STAUFFER CHEMICAL COMPANY

OCCUPATIONAL HEALTH MANUAL: BULLETIN

Date Issued 10/5/78

| Subject | Supercedes Bulletin | |
|---|---|---|
| PHYSICIAN'S GUIDELINES FOR ADMINISTRATION AND EVALUATION OF PULMONARY FUNCTION TESTS OF WORKERS | X X | |
| **Issuing Section** | **No. of Pages** | **Bulletin No.** |
| Occupational Medicine | 1 of 9 | 100 |

PHYSICIAN'S GUIDELINES FOR ADMINISTERING AND

EVALUATING PULMONARY FUNCTION TESTS

PLAINTIFF'S EXHIBIT

SH-2008

Background

In chemical manufacturing plants, a number of toxic compounds may be exposed to workers in various jobs. In order to work safely in this environment, the periodic use of respirators may be required.

The wearing of any type of respirator, however, imposes some work stress on the wearer. These additional work demands result from the following factors:

A.) A negative pressure respirator (an air-purifying type) increases the mechanical work associated with breathing by drawing air through a purifying cartridge or filter during inhalation. They also resist exhalation because expired air must force open a valve. The special exhalation valve on an open circuit pressure-demand self-contained breathing apparatus (SCBA), designed to ensure positive air pressure inside the facepiece, requires the wearer to exhale against considerable resistance. This creates further oxygen demand and results in an additional amount of ventilatory and cardiac work.

B.) All respirators increase the effective anatomical dead space by a variable amount and thus reduce respiratory efficiency.

C.) The weight and size of more complicated respirators (such as a self-contained breathing apparatus weighing up to 35 pounds) and related connections (in the case of air-supplied types having up to 300 feet of air supply hose) place a further physical burden upon the worker which leads to additional work demands for the pulmonary and cardiovascular systems.

Any and all of these factors act to increase the work load. If the worker's cardiovascular or pulmonary function is significantly impaired, wearing a respirator may pose an unacceptable risk. As there is limited information available on the physiological effects of certain respirators, it is difficult to formulate detailed criteria by which a physician may determine whether a worker can wear a specific respirator and perform useful work safely. The most practical approach is to evaluate each subject individually, using reasoned medical judgment based upon history, physical and pulmonary function and other test findings, and with appropriate consideration to the physical burdens imposed upon an individual by the various types of respirators.

MEDICAL HISTORY AND CLINICAL EXAM

To determine if a respirator may be worn safely by an individual, it is necessary to obtain a medical history, conduct a physical examination, perform spirometric studies to evaluate pulmonary function, chest x-ray and EKG are also usually necessary. Particular attention should be given to cardiorespiratory conditions. Cardiovascular impairment should be viewed with serious concern because of the potentially catastrophic consequences. Workers who have indications of coronary artery disease or angina pectoris probably should not wear non-powered air-purifying respirators or the heavy (30 pound- SCBA) equipment. The same restrictions are recommended for those who have severe hypertension unresponsive to medical therapy or who have had a myocardial infarction. Individuals whose emergency duties absolutely require use of respirators (i.e. "rescue teams") should be completely free of clinical myocardial impairment.

In the case of respiratory conditions, the subject should be examined for evidence of respiratory impairment resulting from conditions such as emphysema, chronic obstructive lung disease, or bronchial asthma. Historical and radiologic evidence of significant pulmonary disease, if substantiated by reduced ventilatory function, may justify not allowing a person to wear a respirator that restricts inhalation and exhalation and, instead, limiting him to powered air-purifying or continuous flow airline respirators. If he is reasonably comfortable, mild or moderate respiratory conditions should not necessarily prohibit a worker from wearing air-purifying respirators. However, workers in occupations associated with a high incidence of pulmonary

diseases, such as installing asbestos insulation, coal mining, and sand blasting, need particular attention given to medical evaluation for respirator use.

PULMONARY FUNCTION

To evaluate the pulmonary function characteristics of a subject, there are a number of studies which may be performed, ranging from the basic spirometric test of forced vital capacity (FVC) and one second forced expiratory volume ($FEV_1$) to highly sophisticated investigations of diffusing capacity, airway resistance, and lung compliance. When administered by a trained and knowledgable individual and properly performed, the basic spirometric studies of FVC and $FEV_1$ are reliable, accurate and, if evaluated in association with medical history and physical findings, provide sufficient pulmonary function data for an informed assessment of any significant respiratory impairment in an individual.

There are a number of commercially available spirometers which may be used to assess pulmonary function. Any spirometer of scientific quality which provides a permanent record (in the form of a tracing as in Figure 1 ) may be utilized. The tracing created by the machine should clearly denote the volume of air expelled (in liters) as well as the testing time involved (in seconds).

Both the forced vital capacity (FVC) and the one second forced expiratory volume ($FEV_1$) may be determined from the same spirometric study. The FVC is the maximal amount of air that can be expelled from the lungs following a maximal inspiration. Once a subject is oriented to the operation of a spirometer, this may be performed as follows: First, remove gum or cough drops prior to testing. Next, after a period of minimal activity while standing during which only quiet, resting breaths are drawn, the subject takes a maximal breath in and then exhales the air in his lungs as quickly and completely as possible. The tracing which results will be generally similar to Figure 1.

Three practical parameters may be obtained from analysis of this tracing: (1) the FVC which is the total amount of air expelled during a complete exhalation: (2) the $FEV_1$ which is the volume of air expelled in the first second of a complete expiration: and (3) the ratio of $FEV_1/FVC$, multiplied by 100, denoting the percent of air that can be expelled during the first second.

The absolute volume of the FVC is important in that it is an index of the state of the elastic properties of the respiratory system, whereas the rate at which it is expelled from the lungs is largely a reflection of air flow-resistive properties. $FEV_1$ is used by most laboratories to analyze flow resistance.

This information will be of limited value unless a comparison of these "actual" results can be made to some standard. Fortunately, both nomograms as well as equations are available to calculate "expected" pulmonary function values for an individual based upon age, sex, height and race.

Thus, the age, sex, height and race should be recorded in order to determine the "expected" normal values for each subject. Nomograms and tables of predictive equations are often included among the supplies which accompany a spirometer. For reference and convenience, a predictive equation for vital capacity and nomograms are provided in Appendix 1.

There are two basic patterns of pulmonary disease which alter the normal relationship between expired air volume and time: obstructive and restrictive lung diseases. The obstructive pattern is caused by resistance to the flow of air owing to loss of the lung's normal elasticity or narrowing of the airways.

The result of obstruction to the exit of air from the lungs is reflected in the tests of ventilatory capacity by a decrease in the $FEV_1$, and FEV/FVC%. The restrictive pattern of disease is caused by processes which scar the lungs and thus prevent them full expansion. This may also result from kyphosis and certain arthritic diseases. This results in a decrease in the FVC. However, the restriction applies equally to the $FEV_1$, which is reduced to a degree proportional to the FVC reduction. Since there is no obstruction to air flow, the $FEV_1$/FVC% is normal.

Several practical problems may arise in the performance of spirometry. The first problem concerns the selection of equipment to be used. There are a number of companies that manufacture spirometers in a variety of sizes and shapes. The most important characteristics of spirometers to be used in industrial settings are the reproducibility of accurate results, reliability of performance, and simplicity of use and maintenance. It is also valuable to obtain a permanent tracing of the worker's actual efforts rather than just the numerical results. This can serve as an estimate of the employee's effort and cooperation during the test and also as a record in case questions regarding the subject's pulmonary function arise at a later date.

The second complication to obtaining reliable results is improper instructions or inadequate coaching of the subject by the individuals administering the test. The mouthpiece must be placed behind the teeth and the subject should seal his lips around the tube, but not bite it. Interference with air flow by the teeth or tongue may simulate obstructive lung disease in an otherwise healthy person. Next, the individual should be reminded that the test is not uncomfortable and is easily performed. Finally, when the testing begins, the subject should be coached vigorously to perform his/her best effort.

The last major consideration is that from four to five vital capacity maneuvers are recommended for a thorough evaluation of an individual's pulmonary function. To insure that the subject is giving his/her best effort, the vital capacities of the largest two tracings should be within 10% of each other. Many physicians consider the first two tracings of a series of five to be "practice runs". Subjects usually need a few trials to become familiar with the equipment and the procedure. In an industrial setting, it is appropriate to simply record the largest FVC and largest $FEV_1$ of the last three trials as the final values for the subject.

OTHER CONSIDERATIONS

Several other physical conditions, such as epilepsy or myasthenia gravis, may also limit the wearing of respirators. Skin sensitivity or allergy to certain compounds may prevent some workers from entering certain environments at all, let alone wearing respirators in them. A perforated ear drum which allows air passage through the eustachian tube into the respiratory tract may prohibit a person from working in a toxic environment unless he wears a respirator with a full head enclosure.

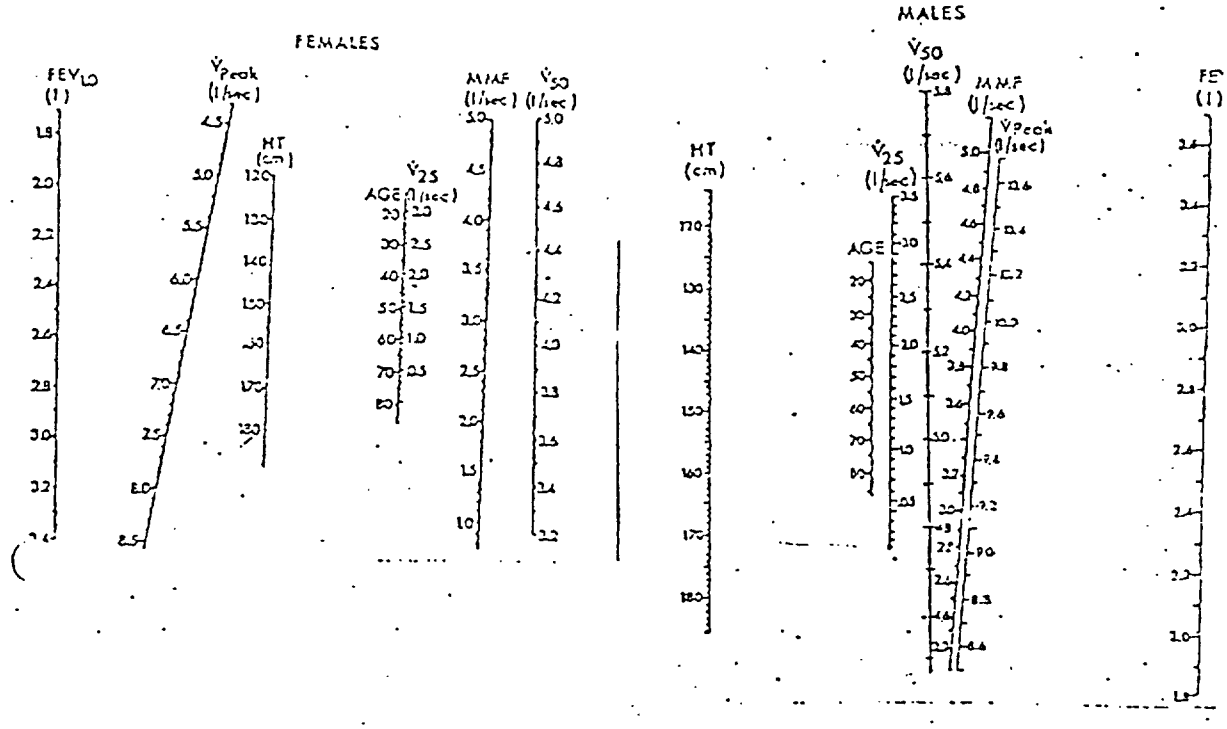
Deep facial scars or blemished, hollow temples or a markedly receding chin may not allow a good seal of certain types of respirator facepieces. In addition, full or partial dentures may prohibit the wearing of certain types of mouthpieces and a beard may limit the use of certain facepieces.

Psychological factors may also prevent a worker from wearing a respirator. These conditions, however, are less clearly defined than are physical limitations. Individuals who experience claustrophobia or anxiety when confined in a small space may be distressed by feelings of restriction resulting from the respirator. Others may become unsettled if the respirator has an ill-fitting or irritating facepiece which causes continual discomfort. Unless a proper and comfortable fitting is achieved with each individual, the wearing of a respirator is bound to have an adverse psychological effect.

STAUFFER CHEMICAL COMPANY

OCCUPATIONAL HEALTH MANUAL: BULLETIN

| Subject | Supercedes Bulletin | |
|---|---|---|
| Issuing Section: APPENDIX 1 | No. of Pages | Bulletin No. |




NOMOGRAMS FOR CALCULATION OF STANDING SPIROMETRY IN HEALTHY NON-SMOKING ADULTS

For Males:
Vital capacity = [27.63 - (0.112 X age)] X (height in cm)

For Females:
Vital capacity = [21.78 - (0.101 X age)] X (height in cm)

EQUATIONS FOR CALCULATING VITAL CAPACITY

A twelve-lead electrocardiogram with interpretation should ordinarily be performed as an integral part of the examination. This test is essential for the assessment of cardiovascular status and for detecting asymptomatic, as well as existing, coronary heart disease.

A 14" by 17" posterior-anterior chest X-ray with an International Labor Office UICC/Cincinnati (ILO U/C) rating, if available, should also be routinely performed to aid in the assessment of chest condition. For those cases requiring further evaluation, a lateral chest film may also be obtained.

GUIDELINES FOR EVALUATION

After appropriate review has been given to the several historical and clinical factors mentioned previously, working guidelines are necessary as to what constitutes acceptable pulmonary function for wearing a respirator. As would be expected, there has been considerable debate about what may be considered adequate (or, conversely, unacceptable) pulmonary function parameters permitting the required use of respirators.

Generally speaking, any worker who has an $FEV_1$ of 2.5 liters or greater and an $FEV_1$ which is at least 60% of the FVC should not be expected to have difficulty using an industrial respirator. On the other hand, workers who have an $FEV_1$ of less than 1.7 liters or an $FEV_1$ less than 48% of the FVC are probably unfit to wear an industrial respirator.

In any biologic entity, a degree of individual variability must be anticipated and, for that reason, the above absolute and percent $FEV_1$ values should be viewed as helpful but not arbitrary guidelines for evaluation. An $FEV_1$ between 1.7 and 2.5 liters or an $FEV_1$ between 48% and 60% of the FVC are parameters deserving consideration in conjunction with other data, such as physical findings and work history, about the subject.

Information which is helpful in arriving at a decision in all situations involves such factors as the existence of significant cardio-respiratory or musculoskeletal conditions, previous or current uncomplicated use of respirators, or difficulties associated with carrying the bulk and weight of the respirator or of a poor fit of the facepiece. In the absence of such conditions, a trial use of the type of respirator to be used should be conducted at the time of the medical examination. The respirator should be worn for a period of 10 minutes at rest. Any significant anxiety or claustrophobic reaction, evidence of significant subjective discomfort, sustained increase in the resting pulse of 25% or more above resting baseline, or sustained increase in the respiratory rate of 25% or more above baseline may be viewed as disqualifying the subject for use of that type of respirator.

| Subject | Supercedes Bulletin | |
|---|---|---|
| PHYSICIAN'S GUIDELINES FOR ADMINISTRATION AND EVALUATION OF PULMONARY FUNCTION TESTS OF WORKERS | X X | |
| Issuing Section: Occupational Medicine | No. of Pages: 7 of 9 | Bulletin No.: 100 |

In summary, various physiological, psychological as well as historical factors may influence whether an individual should wear a respirator. A number of clinical studies including, but not limited to, a respiratory questionnaire, pulmonary function testing, evaluation of electrocardiogram

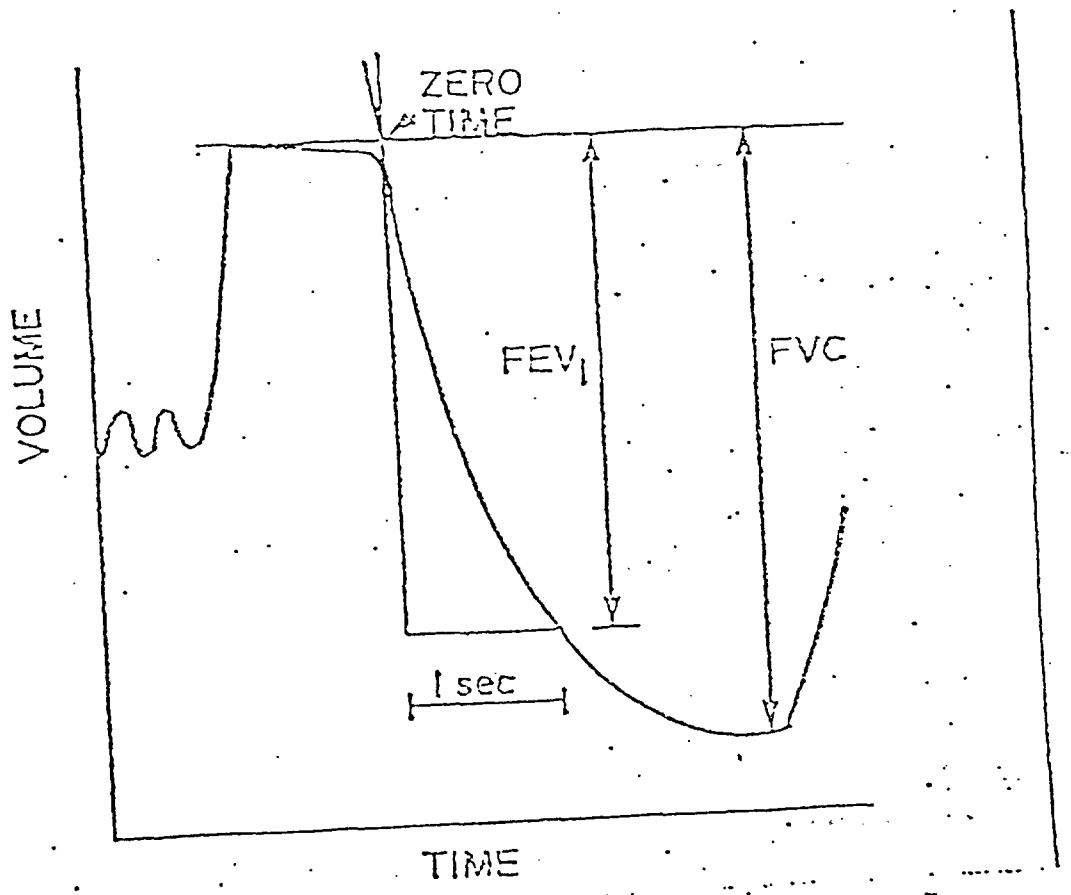



FIGURE 1. FORCED VITAL CAPACITY EXPIRATION

THIS TRACING OF VOLUME (Y AXIS) AND TIME (X AXIS) FROM A FORCED EXPIRATION MANEUVER ILLUSTRATES THE MEASUREMENTS OF FVC AND $FEV_1$.