusasco V. Lung hyperinflation and flow limitation in chronic airway obstruction. *Eur Respir J* 1997; 10: 543–549.

103 Pellegrino R, Brusasco V. On the causes of lung hyperinflation during bronchoconstriction. Review. *Eur Respir J* 1997; 10: 468–475.

104 Fessler HE, Scharf SM, Permutt S. Improvement in spirometry following lung volume reduction surgery. Application of a physiological model. *Am J Respir Crit Care Med* 2002; 165: 34–40.

105 Casanova C, Cote C, de Torres JP, *et al.* Inspiratory-to-total lung capacity ratio predicts mortality in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 2005; 171: 591–597.

106 Stark-Leyva KN, Beck KC, Johnson BD. Influence of expiratory loading and hyperinflation on cardiac output during exercise. *J Appl Physiol* 2004; 96: 1920–1927.

107 Guyatt GH, Townsend M, Nogradi S, Pugsley SO, Keller JL, Newhouse MT. Acute response to bronchodilator, an imperfect guide for bronchodilator therapy in chronic airflow limitation. *Arch Intern Med* 1988; 148: 1949–1952.

108 Lorber DB, Kaltenborn W, Burrows B. Responses to isoproterenol in a general population sample. *Am Rev Respir Dis* 1978; 118: 855–861.

109 Dales RE, Spitzer WO, Tousignant P, Schechter M, Suissa S. Clinical interpretation of airway response to a bronchodilator: epidemiologic considerations. *Am Rev Respir Dis* 1988; 138: 317–320.

10 Watanabe S, Renzetti AD Jr, Begin R, Bigler AH. Airway responsiveness to a bronchodilator aerosol. *Am Rev Respir Dis* 1974; 109: 530–537.

11 Anthonisen NR, Wright EC, the IPPB Trial group. Bronchodilator response in chronic obstructive pulmonary disease. *Am Rev Respir Dis* 1986; 133: 814–819.

12 Sourk RL, Nugent KM. Bronchodilator testing: confidence intervals derived from placebo inhalations. *Am Rev Respir Dis* 1983; 128: 153–157.

3 Tweddale PM, Alexander F, McHardy GJR. Short term variability in FEV1 and bronchodilator responsiveness in patients with obstructive ventilatory defects. *Thorax* 1987; 42: 487–490.

114 Eliasson O, Degraff AC Jr. The use of criteria for reversibility and obstruction to define patient groups for bronchodilator trials: influence of clinical diagnosis, spirometric and anthropometric values. *Am Rev Respir Dis* 1985; 132: 858–864.

115 Brand PL, Quanjer PhH, Postma DS, *et al.* Interpretation of bronchodilator response in patients with obstructive airways disease. *Thorax* 1992; 47: 429–436.

116 Olsen CR, Hale FC. A method for interpreting acute response to bronchodilators from the spirogram. *Am Rev Respir Dis* 1968; 98: 301–302.

117 Boggs PB, Bhat KD, Velovius WA, Debo MS. The clinical significance of volume adjusted maximal mid expiratory flow (iso-volume $FEF_{25-75\%}$) in assessing airway responsiveness to inhaled bronchodilator in asthmatics. *Ann Allergy* 1982; 48: 139–142.

118 Redelmeier DA, Goldstein RS, Min ST, Hyland RH. Spirometry and dyspnea in patients with COPD. When small differences mean little. *Chest* 1996; 109: 1163–1168.

119 Barnes PJ, Gribbin HR, Osmanliev D, Pride NB. Partial flow-volume curves to measure bronchodilator dose-response curves in normal humans. *J Appl Physiol* 1981; 50: 1193–1197.

120 Wang JW, McFadden ER, Ingram RH Jr. Effects of increasing doses of β-agonists on airway and parenchymal hysteresis. *J Appl Physiol* 1990; 68: 363–368.

121 Berry RB, Fairshter RD. Partial and maximal expiratory flow-volume curves in normal and asthmatic subjects before and after inhalation of metaproterenol. *Chest* 1985; 88: 697–702.

122 O'Donnell DE. Assessment of bronchodilator efficacy in symptomatic COPD. Is spirometry useful? *Chest* 2000; 117: 42S–47S.

123 O'Donnell DE, Lam M, Webb KA. Spirometric correlates of improvement in exercise performance after cholinergic therapy in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1999; 160: 542–549.

124 Cerveri I, Pellegrino R, Dore R, *et al.* Mechanisms for isolated volume response to a bronchodilator in patients with COPD. *J Appl Physiol* 2000; 88: 1989–1995.

125 Empey DW. Assessment of upper airways obstruction. *BMJ* 1972; 3: 503–505.

126 Miller MR, Pincock AC, Oates GD, Wilkinson R, Skene-Smith H. Upper airway obstruction due to goitre: detection, prevalence and results of surgical management. *Q J Med* 1990; 74: 177–188.

127 Miller RD, Hyatt RE. Obstructing lesions of the larynx and trachea. *Mayo Clin Proc* 1969; 44: 145–161.

128 Pedersen OF, Ingram RH Jr. Configuration of maximum expiratory flow-volume curve: model experiments with physiological implications. *J Appl Physiol* 1985; 58: 1305–1313.

129 Miller MR, Pedersen OF. Peak flow meter resistance decreases peak expiratory flow in subjects with COPD. *J Appl Physiol* 2000; 89: 283–290.

130 Gibson GJ. Central airway obstruction. *In*: Clinical Tests of Respiratory Function. 2nd edn. London, Chapman&Hall, 1996; pp. 194–202.

131 Lebowitz MD, Quackenboss J, Camilli AE, Bronnimann D, Holberg CJ, Boyer B. The epidemiological importance of

intraindividual changes in objective pulmonary responses. *Eur J Epidemiol* 1987; 3: 390–398.
132 Kangalee KM, Abboud RT. Interlaboratory and intralaboratory variability in pulmonary function testing: a 13 year study using a normal biologic control. *Chest* 1992; 101: 88–92.
133 Frey TM, Crapo RO, Jensen RL, Elliott CG. Diurnal variation of the diffusing capacity of the lung: is it real? *Am Rev Respir Dis* 1987; 136: 1381–1384.
134 Hankinson JL, Stocks J, Peslin R. Reproducibility of lung volume measurements. *Eur Respir J* 1998; 11: 787–790.
135 Bland M. Repeatability and precision in measurement. An Introduction to Medical Statistics, Oxford Medical Publications, 1987; pp. 276–278.
136 Robson AG, Innes JA. Short-term variability of single-breath carbon monoxide transfer factor. *Thorax* 2001; 56: 358–361.
137 Spencer DA, Marshall T, Weller PH, Williams J. A superior method of assessing the reproducibility of pulmonary function measurements. *Am Rev Respir Dis* 1992; 145: A253.
138 Collard HR, King TE Jr, Bartelson BB, Vourlekis JS, Schwarz MI, Brown KR. Changes in clinical and physiological variables predict survival in pulmonary fibrosis. *Am J Respir Crit Care Med* 2003; 168: 538–542.
139 Hathaway EH, Tashkin DP, Simmons MS. Intra-individual variability in serial measurements of *D*LCO and alveolar volume over one year in eight healthy subjects using three independent measuring systems. *Am Rev Respir Med* 1989; 140: 1818–1822.
140 Wells AU, Desai SR, Rubens MB, *et al*. Idiopathic Pulmonary Fibrosis. A composite physiologic index derived from disease extent observed by computed tomography. *Am J Respir Crit Care Med* 2003; 167: 962–969.
141 Gibson GJ, Prescott RJ, Muers MF, *et al*. British Thoracic Society sarcoidosis study: effects of long-term corticosteroid therapy. *Thorax* 1996; 51: 238–247.
142 King TE Jr, Tooze JA, Schwarz MI, Brown KR, Cherniack RM. Predicting survival in Idiopathic Pulmonary Fibrosis. Scoring system and survival model. *Am J Respir Crit Care Med* 2001; 164: 1171–1181.
143 ACOEM Position Statement: Spirometry in the Occupational Setting. *J Occup Environ Med* 2000; 42: 228–245.
144 Hughes JM, Bates DV. Historical review: the carbon monoxide diffusing capacity (*D*LCO) and its membrane (DM) and red cell (Theta.Vc) components. *Respir Physiol Neurobiol* 2003; 138: 115–142.
145 Hughes JM. The single breath transfer factor (*T*L,CO) ar the transfer coefficient (*K*CO): a window onto th pulmonary microcirculation. *Clin Physiol Funct Imagin* 2003; 23: 63–71.
146 McLean A, Warren PM, Gillooly M, MacNee W, Lamb I Microscopic and macroscopic measurements of emph sema: relation to carbon monoxide gas transfer. *Thor* 1992; 47: 144–149.
147 Kitaichi M, Nishimura K, Itoh H, Izumi T. Pulmona lymphangioleiomyomatosis: a report of 46 patien including a clinicopathologic study of prognostic factor *Am J Respir Crit Care Med* 1995; 151: 527–533.
148 Bernstein RJ, Ford RL, Clausen JL, Moser KM. Membra diffusion and capillary blood volume in chronic thror boembolic pulmonary hypertension. *Chest* 1996; 11 1430–1436.
149 Horn M, Ries A, Neveu C, Moser K. Restricti ventilatory pattern in precapillary pulmonary hyperte sion. *Am Rev Respir Dis* 1983; 128: 163–165.
150 Collard P, Njinou B, Nejadnik B, Keyeux A, Frans *D*LCO in stable asthma. *Chest* 1994; 105: 1426–1429.
151 Collard P, Wilputte JY, Aubert G, Rodenstein D Frans A. The *D*LCO in obstructive sleep apnea a obesity. *Chest* 1996; 110: 1189–1193.
152 Greening AP, Hughes JMB. Serial estimations of *D*LCO intrapulmonary hemorrhage. *Clin Sci* 1981; 60: 507–512
153 Hughes JM, Pride NB. In defence of the carbon monoxi transfer coefficient *K*CO (*T*L/Va). *Eur Respir J* 2001; 1 168–174.
154 Kanengiser LC, Rapoport DM, Epstein H, Goldring RI Volume adjustment of mechanics and diffusion interstitial lung disease: lack of clinical relevance. *Ch* 1989; 96: 1036–1042.
155 Stam H, Splinter TAW, Versprille A. Evaluation diffusing capacity in patients with a restrictive lu disease. *Chest* 2000; 117: 752–757.
156 Frans A, Nemery B, Veriter C, Lacquet L, Francis C. Eff of alveolar volume on the interpretation of single-bre *D*LCO. *Respir Med* 1997; 91: 263–273.
157 Chinet T, Jaubert F, Dusser D, Danel C, Chretie Huchon GJ. Effects of inflammation and fibrosis pulmonary function in diffuse lung fibrosis. *Thorax* 45: 675–678.
158 Johnson DC. Importance of adjusting *D*LCO and *K*(alveolar volume. *Respir Med* 2000; 94: 28–37.
159 Chinn DJ, Cotes JE, Flowers R, Marks AM, Ree Transfer factor (diffusing capacity) standardize alveolar volume: validation, reference values anc cations of a new linear model to replace *K*CO (T *Eur Respir J* 1996; 9: 1269–1277.

Appendix H—ACOEM Evaluating Pulmonary Function Change Over Time

American College of Occupational and Environmental Medicine

Evaluating Pulmonary Function Change Over Time

Introduction

Periodic spirometry testing is performed in medical screening and surveillance programs for workers with various occupational exposures and for cigarette smokers. The recent American College of Occupational and Environmental Medicine (ACOEM) evidence-based statement, *Spirometry in the Occupational Setting*, comprehensively reviewed the issues involved in conducting and interpreting standardized spirometry tests in occupational medicine.(1) However, interpreting change over time was only briefly discussed in that statement and little other guidance on assessing longitudinal change in lung function is available for health professionals. As a result, many practitioners do not evaluate change in lung function over time, but instead repeatedly determine whether each year's test results fall within the normal range. Other practitioners evaluate change over time or "trending" but are unaware of the pitfalls that can distort their evaluations.

Although health professionals must determine whether evaluating lung function change over time effectively screens for a specific outcome disease,(2-4) the ACOEM Occupational and Environmental Lung Disorder Committee recognized the need to provide guidance in the selection and use of simple measures of change over time. The Committee developed this separate ACOEM position statement to: 1) explain the need for longitudinal analysis of pulmonary function when evaluating employee respiratory health; 2) describe the pitfalls to be avoided when collecting serial measurements for longitudinal analysis; and 3) recommend simple criteria to use for flagging abnormal change in pulmonary function over time. The statement's key points are summarized in Table 1. Real-life examples illustrate the pitfalls to be avoided and the application of longitudinal methods for evaluating pulmonary function.

Table 1: Evaluating Change over Time
Key Points

1. Why **Look at Change Over Time?**

   - Traditionally, lung function has been compared with average (*i.e.*, predicted) values measured in asymptomatic nonsmokers similar to the worker
   - Change over time compares each worker with him/herself and probably detects earlier lung function loss, especially if the worker's baseline is above average
   - Consistent with OSHA intent of evaluating current and previous results

2. How **to Evaluate?**

   - *Longitudinal Normal Limit (* LNL *)* is based upon baseline results for a specific worker
   - Compare the worker's ***Current*** results to his/her ***LNL***

Is BASELINE result above average (>100% Predicted)?

- YES --> Method 1* for simple calculation analyzing % Predicted values

- NO --> Method 2* for calculations analyzing actual (measured) values

3. Cautions - **To Interpret Serial Tests:**

   - Spirometry must be high quality
   - Timing of tests must be consistent
   - Technician training and quality assurance program essential
   - Results interpreted by well qualified health professionals

* *Note: If a screening program wants to adopt only one method to compute LNLs for all workers, ACOEM recommends choosing* Method 2 .

Why Examine Change Over Time?

Spirometry in Medical Screening and Surveillance Programs
Spirometry is performed periodically in screening and surveillance programs for a variety of

occupational exposures. Occupational Safety and Health Administration (OSHA) regulations require periodic spirometry testing for certain workers exposed to asbestos,(5) coke oven emissions,(6) cadmium,(7) cotton dust,(8) benzene,(9) and formaldehyde.(10) Many companies mandate medical surveillance with periodic spirometry testing for additional exposures as well as incorporating spirometry into their respirator medical clearance screening programs. In each case, health professionals must evaluate current and previous test results to determine whether an employee is at increased risk of impairment from further occupational exposure, or if any limitations should be placed on the employee's activities or use of personal protective equipment. However, the details of the evaluation of current and previous results are usually not specified. The OSHA Cotton Dust Standard is only slightly more explicit than the other OSHA regulations listed above, stating that "a determination [shall be] made by the physician as to whether there has been a significant change [between the current examination results and those of previous examinations]."(8)

Comparing Observed with Cross-sectional Predicted Values

Traditionally, an individual's measured lung function has been compared with a "predicted" value, *i.e.*, the average expected for an asymptomatic non-smoker of the subject's age, height, race/ethnicity, and sex. Many sources of predicted values have been derived from studies of asymptomatic non-smoking populations, and some applications require the use of specific sets of prediction equations. Selection of reference values has been reviewed elsewhere.(1,11-15) The comparison of observed with predicted values is usually summarized in a numerical index, the percent of predicted (% Pred). Lower Limits of Normal should be determined for the prediction equations in use, and the individual's measured results are then interpreted relative to the normal range as normal or abnormal, and possibly impaired. Since Lower Limits of Normal generally decrease with age, the use of 80% Pred as a Lower Limit of Normal for all age groups is no longer recommended.(11) Definitions of the Lower Limit of Normal, choice of measurements for evaluation, and definitions of airways obstruction have evolved over time,(1,11) but the approach of comparing an individual with the average "predicted" from an asymptomatic population has been widely used for decades.

Need for Longitudinal Lung Function Evaluation in Occupational Settings

In the clinical setting, patients with lung disease are often tested to determine the severity of their disease.(3,16) In contrast, in the occupational setting, many healthy workers are tested periodically, not because they have abnormal lung function, but to monitor their response to potentially harmful occupational exposures. Because of their health, working populations usually have higher levels of pulmonary function than clinic populations, and many workers have lung function that is above average, *i.e.*, > 100% Pred. Such individuals may lose their lung function at an excessive rate *but still remain in the normal range* throughout their working lifetime and into retirement. Remaining in the normal range does not indicate respiratory health, since their function may drop from the top to the bottom of the normal range, but these individuals must lose large fractions of their lung function before they will fall below the normal range. For these workers, the widespread practice of repeatedly comparing serial test results with the traditional normal range may not detect serious pulmonary function deterioration. Longitudinal evaluation that compares current measured values with previously measured values, "using the subject as his/her own control," is needed especially for this group, as summarized in Table 2. (11,17,18)

Table 2: Why Examine Change Over Time?

1. OSHA- and industry-mandated medical surveillance programs require health professionals to assess respiratory health using previous and current examination results.

2. Traditional evaluation of pulmonary function determines whether test results are in the normal range, which is based on asymptomatic non-smokers.

3. Unlike clinic patients, many workers have above average lung function, *i.e.*, >100% Pred. Such lung function can deteriorate dramatically, falling from the top to the bottom of the normal range, without dropping *below* the normal range. This loss of function *will not be detected* by simply determining whether each year's test results fall within the traditional normal range.

4. Health professionals must determine whether monitoring change over time is an effective screening test for the outcome disease of interest.

Evaluating Longitudinal Change to Screen for Specific Diseases

While this statement provides a method for evaluating change over time, health professionals must decide whether screening for excessive loss of function is appropriate for specific outcome diseases of interest. Monitoring pulmonary function longitudinally may be more justified for some exposures, *e.g.*, smoking-related chronic obstructive pulmonary disease (COPD), than for others.(2-4) The sensitivity, specificity, and positive and negative predictive values of excessive loss of pulmonary function relative to the outcome disease of interest should be investigated. Screening for excessive loss of function is recommended if the prevalence and severity of the outcome disease are significant and if the effectiveness of the intervention or treatment balances the financial and non-financial costs of the intervention. (19)

Pitfalls in Collecting Serial Measurements

Although "using the subject as own his/her own control" may detect pulmonary function declines that are missed by comparisons with predicted values, practitioners who analyze longitudinal spirometry data are often unaware of the pitfalls that can invalidate their conclusions. Since both technical and biological factors affect spirometry results at each test session, practitioners should attempt to hold these factors constant if longitudinal analysis is anticipated. (20-25) Failure to control these factors produces extraneous variability which may be interpreted as an excessive loss or gain of lung function. Therefore, users of spirometry data should appreciate the effects of technical and biological factors on measurements and be prepared to evaluate test quality and reject inadequate tests before evaluating change over time. Sources of technical and biological variability are summarized in Table 3.

Table 3: Pitfalls in Collecting Serial Measurements

1. Standardize and Document the Testing Protocol, Equipment Used, and All Changes in Protocol or Equipment.

2. Technician Training and Periodic QA Audits of Spirograms

3. Equipment

   - Minimize unnecessary equipment changes

   - Minimize changes in spirometer configuration

   - Insure spirometer accuracy
     a. Laboratory testing of spirometer submitted by manufacturer
     b. Calibration or calibration checks at least daily when in use
     c. On-going scrutiny of spirograms and patterns of test results

   - Retain calibration records indefinitely

4. Biological variability

   - Standardize time of day and season of testing to evaluate long-term change

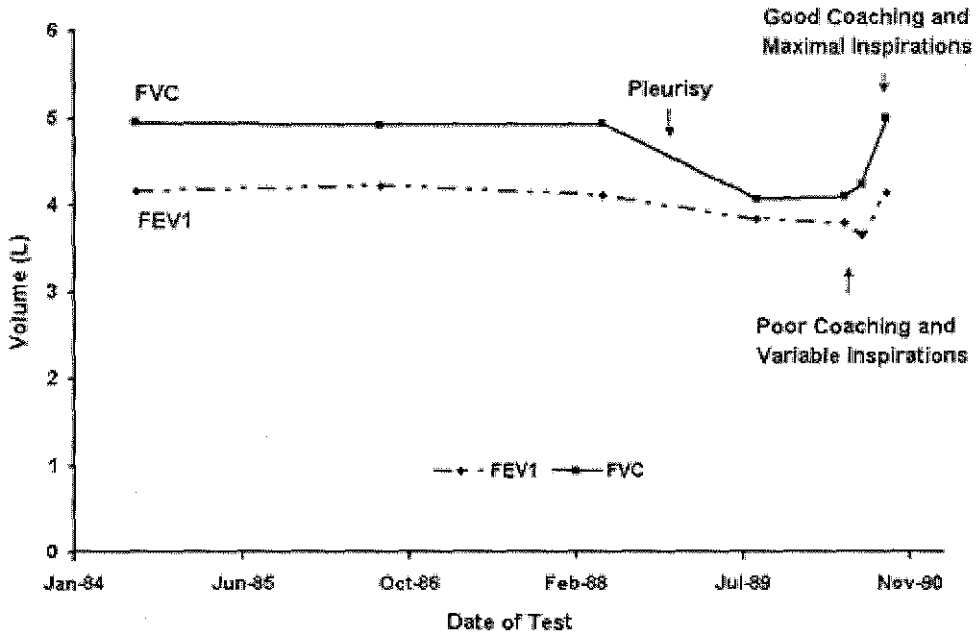
   - Postpone testing for 3 days if subject feels ill, for 3 weeks after severe respiratory or ear infection, for 1 hr after smoking, use of bronchodilator, or a heavy meal, and until medically approved after surgery.

Technical Variability

Standardization and Documentation of Testing Technique and Equipment
Spirometry testing procedures, type of spirometer, and spirometer maintenance and quality assurance (QA) checks should be standardized across location and time, particularly if longitudinal analysis of lung function measurements is anticipated. Current American Thoracic Society (ATS) recommendations were summarized in the recent ACOEM spirometry statement. (1,26) Testing procedures and equipment used should be fully documented, and the documentation should be updated whenever changes occur. Standardization and documentation are particularly important if testing is contracted out to multiple vendors over time. In fact, frequent changes in vendor and/or poor vendor quality control of testing may preclude any meaningful longitudinal evaluation of results. Equipment malfunction and errors in testing technique can cause measurements to be falsely elevated or reduced.(1, 26-32) Some technical errors cause increased variability that is random, though many problems cause results to be biased. When a series of erroneous measurements is examined, healthy workers may appear

to "decline," while others' deteriorating function may be masked by the noise in the measurements. Figures 1and 2, discussed below, illustrate the difficulty in evaluating change over time using technically flawed measurements. A summary of technical errors that raise and lower test results is available on the Internet. (31)

Figure 1. Poor Coaching Reduced the FVC and FEV1



Testing Technique

Health professionals should develop a written testing protocol and insure that technicians understand and follow the specified procedures. The many details involved in conducting tests and maintaining equipment may be easily misunderstood, resulting in non-standardized testing procedures. The details of the testing procedures should be spelled out in the written protocol, *e.g.*, the definition of end-of-test [recording to a forced vital capacity (FVC) plateau vs. recording for a specified number of seconds], testing posture [standing vs. sitting], minimum number of *acceptable* maneuvers to be recorded, criteria for rejecting a maneuver, *i.e.*, what makes a maneuver "unacceptable," and whether to print out curves during a test for coaching if there is no real-time graphical display. Changes in the testing procedures over time should be documented. Figure 1 illustrates the effect of poor coaching which elicited only sub-maximal inspirations from an employee who had recovered from pleurisy but appeared not to have returned to his baseline level of pulmonary function. When an experienced technician urged the employee to inhale maximally, his FVC and forced expiratory volume in one second (FEV_1) results increased by 0.8 and 0.5 L, respectively, returning to their baseline levels. The variability introduced by inconsistent testing technique, such as that shown in Figure 1, probably precludes meaningful evaluation of change over time.(18)

Spirometry training courses such as those approved by the National Institute of Occupational Safety and Health (NIOSH) are recommended, and NIOSH is developing a course-approval web page and reorganizing its program to insure better standardization among courses.(1, 26) A

single vendor should provide training for all technicians at a location, if feasible, and training should be followed by supervised on-the-job testing experience (26) and QA review of spirograms for technical quality.(26, 33, 34) Periodic Refresher courses are recommended (1) and QA reviews of spirograms should be continued indefinitely, perhaps conducted at least on a quarterly basis.

Equipment

When longitudinal evaluation is anticipated, equipment variability should be minimized across locations and time. Variability may be increased if different spirometers are used, if calibrations or calibration checks are not performed correctly and consistently, or if spirometer temperatures vary widely.(35) Recommendations to minimize equipment variability are presented below.

1. *Minimize unnecessary equipment changes*
   Unnecessary equipment changes should be avoided if longitudinal analysis of results is anticipated, though excessively variable spirometers should be replaced by instruments with greater precision. The ATS recommends that spirometers should be accurate to within +/-3% of the volume introduced into a spirometer, so a spirometer meets minimum criteria for accuracy if it records between 2.91-3.09 liters when a 3.00 liter volume is introduced. But since variability exists both within and between spirometers, a 3-liter subject could record 3.09 liters on one spirometer and 2.91 liters on a different spirometer, even though both spirometers met minimum accuracy requirements.(18) Some variation between spirometers may be due to their different mechanisms for determining volume or their use of variable disposable sensors. Some flow-type spirometers measure slightly different volumes when air passes through the sensor at different speeds, while volume-type spirometers are less affected by the speed of air entering the spirometer. Some spirometer sensors may also be subject to changes in calibration over time. Table 4 gives one example of varying volumes recorded by a flow-type spirometer when a 3-liter syringe was injected at different speeds during a calibration check, as described below. Though all of the values are within the acceptable range of 2.91-3.09 L, this spirometer clearly records lower volumes when airflow is slower.

Table 4:
3 L Injected into a Flow-Type Spirometer at Various Speeds

Injection Speed (L/s)	Recorded Volume (L) *
0.52	2.94
0.98	2.98
3.33	3.01
5.45	3.08

* Recorded volumes from 2.91-3.09 meet minimum standards of accuracy.

2. *Minimize changes in spirometer configuration*
Most spirometers permit users to customize various aspects of data-saving and reporting during testing. Often, there is a choice of how many maneuvers' results should be saved and reported [users should choose "all data" and "all curves", which spirometry measurements to save and report [users should choose FEV_1, FVC, or forced expiratory volume in six seconds (FEV_6), FEV_1/FVC or FEV_1/FEV_6, PEF and forced expiratory time (FET) if available, unless other requirements apply], and which values are selected from the maneuvers attempted [users should choose maximum FEV_1, maximum FVC or FEV_6, maximum PEF, and not the "best curve" FEV_1 and FVC values].(26) It should be noted that many regulations do not permit measurement of the FEV_6 in place of the FVC. Any changes in spirometer configuration over time or across locations should be documented. Changing the spirometer's configuration may change the data that are saved and reported, which will adversely affect longitudinal analysis of lung function.

3. *Spirometer accuracy*
several steps help to insure that spirometers function accurately.(1) First, the ATS recommends minimum acceptable levels of accuracy and precision for spirometers.(26) Second, an independent testing laboratory injects 24 standard waveforms into spirometers that are submitted by manufacturers for evaluation, and analyzes the spirometer responses.(26) If a spirometer passes the laboratory testing, a letter is issued stating that the spirometer completed testing following the 1994 ATS Spirometry Update protocol for evaluating diagnostic spirometers. Users should request a copy of this letter, specifically citing the *1994 ATS testing protocol*, from their spirometer manufacturers.(1)

However, passing laboratory testing does not guarantee continued functioning, so the third step in insuring that the spirometer works properly is to regularly check the calibration of the spirometer before it is used for testing.(1) These checks are performed at least daily when the spirometer is in use and more frequently if many subjects are tested. Calibration checks performed at the end of the testing session confirm the status of the spirometer during the preceding tests. Calibration checks are *decision-making prompts*: if the spirometer fails a properly performed calibration check, the spirometer is out-of-calibration and should not be used for subject testing. Though the ATS recommends checking the calibration every four hours and whenever temperature changes occur,(26) the frequency also depends on how many tests the health professional can afford to discard and repeat if a calibrated spirometer loses its calibration.

Spirometer calibration is either *set* or *verified* during the "calibration" routine; users should consult their manufacturer to determine which procedure is performed for their spirometer. If calibration is *verified*, the 3 L should be injected once at a moderate speed for a volume spirometer and 3 times, at slow, medium, and fast speeds (*e.g.*, over 1 s, 3 s, and 6 s) for flow-type spirometers.(1, 26) If calibration is *set*, the 3-L volume should be injected at the speed specified by the manufacturer; after the calibration is set, flow-type spirometer accuracy should be verified at 3 speeds of injection using a manufacturer-recommended protocol. For flow-type spirometers with disposable sensors, it is prudent to perform a calibration check using the sensor that the subject will use,(37) but if this is not feasible, sensors used for calibration should at least be drawn from the same batch as

those used for subject testing. Technicians should avoid the incorrect practice of using one sensor for calibration checks over extended periods of time while changing the subjects' sensors.

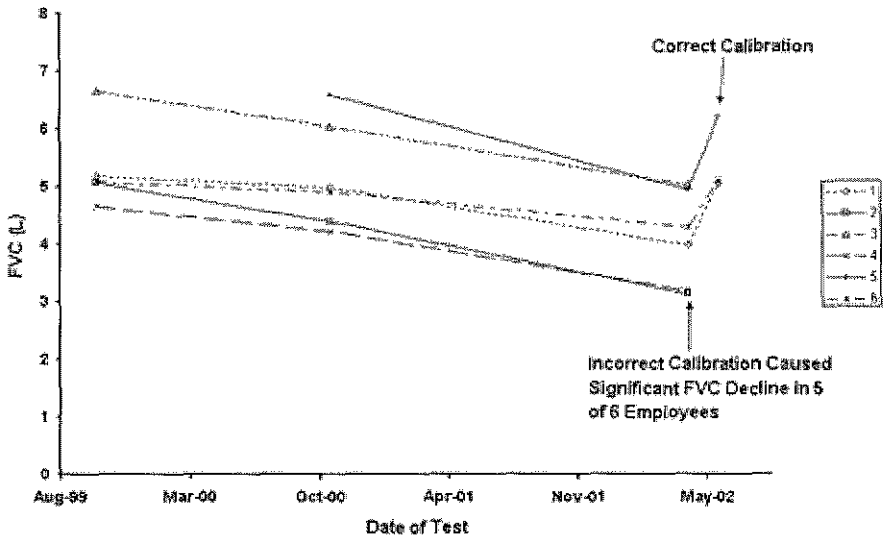
The calibration syringe must be accurate: syringes can be calibrated annually and checked for leaks periodically by trying to empty the syringe with the outlet blocked.(26) Store the calibration syringe near the spirometer in the testing environment, and perform calibrations and calibration checks in that environment. It is unacceptable to perform calibrations or checks in a warm environment to guarantee that the spirometer passes the calibration, and then move the spirometer into a colder environment, *e.g.*, an unheated mobile testing van, for subject testing. If the testing environment can be maintained at 23 degrees C (73 degrees F) or above, testing errors due to cold temperatures will be minimized;(35) the ATS sets a minimum spirometer temperature at 17 degrees C.(11)

Volume-type spirometers should also be checked for leaks, daily and whenever breathing hoses are changed. The current ATS acceptable leak level is 0.01 l/min, though a slightly larger leak may be tolerated under revised ATS recommendations that are under development. If a chart recorder is used, the chart speed should be checked quarterly, along with linearity of the volume measurement.(26)

Finally, attention has recently been drawn to the fact that serious problems can develop during testing even after the spirometer passes its calibration checks.(30, 38) Particularly with flow-type spirometers, problems can develop due to faulty zeroing or contamination of the sensor, causing anomalous results and spirograms with unusual shapes. Therefore, even after calibration checks indicate that a spirometer is acceptably accurate, users should evaluate visual patterns in spirograms and be watchful for unlikely patterns of elevated results during testing.(30, 31, 38) Such vigilance is particularly important when longitudinal analysis is planned since falsely elevated baselines will exaggerate the loss of function over time in many individuals, while falsely elevated follow-up test results will have the opposite effect.

4. *Save calibration records indefinitely*
Calibration records support the accuracy of employee spirometry tests conducted on the calibration date, and should be saved indefinitely.(39) When contracting out to vendor(s), users should obtain and save records from all calibrations or calibration checks performed while testing is conducted at their facility. If problems with test results are discovered later, calibration records may provide the solution to the problems. Figure 2 presents 3 years of spirometry surveillance results, showing that 5 out of 6 employees experienced significant declines in their FVC in April, 2002. The mean FVC for the 6 employees declined by 1.1 L from the previous test 18 months earlier, but then returned to baseline levels on further testing 2 months later. Calibration records later revealed that the spirometer used in April, 2002 was calibrated incorrectly, causing subject volumes to be grossly under-recorded, and producing the apparent FVC declines. As with errors in testing technique (Figure 1), such increased variability probably precludes meaningful evaluation of change over time.(18)

Figure 2. Incorrect Calibration Reduced the FVC



Biological Variability

As airway caliber changes, spirometry measurements demonstrate diurnal (within a day) and seasonal (within a year) variability, so that time of day and year should be standardized when collecting serial measurements for long-term longitudinal analysis. Though diurnal variability, in particular, gives important information when short-term changes are evaluated, *e.g.*, due to asthma, these factors should be controlled when long-term change in function is the outcome of interest. Many medical surveillance programs conduct examinations on the employee's birthday, so that seasonal variability is controlled.

Other factors may also affect test results and should be queried before conducting a spirometry test.(32) NIOSH recommends that testing be postponed for three weeks if the subject has had a recent severe respiratory infection. The test should be postponed for one hour if the subject has had a large meal, smoked a cigarette, or used a bronchodilator within the last hour. The one hour postponement can sometimes be achieved by performing the spirometry test later in a physical examination. If it is not feasible to postpone a test, these factors should at least be documented on the report of test results.

What Is a 'Significant Change' Over Time?

Because measurement variability strongly affects estimates of change in lung function over time, the expected rate of change is not as well defined as the cross-sectional "predicted" value. Definitions of "significant change" should minimize false negatives and false positives; deteriorating lung function should be detected early enough to permit the rate of loss to be slowed and the remaining function to be preserved, but at the same time, workers should not be labeled as having "significant loss" if they are not developing impairment. Definitions of "significant change" should be simple to apply even when practitioners do not have access to sophisticated statistical programs. The current ACOEM recommendations for evaluating change over time are summarized in Table 5.

Table 5: What Change Over Time Is 'Significant'?

1. Quantifying **Change over Time**

    - Method 1 ***for Baselines >100 % Pred**** : Calculate Decrease in *FEV1 % Pred or FVC % Pred* from Baseline to Follow-up

    - Method 2 ***for Baselines <= 100 % Pred**** : Calculate Decrease in *Measured FEV1 or FVC* from Baseline to Follow-up

    - Fit "Slope" through Periodic FEV1s or FVCs over > 4-6 Years

2. **What Change Is "Significant"?**

    - Method 1*: Follow-up *FEV1% Pred or FVC % Pred* falls below *Longitudinal Lower Limit of Normal (LNL) =*

      [Baseline % Pred x 0.85] (See Table 6)

    - Method 2*: Follow-up *Measured FEV1 or FVC* falls below *Longitudinal Lower Limit of Normal (LNL) =*

      [0.85 x Baseline Measured Value - (Baseline Pred - Follow-up Pred)] (See Table 7)

    - Slope Steeper than 90-100 ml/yr over 4-6 or More Years

3. **What If Change Appears to be "Significant"?**

    - Re-test to Confirm Low Value

    - Provide Medical Evaluation, *even if Test Results Remain in the Traditional Normal Range.*

* *Note: If a screening program wants to adopt only one method to compute LNLs for all workers, ACOEM recommends choosing* Method 2 .

Length of Follow-up and Frequency of Testing

Estimates of individual rate of change become more precise as follow-up time increases, and

only large losses of function can be reliably detected over short time periods, *e.g.*, <2 years. To estimate longer term trends in an individual's FEV_1 or FVC, spirometric measurements should be made over at least 4-6 years using standardized equipment and testing techniques.(1,20-24,40) Precision is less affected by measurement frequency than by length of follow-up,(1,20,21,39) but periodic measurements are needed to detect workers experiencing rapid declines in pulmonary function and to detect systematic differences between examinations over time.(1,21,23,40)

ACOEM recommends that spirometry should be conducted every 1-2 years when indicated because of workplace exposures, unless otherwise specified by applicable regulations or recommendations.(1) The frequency of testing may vary with age and length of exposure as in the National Fire Protection Association (NFPA) examination protocol, which recommends spirometry testing every 3 years for fire fighters under age 30, every 2 years for ages 30-39, and annually for ages 40 and above.(41)

Evaluating and Defining 'Significant Change'
Loss of FEV_1 or FVC over time can be estimated simply by evaluating the difference between measurements at two points in time, or by fitting a least squares "slope" through an individual's periodic measurements.(1) Though epidemiologic studies often use complex statistical methods, this statement focuses on two simple approaches to use when evaluating individual workers: *Method 1* (for BASELINE results > 100% Pred) evaluates change in *FEV1 % Pred or FVC % Pred* over time; and *Method 2* (for BASELINE results <= 100% Pred) evaluates change in *measured FEV1 or FVC* over time. Method 1 is important because it provides a simple and more sensitive definition of abnormality for employees with above average baseline lung function. However, if a medical program wishes to adopt *only one method for all workers, ACOEM recommends choosing* Method 2, as recommended in the previous ACOEM Statement.(1)

Method 1. for BASELINES >100% Pred: Evaluate Change in % Pred
Method 1 provides a simple **Longitudinal Lower Limit of Normal (LNL)** for *FEV1% Pred and FVC% Pred* for individuals whose Baseline results exceed 100% Pred. The LNL should identify workers with accelerated lung function decline even though they remain in the traditional normal range. *An employee is expected to remain above the LNL as he/she ages.* Using the current estimate of 15% year-to-year measurement variability,(11) the Baseline % Pred is multiplied by 0.85 to obtain the LNL. *Note that the same set of reference values (prediction equations) must be used for baseline and all follow-up tests.*

Method 1: *Longitudinal Lower Limit of Normal (LNL) for Follow-up FEV_1 (or FVC) % Predicted = [0.85 x Baseline % Predicted)].*

Table 6 and Figure 3 present FVC results for a 66-inch tall Caucasian woman, tested periodically from age 30-50 years. Her baseline FVC was 4.39 L, or 109% Pred, based on the National Health and Nutrition Examination Survey (NHANES) prediction equations.(12) At age 50, her FVC was 84% Pred. When each test was simply compared with the traditional normal range, all of her measured FVCs were above the traditional lower limit of normal and she appeared to be "normal."

However, evaluating her results relative to her own baseline value leads to a different conclusion. For her baseline FVC of 109% Pred, the LNL is [0.85 x 109%] = *93% Pred.* As shown in Table 6, each of her tests remained above 93% Pred until age 50, when her result fell below the LNL. If this low value is confirmed by a re-test, she should be medically evaluated, *even though her results remain within the traditional normal range.* (17,42)

This example illustrates the insensitivity of repeatedly comparing periodic test results with the traditional normal range, particularly for employees with above average levels of pulmonary function. When baseline values exceed 100% Pred, lung function must decline dramatically before test results will fall below the traditional normal range. However, longitudinal evaluation using a LNL will be more sensitive to possible accelerated lung function decline.

Table 6: Is This a Significant Decline in % Predicted?

A 66-inch tall Caucasian woman was tested periodically from age 30 - 50 years (Figure 3). Is her FVC loss "significant" at age 50?

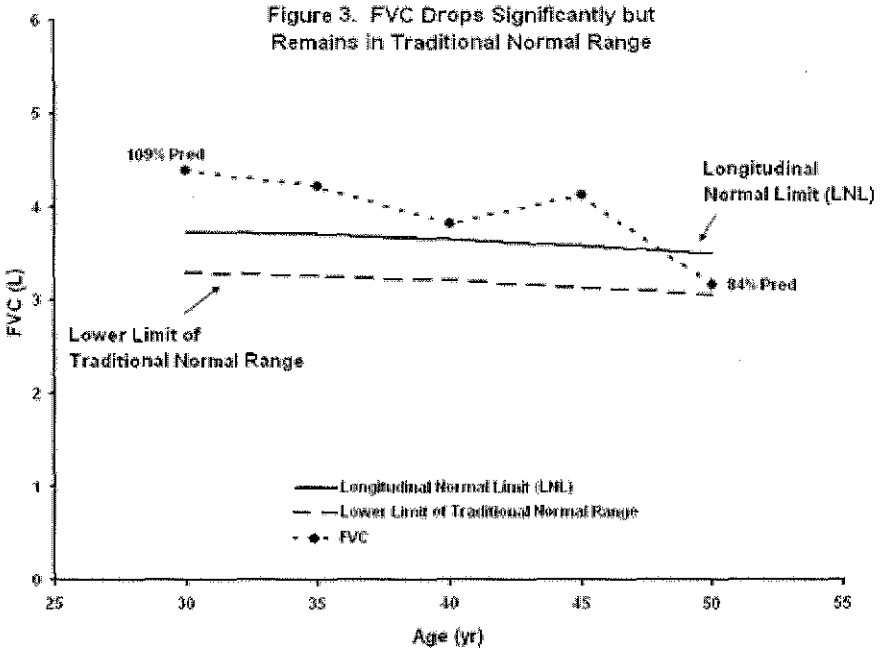
Since ***Baseline FVC > 100% Pred*** , determine a Longitudinal Lower Limit of Normal (***LNL***) for *% Pred.* The subject should remain above this LNL as she ages.

Age	FVC (L)	FVC % Pred	Lower Limit of Traditional Normal Range
30	4.39	109	3.29
35	4.22	106	3.26
40	3.82	97	3.21
45	4.12	106	3.14
50	3.17	**84**	3.05

- Use ***Method 1*** to calculate the LNL for Follow-up *% Pred*:

  Longitudinal Lower Limit of Normal (LNL) =
  Baseline % Pred x 0.85 = 109% x 0.85 = 93% Pred.

- FVC remains > 93% Pred until age 50, when it falls to 84% Pred. If retest confirms this low value, *medical review is recommended, even though her FVC remains in the traditional normal range.*



Method 2. for BASELINES <= 100% Pred: Evaluate Change in Measured Values
ACOEM recommends *Method 2* to calculate a **Longitudinal Lower Limit of Normal (LNL)** particularly for employees with Baseline results <= 100% Pred.(43) However, some medical programs may want to adopt *only one LNL method for all workers*. In that case, Method 2 can also be applied to workers with Baselines > 100% Pred, since both methods give the same results for this group. *If only one method will be used for all workers, ACOEM recommends choosing Method 2 to compute the LNL.*(1)

A "significant" decline should exceed both: 1) year-to-year measurement variability, currently estimated at 15%; (11) and 2) the expected age-related decline, which can be calculated as the difference between the baseline and follow-up predicted values.(1, 39, 42) These factors are used below to determine the LNL for follow-up test results. An employee is expected to remain above the LNL as he/she ages. *Note that the same set of reference values (prediction equations) must be used for the baseline and all follow-up tests.*

Method 2: *Longitudinal Lower Limit of Normal (LNL) for Follow-up Measured FEV_1 (or FVC) = [0.85 x Baseline Measured Value - (Baseline Predicted - Follow-up Predicted)].*

Table 7 and Figure 4 present FEV_1 results for a 65-inch tall Caucasian woman, tested annually from age 67¨C73 years. Her baseline FEV_1 was 2.42 L, or 97% Pred, based on the NHANES prediction equations.(12) Though a LNL was computed for each test date, only the age 69 results are evaluated here. As illustrated in Table 7, the LNL at age 69 is *2.00 L, i.e.*, the FEV1 could drop as low as 2.00 L at age 69, due to measurement variability and aging alone. Since the age 69 test result is below 2.00 L, the FEV1 decline may be "significant" and should be medically evaluated if the low result is confirmed by a re-test.(17,41) Figure 4 shows that the FEV_1 remained below the LNL for all

subsequent tests, though it did not fall below the traditional normal range until several years later, at age 73. This subject's deteriorating lung function was identified by longitudinal evaluation 4 years earlier than it would have been detected by comparisons with the traditional normal range.

Table 7: Is This Decline Significant?

A "significant" loss of FEV_1 should exceed year-to-year *measurement variability* and expected *loss due to aging*.

A 65-inch tall 67- year old Caucasian woman with **Baseline FEV <= 100% Pred** was tested annually; biennial results are shown below. Longitudinal Lower Limits of Normal (LNL) were calculated for each test (Figure 4). Has her FEV_1 declined "significantly" by age 69?

Age	FEV_1 (L)	Pred FEV_1	FEV_1% Pred	Longitudinal Normal Limit (LNL)
67	2.42	2.49	97	2.06
69	**1.93**	2.43	79	**2.00**
71	1.82	2.37	77	1.94
73	1.61	2.30	70	1.87

- Using Method 2, allow 15% *measurement variability*:

  [0.85 x Baseline FEV_1] = 0.85 x 2.42 L = 2.06 L

- Calculate *expected aging effect*:

[Baseline Pred FEV_1 - Pred FEV_1 at Age 69] = 2.49 L ¨C 2.43 L = 0.06 L

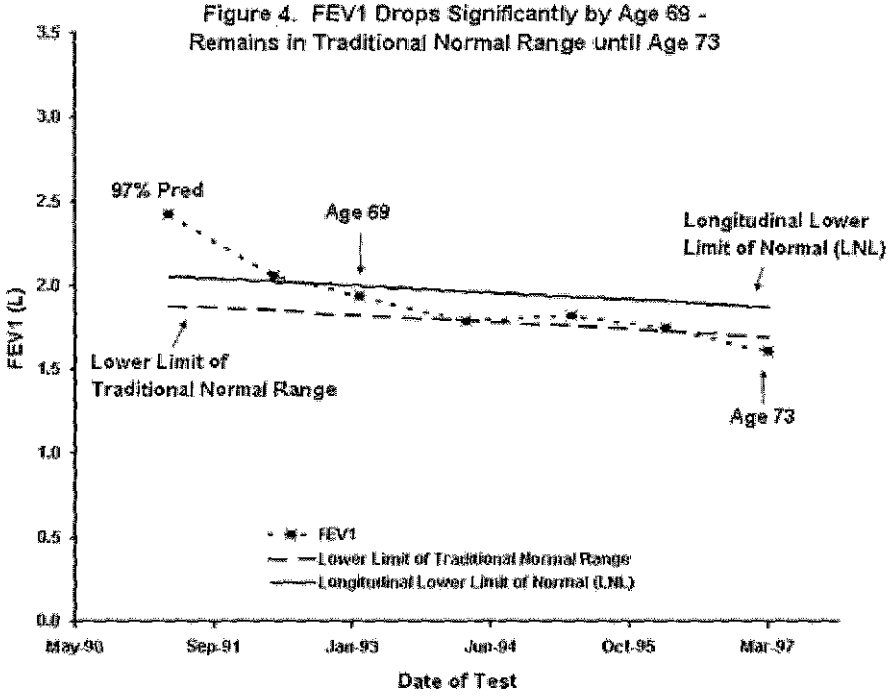
- Calculate *Longitudinal Normal Limit (LNL)* for follow-up FEV_1 =

[0.85 x Baseline FEV_1 - Expected Aging Effect] = 2.06 - 0.06 = 2.00 L

- *Her FEV_1 at age 69 should be >=; 2.00 L (LNL)*. Since her FEV_1 (1.93 L) is < LNL, she should be retested to confirm this result.

- If confirmed, *medical review is recommended*, even though the FEV_1 remains in the traditional normal range until age 73, as shown in Figure 4.

Figure 4. FEV1 Drops Significantly by Age 69 - Remains in Traditional Normal Range until Age 73



Initial Identification vs. Progression

Once a worker is identified as having impaired lung function, ATS recommends a less conservative definition for evaluating progression of disease, since both the measured volumes and the percents of predicted are smaller than for the healthy individuals discussed above. In the statement on "Idiopathic Pulmonary Fibrosis: Diagnosis and Treatment," ATS and the European Respiratory Society (ERS) recommend interpreting *a loss of 10% or more of the measured baseline VC (or at least 0.20 L)* as a "failure to respond to therapy," *i.e.*, a significant decline, if the change is accompanied by parallel changes in single-breath diffusing capacity or oxygen saturation 6 months after the baseline test.(44)

In addition, *an increase from the measured baseline VC of 10% or more (or at least 0.20 L)* is interpreted as a significant improvement if the change is accompanied by parallel changes in single-breath diffusing capacity or oxygen saturation and is maintained for two consecutive visits within a 3-6 month period.

Changes smaller than +/- 10 % of measured baseline VC (or < 0.20 L) maintained for two consecutive visits within a 3-6 month period indicate stable pulmonary function.(44)

Fitting a Least Squares 'Slope' through Periodic Measurements

Calculating a best-fit line of lung function measurements on test date requires more computational capability than calculating differences, but can be programmed or computed on a calculator. Based on reviews of the longitudinal spirometry literature, the previous ACOEM spirometry statement recommended that an FEV_1 or FVC decrease of 90-100 ml/ year, calculated over at least 4-6 years, should trigger further medical evaluation of pulmonary function.(1,21,24,45) Though this area remains one of current

investigation, neither longitudinal predicted values nor 5th percentile LLNs have yet been recommended for the evaluation of individual rates of change over time in occupational or clinical settings.(1,21,46)

Conclusion

As summarized in Table 1, longitudinal evaluation of pulmonary function should be considered, particularly in the occupational setting, because many workers have above average levels of pulmonary function (*i.e.*, >100% Pred). Such high levels of lung function can deteriorate substantially, falling from the top to the bottom of the normal range, without dropping *below* the normal range. This loss of function *may not be detected* by the common practice of simply determining whether each year's results fall within the traditional normal range.

To address this problem, ACOEM recommends simple methods for comparing an employee's periodic spirometry results with a ***Longitudinal Lower Limit of Normal (LNL)*** specific for that employee. Starting with an individual's baseline lung function level, the LNL describes the lowest results that might be expected for his/her lung function during follow-up, due to normal aging and measurement variability. Test results falling below the LNL may indicate significant deterioration of pulmonary function. However, to make such evaluations possible, spirometry data must be collected carefully, following standardized protocols. *The rate of false positives will be high if test variability is not minimized through QA protocols, standardized testing procedures, and the continuity of well-maintained equipment.*

Based on current recommendations, ACOEM recommends two methods to compute a worker's LNL. *Method 1* (for employees with BASELINE results > 100% Pred) computes a simple LNL for the follow-up *FEV1 % Pred or FVC % Pred* using [Baseline % Pred x 0.85]. Each serial test can be compared to the LNL to determine whether the worker's pulmonary function has deteriorated significantly relative to his/her own baseline result. This approach is shown in detail in Table 6and Figure 3.

Method 2 (for employees with BASELINE results <= 100% Pred) computes a LNL for the *measured* FEV_1 or *FVC* using [0.85 x Baseline Measured Value - (Baseline Predicted - Follow-up Predicted)]. Each serial test can be compared to the LNL to determine whether the worker's pulmonary function has deteriorated significantly relative to his/her measured baseline value. This approach is shown in detail in Table 7and Figure 4. (In addition, if a medical program wishes to adopt *only one method for all workers, ACOEM recommends choosing* Method 2 *to calculate the LNL.* Both methods give the same results if a worker's Baseline exceeds 100% Pred, but only Method 2 should be used for those with lower Baseline values.)

If a test result falls below the longitudinal LLN calculated using either method, it should be confirmed by a re-test. Once confirmed, *medical evaluation is recommended, even if the test results remain in the traditional normal range.*

Finally, if multiple measurements are available over 4-6 or more years, a slope of lung function measurements over time can be calculated. ACOEM recommends that slopes that are steeper

than 90-100 ml/yr should be flagged as significant losses of function, *even if the worker's test results remain in the normal range.*

Acknowledgement: This ACOEM guideline was developed by Mary C. Townsend, DrPH , and members of the ACOEM Occupational and Environmental Lung Disorder Committee under the auspices of the Council on Scientific Affairs. The guideline was peer reviewed by the Committee and Council and by John L. Hankinson, PhD, and William L. Eschenbacher, MD. It was approved by the ACOEM Board of Directors on July 26, 2003.

References

1. American College of Occupational and Environmental Medicine. Spirometry in the occupational setting. J Occup Enivron Med. 2000;42:(3)228-245.

2. Burrows B, Knudson RJ, Camilli AE, Lyle SK, Lebowitz MD. The "horse-racing effect" and predicting decline in forced expiratory volume in one second from screening spirometry. Am Rev Respir Dis. 1987;135(4):788-93.

3. Ferguson GT, Enright PL, Buist AS, Higgins MW. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. Chest. 2000;117(4):1146-1161.

4. American Thoracic Society. Occupational contribution to the burden of airway disease. Am J Respir Crit Care Med. 2003;167(5):787-97.

5. U.S. Code of Federal Regulations. Title 29, Part 1910.1001, Asbestos, revised 1994.

6. U.S. Code of Federal Regulations. Title 29, Part 1910.1029, Coke Oven Emissions, 1976.

7. U.S. Code of Federal Regulations. Title 29, Part 1910.1001, Cadmium, 1992.

8. U.S. Code of Federal Regulations. Title 29, Part 1910.1043, Cotton Dust, revised 1985.

9. U.S. Code of Federal Regulations. Title 29, Part 1910.1028, Benzene, 1987.

10. U.S. Code of Federal Regulations. Title 29, Part 1910.1048, Formaldehyde, 1987.

11. American Thoracic Society. Lung function testing: selection of reference values and interpretative strategies. Am Rev Resp Dis. 1991;144(5):1202-18.

12. Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. Am J Resp Crit Care Med. 1999;159(1):179-87.

13. Knudson RJ, Lebowitz MD, Holberg CJ, Burrows B. Changes in the normal maximal expiratory flow-volume curve with growth and aging. Am Rev Resp Dis. 1983;127(6):725-34.

14. Crapo RO, Morris AH, Gardner RM. Reference spirometric values using techniques and equipment that meet ATS recommendations. Am Rev Resp Dis. 1981;123(6):659-64.

15. Knudson RJ, Slatin RC, Lebowitz MD, Burrows B. The maximal expiratory flow-volume curve. Normal standards, variability, and effects of age. Am Rev Resp Dis. 1976;113(5):587-600.

16. Pauwels RA, Buist AS, Calverley PM, Hurd SS. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. Am J Respir Crit Care Med. 2001;163(5):1256-76.

17. Hankinson JL, Wagner GR. Medical screening using periodic spirometry for detection of chronic lung disease. Occup Med: State Art Rev. 1993;8(2):353-61.

18. Hankinson JL. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance, and interpretation. J Occup Med. 1986;28(10):1081-92.

19. Harber P, Lockey JE. Pulmonary function testing in pulmonary prevention. Occ Med: State Art Rev. 1991;6(1):69-79.

20. Berry G. Longitudinal observations. Their usefulness and limitations with special reference to the forced expiratory volume. Bull Physiopathol Respir (Nancy). 1974;10(5):643-56.

21. Burrows B, Lebowitz MD, Camilli AE, Knudson RJ. Longitudinal changes in forced expiratory volume in one second in adults. Methodologic considerations and findings in healthy nonsmokers. Am Rev Respir Dis. 1986;133(6):974-80.

22. Clement J, Van de Woestijne KP. Rapidly decreasing forced expiratory volume in one second or vital capacity and development of chronic airflow obstruction. Am Rev Respir Dis. 1982;125(5):553-8.

23. Vollmer WM. Reconciling cross-sectional with longitudinal observations on annual decline. Occup Med: State Art Rev. 1993;8(2):339-51.

24. Buist AS, Vollmer WM. The use of lung function tests in identifying factors that affect lung growth and aging. Stat Med. 1988;7(1-2):11-8.

25. Becklake MR, White N. Sources of variation in spirometric measurements. Identifying the signal and dealing with noise. Occup Med. 1993;8(2):241-64.

26. American Thoracic Society. Standardization of spirometry, 1994 update. Am J Resp Crit Care Med. 1995;152(3):1107-36.

27. Graham WG, O'Grady RV, Dubue B. Pulmonary function loss in Vermont granite workers. A long-term follow-up and critical reappraisal. Am Rev Respir Dis. 1981;123(1):25-8.

28. Townsend MC. The effects of leaks in spirometers on measurements of pulmonary function. The implications for epidemiologic studies. J Occup Med. 1984;26(11):835-41.

29. Townsend MC, Morgan J, Durkin D, DuChene AG, Lamb S. Quality control aspects of pulmonary function testing in the Multiple Risk Factor Intervention Trial. Control Clin Trials. 1986;7(3 Suppl):179S-92S.

30. Townsend MC, Hankinson JL, Lindesmith L, Slivka WA, Ayres GT. Is my lung function really that good? Spirometer problems that inflate test results (Abstract). Am J Respir Crit Care Med. 2002;165:A200.

31. Townsend MC. Technique and Equipment Pitfalls in Spirometry Testing: Serious Threats to Your Respiratory Surveillance Program. NORA Medical Surveillance Workshop. November 8, 2001. www.cdc.gov/niosh/sbw/osh_prof/townsendhandout.html.

32. National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies: NIOSH Spirometry Training Guide, 1997.

33. Enright PL, Johnson LR, Connett JE, Voelker H, Buist AS. Spirometry in the Lung Health Study. 1. Methods and quality control. Am Rev Resp Dis. 1991;143(6):1215-23.

34. Hankinson JL, Bang KM. Acceptability and reproducibility criteria of the American Thoracic Society as observed in a sample of the general population. Am Rev Resp Dis. 1991;143(3):516-21.

35. Hankinson JL, Castellan RM, Kinsley KB, Keimig DG. Effect of spirometer temperature on measurement of FEV1 shift changes. J Occup Med. 1986;28(12):1222-5.

36. Harber P, Peterson K, Lehman A. Change in spirometer: impact on longitudinal data (Abstract). Am Rev Resp Dis. 1996;153(1):A97.

37. Hankinson JL. Spirometry Training Program CD. Valdosta, Ga: Hankinson Consulting, Inc.; 2001.

38. Townsend MC, Hankinson JL, Lindesmith L, Slivka, WA, Stiver G, Ayres GT. Is my lung function really that good? Flow-type spirometer problems that elevate test results. Chest, 2004; In Press.

39. Hankinson JL. Instrumentation for spirometry. Occup Med: State Art Rev. 1993;8(2):397-407.

40. Wang ML, Gunel E, Petsonk EL. Design strategies for longitudinal spirometry studies: study duration and measurement frequency. Am J Respir Crit Care Med. 2000;162(6):2134-8.

41. National Fire Protection Association. Medical Requirements for Fire Fighters, NFPA 1582, 2000 edition. National Fire Protection Association, Quincy, MA, 2000.

42. USDHHS, PHS, CDC, NIOSH. Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust. September 1995.

43. Townsend MC. Personal Communication. 2003.

44. American Thoracic Society/European Respiratory Society. Idiopathic pulmonary fibrosis: diagnosis and treatment. International Consensus Statement. Am J Respir Crit Care Med. 2000;161(2):646-64.

45. Camilli AE, Burrows B, Knudson RJ, Lyle SK, Lebowitz MD. Longitudinal changes in forced expiratory volume in one second in adults. Effects of smoking and smoking cessation. Am Rev Respir Dis. 1987;135(4):794-9.

46. Wang ML, Petsonk EL. Repeated measures of FEV1 over 6 to 12 months: what change is abnormal? (Abstract). Am J Respir Crit Care Med. 2003;167:A839

Return to Policies and Position Statements

Appendix I—Checklist for Evaluating Spirometry Services

NISA Occupational Health Program

Checklist for Evaluating Spirometry Services

Though not a comprehensive listing, this checklist can assist in evaluating the proficiency of a spirometry testing provider.

Standardization

- Does the spirometry testing provided meet the requirements of the ATS "Standardization of Spirometry—1994 Update"?
- Are the criteria of the ATS "Standardization of Spirometry—1994 Update" specified in any agreement for services or cited by the contractor in a discussion of services to be provided?

Technicians

- Have spirometry technicians successfully completed a NIOSH-approved course in spirometry? Many providers advertise that their technicians are NIOSH-approved or certified, but NIOSH approves only the course, not individuals.
- Does the technician elicit vigorous subject effort in performing the forced expiratory maneuver?
- Does the technician observe the subject and instruments to detect faulty technique during testing?
- Does the technician obtain a minimum of three acceptable forced expiratory volume maneuvers on each subject?

Spirometer

- Does the provider use a dry-rolling-seal spirometer?
- Has the instrument been independently tested at the LDS Hospital, Salt Lake City, Utah, in the laboratory of Drs. Gardner and Crapo?
- Does the provider have a copy of the results of the tests by Drs. Gardner and Crapo on the instrument being used?
- Does the provider calibrate the spirometer daily, using a 3-liter syringe according to ATS recommendations?

Measurements

- Does the provider measure FVC and FEV_1 and express their ratio (FEV_1/FVC%)?

Note: Some providers report mean forced expiratory flow at the middle portion of the FVC ($FEF_{25\%-75\%}$). $FEF_{25\%-75\%}$ has much larger intrasubject variability, has a wider normal range, and is less sensitive than FEV_1/FVC%. For these and other reasons, $FEF_{25\%-75\%}$ is not generally recommended for occupational surveillance programs.

- Are the spirometry results corrected to BTPS?
- Are predicted FVC and FEV_1 corrected for non-Caucasians by multiplying results by 0.85?
- Are the observed values compared with predicted values from Knudson's equations in accordance with ATS standards?

NISA Occupational Health Program

Checklist for Evaluating Spirometry Services

Reports

- In addition to comparison with predicted normals, does the provider compare serial results (repeat testing) from an individual and report significant changes?
- Are the spirometry results reported to the company in an understandable manner?
- Does the provider or company notify individual workers of results and answer questions satisfactorily?

Appendix J—29 CFR 1910.134, Appendix C
OSHA Respirator Medical Evaluation Questionnaire
(Mandatory)

B. *Negative pressure check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s). Inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

II. Manufacturer's Recommended User Seal Check Procedures

The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are equally effective.

APPENDIX B–2 TO § 1910.134: RESPIRATOR CLEANING PROCEDURES (MANDATORY)

These procedures are provided for employer use when cleaning respirators. They are general in nature, and the employer as an alternative may use the cleaning recommendations provided by the manufacturer of the respirators used by their employees, provided such procedures are as effective as those listed here in Appendix B–2. Equivalent effectiveness simply means that the procedures used must accomplish the objectives set forth in Appendix B–2, i.e., must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

I. Procedures for Cleaning Respirators

A. Remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure demand valve assemblies, hoses, or any components recommended by the manufacturer. Discard or repair any defective parts.

B. Wash components in warm (43 °C (110 °F) maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.

C. Rinse components thoroughly in clean, warm (43 °C (110 °F) maximum), preferably running water. Drain.

D. When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following:

1. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 °C (110 °F); or,

2. Aqueous solution of iodine (50 ppm iodine) made by adding approximately 0.8 milliliters of tincture of iodine (6–8 grams ammonium and/or potassium iodide/100 cc of 45% alcohol) to one liter of water at 43 °C (110 °F); or,

3. Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.

E. Rinse components thoroughly in clean, warm (43 °C (110 °F) maximum), preferably running water. Drain. The importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.

F. Components should be hand-dried with a clean lint-free cloth or air-dried.

G. Reassemble facepiece, replacing filters, cartridges, and canisters where necessary.

H. Test the respirator to ensure that all components work properly.

APPENDIX C TO § 1910.134: OSHA RESPIRATOR MEDICAL EVALUATION QUESTIONNAIRE (MANDATORY)

To the employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:

Can you read (circle one): Yes/No

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date: _____
2. Your name: _____
3. Your age (to nearest year): _____
4. Sex (circle one): Male/Female
5. Your height: ____ ft. ____ in.
6. Your weight: ____ lbs.
7. Your job title: _____
8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): _____
9. The best time to phone you at this number: ____

10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No
11. Check the type of respirator you will use (you can check more than one category):
    a. ___ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
    b. ___ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).
12. Have you worn a respirator (circle one): Yes/No
7 If "yes," what type(s): _____

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you *currently* smoke tobacco, or have you smoked tobacco in the last month: Yes/No
2. Have you *ever had* any of the following conditions?
    a. Seizures (fits): Yes/No
    b. Diabetes (sugar disease): Yes/No
    c. Allergic reactions that interfere with your breathing: Yes/No
    d. Claustrophobia (fear of closed-in places): Yes/No
    e. Trouble smelling odors: Yes/No
3. Have you *ever had* any of the following pulmonary or lung problems?
    a. Asbestosis: Yes/No
    b. Asthma: Yes/No
    c. Chronic bronchitis: Yes/No
    d. Emphysema: Yes/No
    e. Pneumonia: Yes/No
    f. Tuberculosis: Yes/No
    g. Silicosis: Yes/No
    h. Pneumothorax (collapsed lung): Yes/No
    i. Lung cancer: Yes/No
    j. Broken ribs: Yes/No
    k. Any chest injuries or surgeries: Yes/No
    l. Any other lung problem that you've been told about: Yes/No
4. Do you *currently* have any of the following symptoms of pulmonary or lung illness?
    a. Shortness of breath: Yes/No
    b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No
    c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
    d. Have to stop for breath when walking at your own pace on level ground: Yes/No
    e. Shortness of breath when washing or dressing yourself: Yes/No
    f. Shortness of breath that interferes with your job: Yes/No
    g. Coughing that produces phlegm (thick sputum): Yes/No
    h. Coughing that wakes you early in the morning: Yes/No
    i. Coughing that occurs mostly when you are lying down: Yes/No
    j. Coughing up blood in the last month: Yes/No
    k. Wheezing: Yes/No
    l. Wheezing that interferes with your job: Yes/No
    m. Chest pain when you breathe deeply: Yes/No
    n. Any other symptoms that you think may be related to lung problems: Yes/No
5. Have you *ever had* any of the following cardiovascular or heart problems?
    a. Heart attack: Yes/No
    b. Stroke: Yes/No
    c. Angina: Yes/No
    d. Heart failure: Yes/No
    e. Swelling in your legs or feet (not caused by walking): Yes/No
    f. Heart arrhythmia (heart beating irregularly): Yes/No
    g. High blood pressure: Yes/No
    h. Any other heart problem that you've been told about: Yes/No
6. Have you *ever had* any of the following cardiovascular or heart symptoms?
    a. Frequent pain or tightness in your chest: Yes/No
    b. Pain or tightness in your chest during physical activity: Yes/No
    c. Pain or tightness in your chest that interferes with your job: Yes/No
    d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No
    e. Heartburn or indigestion that is not related to eating: Yes/No
    f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No
7. Do you *currently* take medication for any of the following problems?
    a. Breathing or lung problems: Yes/No
    b. Heart trouble: Yes/No
    c. Blood pressure: Yes/No
    d. Seizures (fits): Yes/No
8. If you've used a respirator, have you *ever had* any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)
    a. Eye irritation: Yes/No
    b. Skin allergies or rashes: Yes/No
    c. Anxiety: Yes/No
    d. General weakness or fatigue: Yes/No
    e. Any other problem that interferes with your use of a respirator: Yes/No
9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use

other types of respirators, answering these questions is voluntary.

10. Have you *ever lost* vision in either eye (temporarily or permanently): Yes/No
11. Do you *currently* have any of the following vision problems?
    a. Wear contact lenses: Yes/No
    b. Wear glasses: Yes/No
    c. Color blind: Yes/No
    d. Any other eye or vision problem: Yes/No
12. Have you *ever had* an injury to your ears, including a broken ear drum: Yes/No
13. Do you *currently* have any of the following hearing problems?
    a. Difficulty hearing: Yes/No
    b. Wear a hearing aid: Yes/No
    c. Any other hearing or ear problem: Yes/No
14. Have you *ever had* a back injury: Yes/No
15. Do you *currently* have any of the following musculoskeletal problems?
    a. Weakness in any of your arms, hands, legs, or feet: Yes/No
    b. Back pain: Yes/No
    c. Difficulty fully moving your arms and legs: Yes/No
    d. Pain or stiffness when you lean forward or backward at the waist: Yes/No
    e. Difficulty fully moving your head up or down: Yes/No
    f. Difficulty fully moving your head side to side: Yes/No
    g. Difficulty bending at your knees: Yes/No
    h. Difficulty squatting to the ground: Yes/No
    i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No
    j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

Part B Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No
   If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No
2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (*e.g.*, gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

   If "yes," name the chemicals if you know them: _____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below:
   a. Asbestos: Yes/No
   b. Silica (*e.g.*, in sandblasting): Yes/No
   c. Tungsten/cobalt (*e.g.*, grinding or welding this material): Yes/No
   d. Beryllium: Yes/No
   e. Aluminum: Yes/No
   f. Coal (for example, mining): Yes/No
   g. Iron: Yes/No
   h. Tin: Yes/No
   i. Dusty environments: Yes/No
   j. Any other hazardous exposures: Yes/No

   If "yes," describe these exposures: _____

4. List any second jobs or side businesses you have: _____

5. List your previous occupations: _____

6. List your current and previous hobbies: _____

7. Have you been in the military services? Yes/No
   If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No
8. Have you ever worked on a HAZMAT team? Yes/No
9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No

   If "yes," name the medications if you know them: _____

10. Will you be using any of the following items with your respirator(s)?
    a. HEPA Filters: Yes/No
    b. Canisters (for example, gas masks): Yes/No
    c. Cartridges: Yes/No
11. How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:
    a. Escape only (no rescue): Yes/No
    b. Emergency rescue only: Yes/No
    c. Less than 5 hours *per week:* Yes/No
    d. Less than 2 hours *per day:* Yes/No
    e. 2 to 4 hours *per day:* Yes/No
    f. Over 4 hours *per day:* Yes/No
12. During the period you are using the respirator(s), is your work effort:
    a. *Light* (less than 200 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift: _____ hrs. _____ mins.

Examples of a light work effort are *sitting* while writing, typing, drafting, or performing light assembly work; or *standing* while operating a drill press (1-3 lbs.) or controlling machines.

    b. *Moderate* (200 to 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift: _____ hrs. _____ mins.

Examples of moderate work effort are *sitting* while nailing or filing; *driving* a truck or bus in urban traffic; *standing* while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; *walking* on a level surface about 2 mph or down a 5-degree grade about 3 mph; or *pushing* a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.

c. *Heavy* (above 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift: _____ hrs. _____ mins.

Examples of heavy work are *lifting* a heavy load (about 50 lbs.) from the floor to your waist or shoulder; *working* on a loading dock; *shoveling; standing* while bricklaying or chipping castings; *walking* up an 8-degree grade about 2 mph; *climbing* stairs with a heavy load (about 50 lbs.).

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No

If "yes," describe this protective clothing and/or equipment: _____

14. Will you be working under hot conditions (temperature exceeding 77 °F): Yes/No

15. Will you be working under humid conditions: Yes/No

16. Describe the work you'll be doing while you're using your respirator(s):

17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):

18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

Name of the first toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the second toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the third toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

The name of any other toxic substances that you'll be exposed to while using your respirator:

19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):

~~APPENDIX D TO §1910.134 (MANDATORY) INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD~~

~~Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.~~

~~You should do the following:~~

~~1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations.~~

~~2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.~~

~~3. Do not wear your respirator into atmospheres containing contaminants for which your respirator is not designed to protect against. For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke.~~

~~4. Keep track of your respirator so that you do not mistakenly use someone else's respirator.~~

~~[63 FR 1270, Jan. 8, 1998; 63 FR 20098, 20099, Apr. 23, 1998, as amended at 69 FR 46093, Aug. 4, 2004]~~

Appendix K—Acronyms Used in This Manual

ACOEM	American College of Occupational and Environmental Medicine
AIHA.	American Industrial Hygiene Association
ASTM	ASTM International
ACGIH	American Conference of Governmental Industrial Hygienists
ATS	American Thoracic Society
BIA	Brick Industry Association
C	Degrees Celsius
CDC	Centers for Disease Control
CKD	Chronic kidney disease
COPD	Chronic obstructive pulmonary disease
E%	Percentage exposure
ERS	European Respiratory Society
°F	Degrees Fahrenheit
FEV_1	Forced expiratory volume in 1 second
FEV_1/FVC	Ratio of FEV_1 to FVC
FVC	Forced vital capacity
IARC	International Agency for Research on Cancer
ILO	International Labor Office
ISO	International Standards Organization
Lpm	Liters per minute
MSHA	Mine Safety and Health Administration
NIOSH	National Institute for Occupational Safety and Health

NISA	National Industrial Sand Association
NTP	National Toxicology Program
OEL	Occupational exposure limit
OHP	Occupational Health Program
OSHA	Occupational Safety and Health Administration
PA	Posterioranterior
PAT	Proficiency Analytical Testing program
PLHCP	Physician or other licensed health care professional
PPD	Purified protein derivative
PVC	Polyvinyl chloride
TLVs®	Threshold Limit Values
VC	Vital capacity

Appendix L—Glossary of Terms

Albumin, a water-soluble, heat-coagulable protein; the most abundant protein in blood plasma. Various albumins are found in practically all animal tissues. Determination of the levels and kinds of albumin in urine, blood, and other body tissues is the basis of a number of laboratory diagnostic tests.

Alveoli, small thin-walled air-containing compartments of the lung arranged in saclike clusters into which an alveolar duct terminates and from which respiratory gases are exchanged with the pulmonary capillaries. A single alveolus is termed an **alveolus**.

Area Sample, an air sample taken from samplers placed at fixed locations in the general work area and can be used to evaluate the effectiveness of control measures and to document chemical concentrations in a work area.

Autoimmune diseases, a disease in which impaired function and the destruction of tissue are caused by an immune reaction in which abnormal antibodies are produced and attack the body's own cells and tissues. Autoimmune diseases include a wide variety of disorders, including many disorders of connective tissue, such as systemic lupus erythematosus and rheumatoid arthritis.

Blood Urea Nitrogen (BUN), a measure of the amount of urea in the blood. Urea forms in the liver as the end product of protein metabolism, circulates in the blood, and is excreted through the kidney in urine. The BUN, determined by a blood test, is directly related to the metabolic function of the liver and the excretory function of the kidney.

Breathing Zone Sample, an air sample taken from a sampler attached to a worker in roughly a one foot hemisphere forward of the shoulders around a persons nose and mouth.

Bronchi, either of the two primary divisions of the trachea that lead respectively into the right and the left lung. The bronchi arise from the branching of the trachea.

Bronchioles, a small thin-walled branch of the bronchi that connects to the alveoli where oxygen exchange takes place.

Brownian Movement, also referred to as diffusion, is particle deposition in the lung influenced by collisions with air molecules, very small particles (<0.01 micrometer) start to move in a random manner over random distances and a chance is present of a collision with the walls of the airway or alveolar surfaces.

Carcinogen, a substance or agent that causes the development or increases the incidence of cancer.

Chronic Bronchitis, an inflammation of the main air passages (bronchi) to the lungs that lasts for more than three months. It causes a cough, shortness of breath and chest tightness. Coughing often brings up yellow or greenish mucus.

Chronic Kidney Disease, occurs when disease or disorder damages the kidneys so that they are no longer capable of adequately removing fluids and wastes from the body or of maintaining the proper level of certain kidney-regulated chemicals in the bloodstream.

Chronic obstructive pulmonary disease (COPD), a group of lung diseases that block airflow and make it increasingly difficult for you to breathe. Emphysema and chronic bronchitis are the two main conditions that make up COPD, but COPD can also refer to damage caused by chronic asthmatic bronchitis.

Cilia, a minute short hairlike process often forming part of a fringe; *especially*: one of a cell that is capable of lashing movement and serves especially to produce a current of fluid. The movement of cilia on a ciliated epithelium serves to propel a surface layer of mucus or fluid.

Creatinine, a substance formed from the metabolism of creatine, commonly found in blood, urine, and muscle tissue. It is measured in blood and urine tests as an indicator of kidney function.

Crystalline silica, Silicon dioxide (SiO_2). "Crystalline" refers to the orientation of SiO_2 molecules in a fixed pattern as opposed to a nonperiodic, random molecular arrangement defined as amorphous. The three most common crystalline forms of silica encountered in the workplace environment are quartz, tridymite, and cristobalite.

Emphysema, a chronic lung disease characterized by progressive, irreversible expansion of the alveoli with eventual destruction of alveolar tissue, causing obstruction to airflow. Patients with emphysema often have labored breathing, wheezing, chronic fatigue, and increased susceptibility to infection, and may require oxygen therapy. Long-term smoking is a common cause of emphysema

End Stage Renal Disease, a progressive loss of renal function over a period of months or years through five stages. Each stage is a progression through an abnormally low and progressively worse glomerular filtration rate, which is usually determined indirectly by the creatinine level in blood serum.[1]

Fibrosis, a condition marked by increase of interstitial fibrous tissue. Any pathological condition where fibrous connective tissue invades any organ, usually as a consequence of inflammation or other injury.

Flow Spirometer, a type of spirometer that measures how fast the air moves in or out of the lungs. Flow spirometers are usually smaller than volume spirometers. Examples include pneumotachograph, hot wire anemometer, and rotating vane.

Forced Expiratory Maneuver, the basic maneuver of spirometry where the subject takes the deepest possible breath and blows into the mouthpiece as hard, fast and completely as possible. Also known as the forced vital capacity maneuver.

Forced Expiratory Volume at One Second (FEV_1), the volume of air exhaled during the first second of a forced expiratory maneuver. It may also be considered the average flow during the first second of the FVC maneuver.

FEV_1/FVC (given as % or ratio). Forced expiratory volume in one second expressed as a percent of the forced vital capacity is the fraction of the total that is exhaled in the first second. It is the index of the speed of expiratory airflow. It is calculated by using the largest FEV 1 and the largest FVC, even if they are not from the same curve. A low FEV_1/FVC% is associated with airways obstruction.

Forced Vital Capacity (FVC), the maximal volume of air which can be exhaled forcefully after maximal inspiration. **NOTE:** The **vital capacity** is the amount of air that can be exhaled by an individual after taking the deepest breath possible, whether or not the air is exhaled forcefully (FVC) or slowly (VC).

Glomerulonephritis, a primary or secondary immune-mediated renal disease characterized by inflammation of the glomeruli, or small blood vessels in the kidneys.

Glomerular Filtration Rate (GFR), is the volume of fluid filtered from the kidney's glomerular capillaries into the Bowman's capsule per unit time. Clinically, this is often measured to determine kidney (renal) function.

Inertial Impaction, particle deposition in the lung influenced by air traveling through the airways, making a flow of air changes direction often and suddenly, where entrained particles are not able to follow these changes, causing them to collide with the wall of the airways.

Inhalable Dust, the particulate mass fraction of dust in the work environment that can be inhaled and deposited anywhere in the respiratory tract.

Larynx, commonly known as the *voicebox*, is an organ in the neck involved in protection of the trachea and sound production. The larynx houses the vocal folds, and is situated just below where the tract of the pharynx splits into the trachea and the esophagus.

Lupus, also known as Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease similar to other autoimmune diseases in which the immune system attacks the body's cells and tissue, resulting in inflammation and tissue damage. SLE can affect any part of the body, but most often harms the heart, joints, skin, lungs, blood vessels, liver, kidneys and nervous system.

Lymphatic System, the part of the circulatory system that is concerned especially with scavenging fluids and proteins that have escaped from cells and tissues and returning them to the blood, with the phagocytic removal of cellular debris and foreign material, and with immune responses, that overlaps and parallels the system of blood vessels in function and shares some constituents with it, and that consists especially of the thymus, spleen, tonsils, lymph, lymph nodes, lymphatic vessels, lymphocytes, and bone marrow.

Macrophage, a phagocytic tissue cell of the immune system that may be fixed or freely motile, and functions in the destruction of foreign antigens (such as bacteria and viruses).

Micrometer, a unit of length equal to one-millionth of a meter or one-thousandth of a millimeter. The micrometer is a convenient length for measuring small respirable dust particles.

Mucociliary Clearance, a lung defense mechanism important in the removal of inhaled particles by specialized cilia, which line both the upper and lower airways, are covered by a thin layer of mucus, and beat rapidly in a coordinated fashion propelling particles trapped in the mucus layer to the pharynx.

NIOSH B-Reader, an approval granted to physicians with a valid medical license who demonstrates proficiency in the classification of chest radiographs for the pneumoconioses using the International Labour Office (ILO) Classification System.

Obstructive Lung Diseases, diseases that reduce flow from the lungs. These diseases include asthma, chronic bronchitis, and emphysema.

Pharynx, the part of the digestive and respiratory tracts situated between the cavity of the mouth and the esophagus and in humans being a conical musculomembranous tube about four and a half inches (11.43 centimeters) long that is continuous above with the mouth and nasal passages, communicates through the eustachian tubes with the ears, and extends downward past the opening into the larynx to the lower border of the cricoid cartilage where it is continuous with the esophagus.

Pneumoconiosis, a lung disease condition characterized by the permanent deposition of dust in the lungs over a long period of time and at sufficient amounts that result in the formation of scar tissue, referred to as pulmonary fibrosis.

Proteinuria, the presence of excessive amounts of protein in the urine.

Pulmonary fibrosis, the formation of scar tissue in the connective tissue of the lungs as a result of any inflammation or irritation of alveolar tissue with many causes including the inhalation of crystalline silica.

Quartz, crystalline silicon dioxide (SiO2) not chemically combined with other substances and having a distinctive physical structure.

Respirable Dust, that portion of dust that is capable of entering the gas-exchange regions of the lungs if inhaled; by convention, a particle-size-selective fraction of the total airborne dust; includes particles with aerodynamic diameters less than approximately 10 micrometers and has a 50 percent deposition efficiency for particles with an aerodynamic diameter of approximately four micrometers.

Restrictive Lung Diseases, diseases that reduce the ability of the lungs to expand fully but do not necessarily affect air flow. Asbestosis and silicosis, two of the most common of the occupationally caused restrictive diseases, are caused by the development of fibrotic tissue in the lungs.

Rheumatoid arthritis, a chronic autoimmune disease that causes inflammation and deformity of the joints. Other problems throughout the body (systemic problems) may also develop, including inflammation of blood vessels (vasculitis), the development of bumps (called rheumatoid nodules) in various parts of the body, lung disease, blood disorders, and weakening of the bones.

Scleroderma, a progressive disease that affects the skin and connective tissue (including cartilage, bone, fat, and the tissue that supports the nerves and blood vessels throughout the body). There are two major forms of the disorder. The type known as localized scleroderma mainly affects the skin. Systemic scleroderma, which is also called systemic sclerosis, affects the smaller blood vessels and internal organs of the body.

Sedimentation, also referred to as gravitational settling, is particle deposition in the lung influenced by as the airways branch and become smaller and smaller the dust particles slow up because the total cross-sectional area of the airways is actually increasing; and as the dust particles slow, they settle out because of the influence of gravity, and come to rest on the airway walls or surfaces of the alveoli.

Silicosis, a type of pneumoconiosis due to the inhalation of dust containing crystalline silica characterized by formation of generalized, nodular fibrotic lesions in the lung. Three types of silicosis are recognized based on the airborne concentration of crystalline silica to which a worker has been exposed.

> **Chronic silicosis,** usually occurs after 10 or more years of exposure at relatively low concentrations of crystalline silica.
>
> **Accelerated silicosis,** develops 5 to 10 years after the first exposure.
>
> **Acute silicosis,** which develops after exposure to high concentrations of respirable crystalline silica and results in symptoms within a period ranging from a few weeks to 5 years after the initial exposure.

Spirometry, a pulmonary function test that measures lung volumes and flow rates of air leaving the lungs by means of a spirometer.

Spirometer, an instrument for measuring the air leaving the lung on exhalation.

Systemic Vasculitis, is an inflammation of blood vessels in the body. Vasculitis causes changes in the walls of blood vessels, including thickening, weakening, narrowing and scarring.

Time-Weighted Average (TWA), an average value of exposure to a chemical over the course of a work shift. For an eight hour work shift the value is expressed as a 8-hour TWA.

Trachea, the main trunk of the system of tubes by which air passes to and from the lungs that is about four inches long and somewhat less than an inch in diameter, extends down the front of the neck from the larynx, divides in two to form the bronchi, has walls of fibrous and muscular tissue stiffened by incomplete cartilaginous rings which keep it from collapsing, and is lined with mucous membrane whose epithelium is composed of columnar ciliated mucus-secreting cells -- called also *windpipe.*

Urea, a by-product of protein metabolism that is formed in the liver. Because urea contains ammonia, which is toxic to the body, it must be quickly filtered from the blood by the kidneys and excreted in the urine.

Volume Spirometer, a type of spirometer that records the amount of air inhaled or exhaled within a certain time. Examples include water-seal, dry rolling-seal, and bellows instruments.