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Use of Spirometry for Medical Clearance and Surveillance in Occupations Requiring Respirator Use

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Use of Spirometry for Medical Clearance and Surveillance in Occupations Requiring Respirator Use

by

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Dedication

I dedicate my dissertation to my parents, Prakash and Geeta Desai, who always believe in me, and encouraged and supported me to achieve my goals in life. I also dedicate to my elder brother Shivang, who guided me in my all academic endeavors.

Acknowledgements

First, I would like to thank my advisor, Dr. Raymond Harbison, for his guidance throughout my doctoral program. I am so grateful that you accepted to be my advisor and taught me “Science is not consensus.” Without your mentorship and encouragement, I may never have made it to the finish line.

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List of Acronyms and Abbreviations

ACOEM- American College of Occupational and Environmental Medicine

AIHA- American Industrial Hygiene Association

AIC- Akaike Information Criterion

ANSI- American National Standards Institute

ATS-America Thoracic Society

BIC- Bayesian Information Criterion

BLS – Bureau of Labor Statistics

CFR- Code of Federal Regulations

COPD- Chronic Obstructive Pulmonary Diseases

ERS- European Respiratory Society

ERV- Expiratory Reserve Volume

FVC - Forced Vital Capacity

FEV1- Forced Expiratory Volume in 1 second

FRP- Fiber Reinforced Plastic

IARC- International Agency for Research on Cancer

IC- Inspiratory Capacity

ICC-Interclass Correlation Coefficient

IRV- Inspiratory Reserve Volume

MEKP- Methyl Ethyl Ketone Peroxide

MMA- Methyl Methacrylate

MLM-Longitudinal Multilevel Model

NFPA- National Fire Protection Association

NHANES III- National Health and Nutrition Examination Survey III

NIOSH- National Institute for Occupational Safety and Health

NMMA- National Marine Manufacturers Association

OB- Obliterative Bronchiolitis

OSHA- Occupational Safety and Health Administration

PEF – Peak Expiratory Flow

RADS-Reactive Airway Dysfunction Syndrome

SCBA- Self –Contained Breathing Apparatus

VC- Vital Capacity

WTC-World Trade Center

Abstract

Medical certification of workers for respirator use is an important activity of occupational medicine health professionals. Spirometry is a diagnostic tool to evaluate respiratory distress/insufficiency that may affect respirator use. In this study, we analyzed the pulmonary function data of 337 workers from different occupations which required medical evaluation to wear a respirator. The American Thoracic Society and National Fire Protection Association criteria were used to evaluate employees. Of 337 workers who were cleared for respiratory use on the basis of medical questionnaires for respirator compliance, 14 (4.15%) failed to pass respirator compliance on the basis of NFPA criteria and 5 (1.48%) failed to pass respirator compliance criteria on the basis of ATS criteria. We compared the use of different Spirometric equations to evaluate these criteria and we found the Crapo equation cleared more workers for respirator use as compared to the Knudson and NHANES III equations. We also measured repeated Forced Expiratory Volume in 1st Second (FEV1) and Forced Vital Capacity (FVC) and compared the results longitudinally over time. Age was the only significant factor affecting the reduction in the lung function in longitudinal analysis. Longitudinal spirometry results suggested that workers were protected while using a respirator in the workplace, but age is the significant factor in reducing their lung function. As some workers were able to qualify for respirator use based on questionnaire alone but failed respirator clearance subsequent to pulmonary function testing, it is recommended that spirometry be used to evaluate clearance for all workers who will use a respirator in the workplace. As well, using different Spirometric equations can affect the

outcome on passing or failing clearance for respirator use, and this should be considered in a respiratory medical certification program.

Chapter 1. Introduction and Statement of Problem

Various control measures prevent hazardous airborne exposures at the workplace. Commonly used methods to prevent harmful airborne contaminants in the workplace are engineering and work practice controls, administrative controls, and personal protective equipment. Engineering controls include the substitution, the isolation, and the elimination of hazardous substances as well as changes in work processes or equipment. It also includes the use of natural ventilation as well as local exhaust and mechanical ventilation systems. Work practice measures such as protective methods are used during exposure to high-risk contaminants. Such measures include the implementation of robotics to cut chemical exposure during spraying and coating procedures or wet methods for dust suppression. Examples of administrative control measures include written work policies and procedures, permit requirements and restrictions for hazardous areas, job rotation of workers and reducing the use of hazardous chemicals. Administrative actions are the weakest control measures because they do not reduce contaminant production in the workplace and require stringent adherence to other control methods. When all of these control measures are not effective or feasible, personal protective equipment like a respirator should be used. These measures are used when all other measures have been implemented, and the risk of hazardous airborne contaminants remains. Respiratory protection is the last line of control measure and is widely used in industries to reduce the risk of chemical exposure (Australia, 2012; Cohen and Birkner, 2012). **Figure 1** outlined the hierarchy of control measures at the workplace.

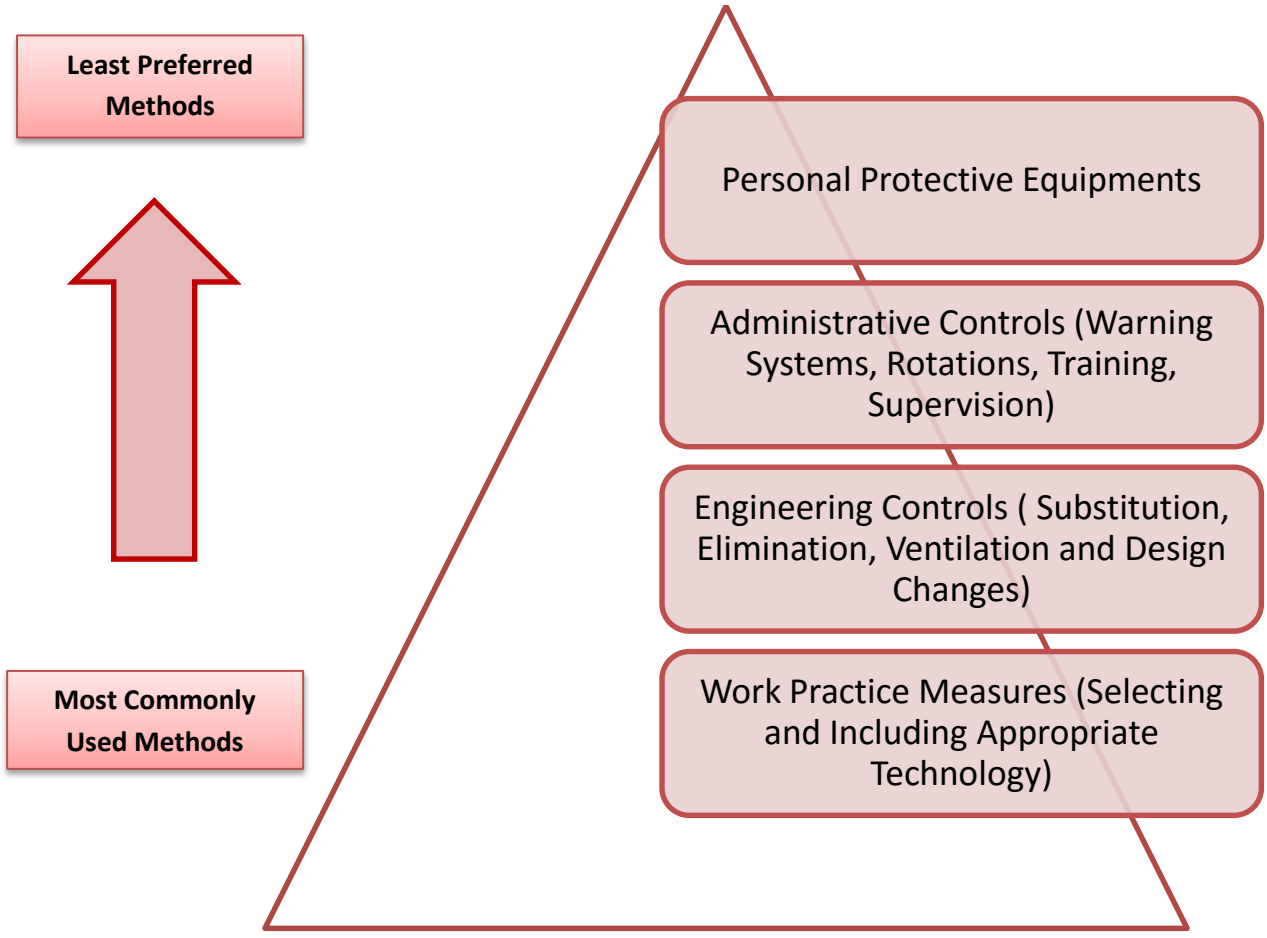


Figure 1 Hierarchy of Workplace Exposure Control Measures

According to Occupational Safety & Health Administration (OSHA), approximately 2.6 million workers use respirators either occasionally or frequently to protect their health in the workplace ((OSHA), 1994). OSHA allows the use of respirators in the conditions as discussed earlier, where implementation of other control measures are not efficient and pragmatic. To protect the workers' health and provide proper guidance regarding respirator use, OSHA requires a respirator protection program in the workplace. In 1998, OSHA revised the criteria for respiratory protection for general industry, shipyards, construction, and maritime industries under 29 CFR.1910 & 1926 ((OSHA), 1998). According to these standards, employers require establishing a written respiratory protection program where the use of a respirator is mandatory to protect the health of employees in the workplace. It also allows the voluntary use of respirators to prevent exposure to hazardous airborne contaminants. **The goals of the respiratory protection program are to provide information on selecting respirators for specific work conditions, a medical evaluation of the workers who are using respirators, and training and maintenance of the respirators in the workplace (Health and (OSHA), 2009)**. **Table 1** shows major components of the written respiratory program required according to OSHA standards.

Table 1 Components of the Written Respiratory Protection Program (Based on 29 CFR 1910.134)

Components of the Written Respiratory Protection Program
• Written Standard Operating Procedures • Selection of Respirators • Training of workers • Maintenance of equipment • Storage of Equipment • Inspection of Equipment • Cleaning and Disinfection of respirators • Exposure Monitoring • Program Analysis/Evaluation • Workers Medical Evaluation/ Medical Surveillance • Use of Respirators Approved/Certified

The respirator protection program is administered by assigning someone in the workplace who regularly evaluates the effectiveness of the program. Other health and scientific research agencies such as National Institute for Occupational Safety and Health (NIOSH), American Industrial Hygiene Association (AIHA), American National Standard Institute (ANSI), and National Fire Protection Association (NFPA) also provide valuable information to employers for the implementation of an effective respiratory protection program in the workplace (NIOSH 1991, ANSI/AIHA 2006, NFPA 2013). **Appendix I** shows a sample written respiratory protection program based on the 29 CFR 1910.134 developed by Oklahoma state.

The most commonly used respirators are divided into two groups: 1) air purifying and 2) supplied air respirators. Air purifying respirators use filters or chemical sorbent cartridges to remove hazardous airborne contaminants from the ambient air, and they are further divided on the basis of contaminants they eliminate while air supplied respirators with an independent air supply from non-contaminated air source provides protection. They are further divided on the basis of methods used for non-contaminant air supply of the workers. All respirators used in the workplace should be certified by the National Institute for Occupational Safety and Health (NIOSH). These respirators not certified by NIOSH and used by health care professionals are called masks. Respirators are also divided on the basis of the types of face pieces available such as half or full facepiece respirators. **Figure 2** shows different types of respirators commonly used to prevent exposure. The selection of respirators based on the oxygen content, types of hazards, toxic contaminants and level at the workplace. **Figure 3** shows guidelines for the choice of respirators for the routine procedure at the workplace.

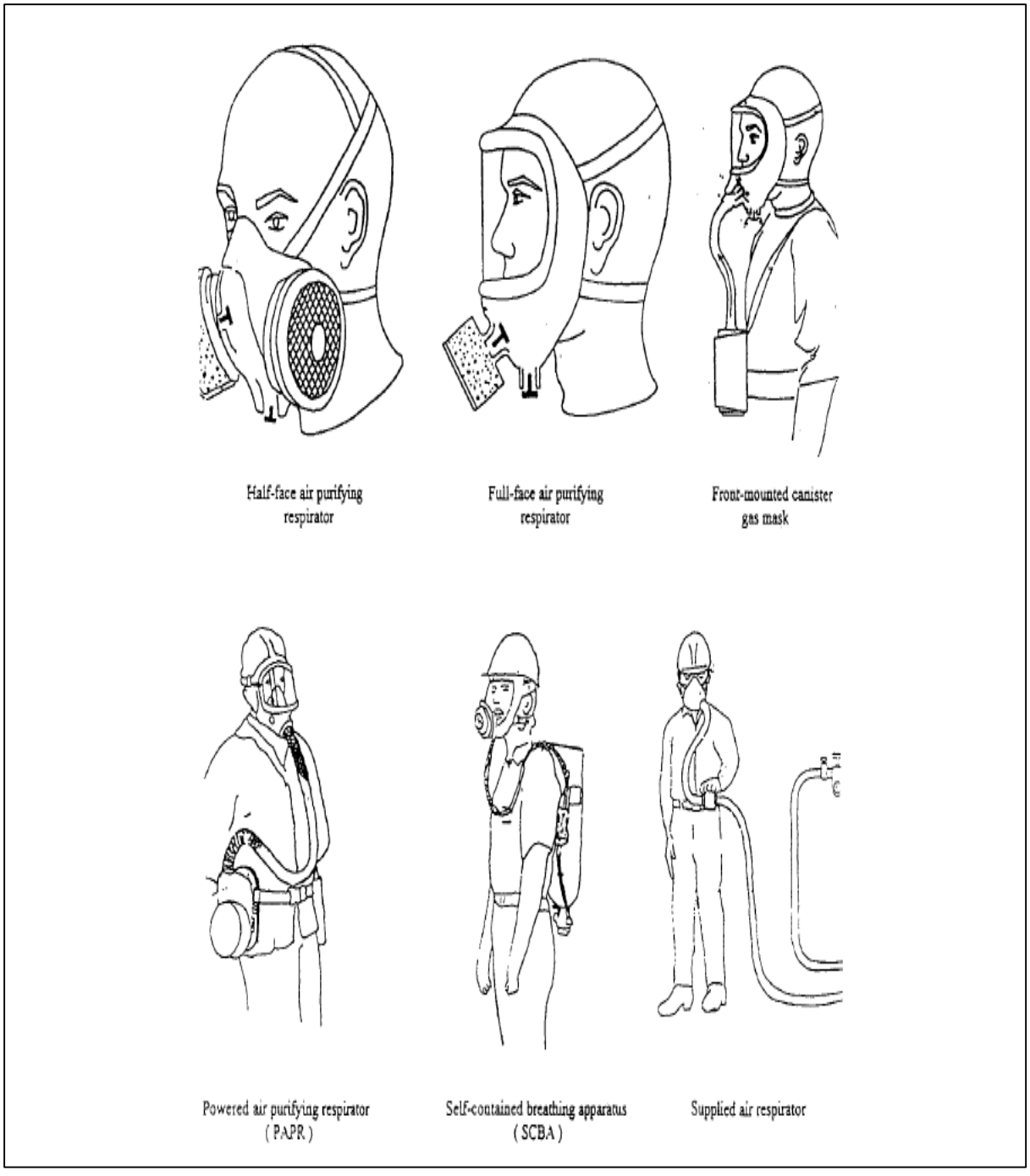


Figure 2 Types of Respirators

(Adopted from the NIOSH "Guide to Industrial Respiratory Protection"(1987) and NJDOH, Powered Air Purifying Respirators, Better Protection From Dusted Fumes"(1990)) and Szeinuk et al.2000).

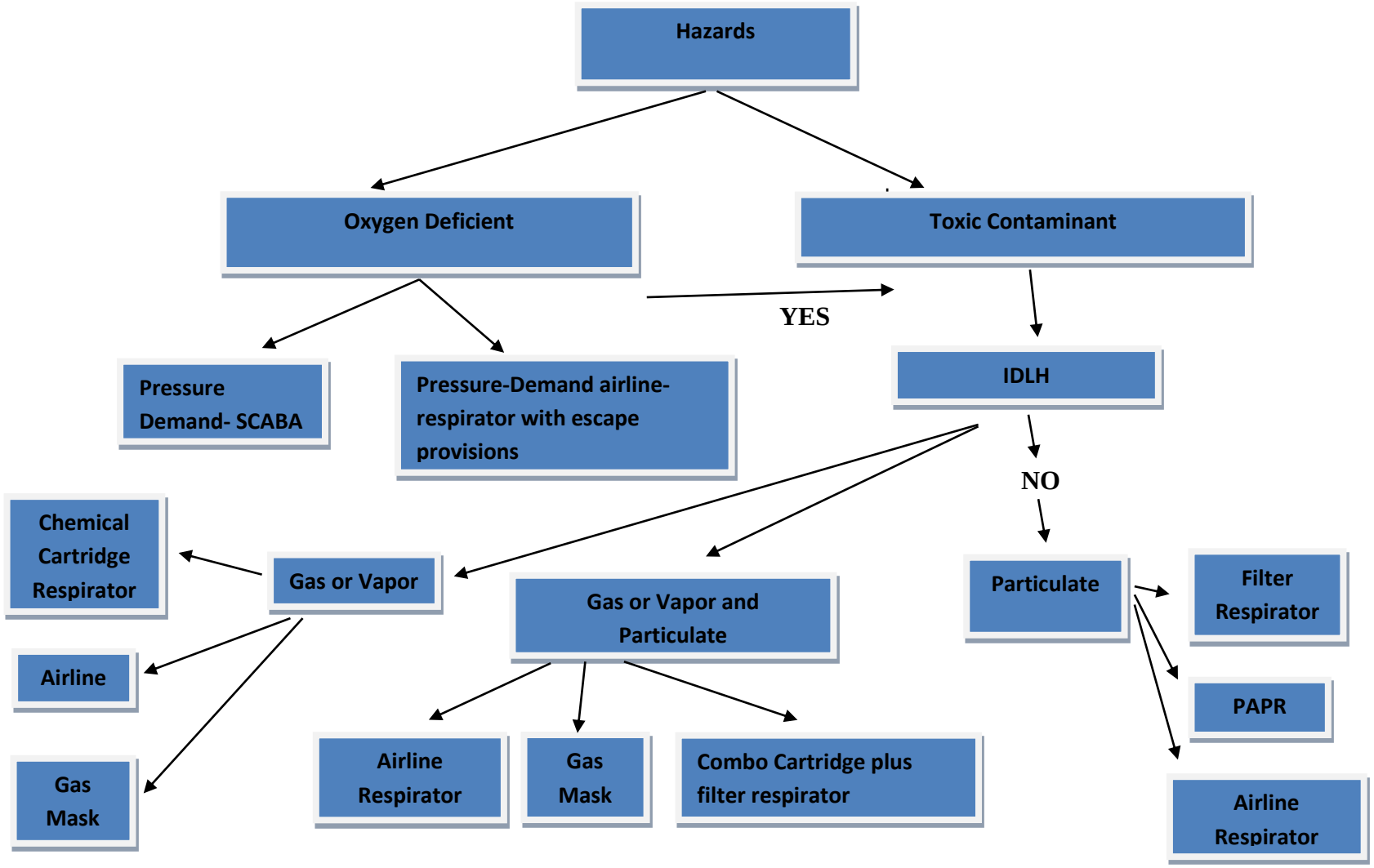


Figure 3 Respirator Selection Process

(Adapted from OSHA Industrial Hygiene Technical Manual, OSHA Instruction, CPC-2-2-20A, Washington, DC, US Government Office, 1984)

Using respirators in the workplace may induce various physiological and psychological effects on the workers (Szeinuk *et al.*, 2000). Most common physiological effects of using respirators are on cardiopulmonary systems of the workers (Louhevaara, 1984b; Louhevaara, 1984a). Other effects of using respirators are discomfort, extra weight and ergonomic concerns, psychological and social effects, dermatological problems, visual impairments and impact in pregnancy.

Respiratory Effects: Two most common effects of respirator use on the respiratory system are:

1. Increases dead space volumes 2. Increases airways resistance

Using respirator increases dead space volume that is added to the anatomical dead space in the lungs (P.B., 1984; T.K., 1986). It requires the worker to increase the depth and frequency of respiration to obtain an equal quantity of fresh air. The physiological responses to increases in dead space are an increased respiratory rate, and tidal volume that in turn leads to an increase in the effort of respiration (Harber, 1982). Increased airway resistance during breathing leads to a decrease in minute ventilation. These physiological effects are opposite to each other in the context of minute ventilation while using a respirator. It also further limits a worker's ability to acclimatize either physiological effect. Respirators also increase the burden of a cough in those who are suffering acute or chronic cough conditions (Belafsky *et al.*, 2013; Szeinuk, Beckett, Clark and Hailoo, 2000).

Cardiovascular effects: Increase in intrathoracic pressure while using a respirator interferes with the venous return and thus, reduces cardiac output. Heavy respirators such as Self-Contained Breathing Apparatus (SCBA) increases heart rate by 20% at the submaximal physical activity and reduces exertion level by the same amount. People with cardiopulmonary illnesses require more

oxygen consumption from respiratory muscles while using a respirator as compared to healthy young subjects and this should be considered while wearing a respirator ((Belafsky, Vlach and McCurdy, 2013; Harber, 1982; Louhevaara, 1984b; Louhevaara, 1984a; Szeinuk, Beckett, Clark and Hailoo, 2000).

Other health effects of wearing respirators are discomfort because of heat stress, pressure on the face from elastic strap of the face-piece, anxiety, claustrophobia, individual feelings of shortness of breath, worker's acceptability, vision impairment and hearing difficulty. Carrying a Self-contained Breathing Apparatus (SCBA) is associated with ergonomic issues such as herniated discs, neck and back muscle illnesses, fall and other injuries. These adverse health effects are associated with SCBA because respirators increase the size of the workers and make it difficult to pass through narrow spaces or when climbing. Wearing a respirator is also responsible for several dermatological changes among workers (Szeinuk, Beckett, Clark and Hailoo, 2000). **Table 2** shows different physiological and adverse health effects of using respirators.

Table 2 Physiological and Negative Health Effects of Using Respirators

Respiratory Effects	• Increases dead space volumes • Increases airway resistance
Cardiovascular Effects	• Increases intrathoracic pressure • Reduces cardiac output
Other ill-health effects	• Heat stress • Dehydration • Vision and hearing impairment • Claustrophobia • Ergonomic health issues • Dermatological effects

Workplace factors such as heavy workloads, duration of work and break period, heat stress, night or rotating shift, personal protective clothing, other personal protective equipment, and time pressure also affect the physiological and psychological conditions of the workers wearing a respirator. In recent years, use of the respirators are not restricted to workplaces but extended in infection control, natural disasters or bioterrorism activity. It leads to these physiological and psychological effects of respirator usage on a broad range of people.

All these physiological and psychological effects are associated with respirator use and result from the OSHA under the respiratory protection program to evaluate the health of the workers prior to respirator use. OSHA requires a medical evaluation of employees who are wearing a respirator at the workplace by a physician or licensed health care professional (PLHCP) according to the guidelines provided in 29 CFR.1910.134. The respiratory protection standards 29 CFR 1910.134 were developed to provide a mandatory medical evaluation for the workers who are required to use a respirator. The purpose of a medical evaluation is to determine employees' ability to wear a respirator before fit testing ((NIOSH), 2003a).

1.1 Statement of the Problem

According to the guideline 29 CFR.1910.134, OSHA provided a questionnaire for health care professionals for medical clearance for respirator use. Workers' who pass the OSHA medical evaluation questionnaire will not require annual medical evaluation. There is limited data on the efficacy of the questionnaire in identifying employees who may not be eligible for respirator usage. OSHA does not recommend the usage of physical examination and other tests such as spirometry and exercise tolerance testing. Certain conditions such as workers' complaint of medical signs and symptoms related to ability to wear respirators, PLHCP's recommendation for follow-up medical examination, and change in work conditions that may increase physiological burden the worker

are exceptional. The use of physical examination and additional testing is helpful to identify the current situation that restricts the usage of a respirator and also identifies the cardiopulmonary distress/insufficiency because of wearing a respirator. Also, limited data is available for the usage of spirometry for the medical clearance for respirator screening. There is a controversy over the components included in the medical evaluation of the respirator screening. There are sources recommending only the use of the OSHA questionnaire while others advocate the use of physical examination and spirometry in their screening procedure for wearing a respirator. Also, different reference values/equations are available for interpretation of spirometry results. Several regulatory and academic agencies recommended the National Health and Nutritional Survey III (NHANES III) reference equation, because this equation included Caucasian, African American, and Hispanic populations to develop reference values as compared to other reference values that are based on Caucasian non-smoking healthy subjects. Currently, there is no standard mandatory reference value required for the interpretation of the spirometry results. Spirometric equations such as Crapo, Knudson and Morris were developed previously to interpret lung functions. As compared to NHANES III spirometric equations developed based on the small non-smoking Caucasian population. There is a perception among health care professionals that using these equations instead of NHANES III for African-American and Mexican-American will pass the spirometry screening criteria to wear respirators at the workplace.

Measuring lung function of a worker either following an intervention or over a period of time is more clinically significant than evaluating one-time lung function at the beginning of using a respirator at the workplace. Evaluating the pulmonary function over a period of time (“serial”) is also known as “longitudinal spirometry evaluation”. This longitudinal spirometry evaluation will identify the baseline lung function before using respirators and compare the baseline lung

function to the follow-up lung function over a period of time. These longitudinal spirometry results help in identifying pulmonary function loss over a period of time in workers who are using respirators in the workplace.

1.2 The Purposes of the Study

Objectives of this study are:

1. Evaluate the use of spirometry as a screening tool for pulmonary fitness for respirator usage in the workplace.

2. Assessment and use of different Spirometric criteria for the respirator clearance for pulmonary fitness.

3. Comparison of different Spirometric reference values to classify different spirometric criteria for respirator clearance.

4. Application of occupational health surveillance for assessing longitudinal pulmonary function changes.

1.3 Research Questions

Null Hypothesis 1: There is no significant difference between spirometric criteria and medical questionnaire results for medical clearance for respirator usage in the workplace.

Null Hypothesis 2: There is no significant difference between different Spirometric reference values for measuring respiratory function to determine safe respirator use.

Null Hypothesis 3: There is no significant change, statistical or biological, in longitudinal spirometry of workers among selected occupations who are using respirators.

Chapter 2. Spirometry

2.1 Spirometry

Spirometry is an important tool to measure inhalation and exhalation of air from lungs as a function of time. Spirometry measures the dynamic performance of the lungs and does not measure static lung volumes. The main indicators of the spirometry test are lung volume and respiratory air flow over time. Spirometry is an important indirect diagnostic tool to evaluate the respiratory health of a person. The most common applications and uses of spirometry are compiled in **Table 3.** Spirometry tests are conducted at different places, ranging from primary care clinics, hospital facilities, and occupational medical departments in the workplace.

Table 3 Use of Spirometry

Diagnostic

- To assess respiratory signs and symptoms.
- To evaluate effects of respiratory illness on lung functions.
- To screen persons at risk of developing respiratory illness.
- To estimate preoperative risk.
- To determine prognosis.
- To assess health status before strenuous physical activity.

Monitoring

- To evaluate therapeutic intervention.
- To measure the lung function following a period of respiratory illnesses.
- To monitor people who are exposed to harmful agents.
- To monitor known pulmonary toxicity of drugs.

Disability/ Impairment evaluations

- To evaluate patients as a part of a rehabilitative program.
- To assess lung function as a part of a medical insurance fitness assessment.
- To measure lung function as an assessment for worker compensation claim.

Public Health

- Epidemiological survey.
- To conduct clinical research.
- Derivation of reference equations and functional guidelines.

2.2 Lung Volumes

The most significant dynamic lung volumes that are reported in spirometry are Forced Vital Capacity (FVC) and Force Expiratory Volume in First Second (FEV1).

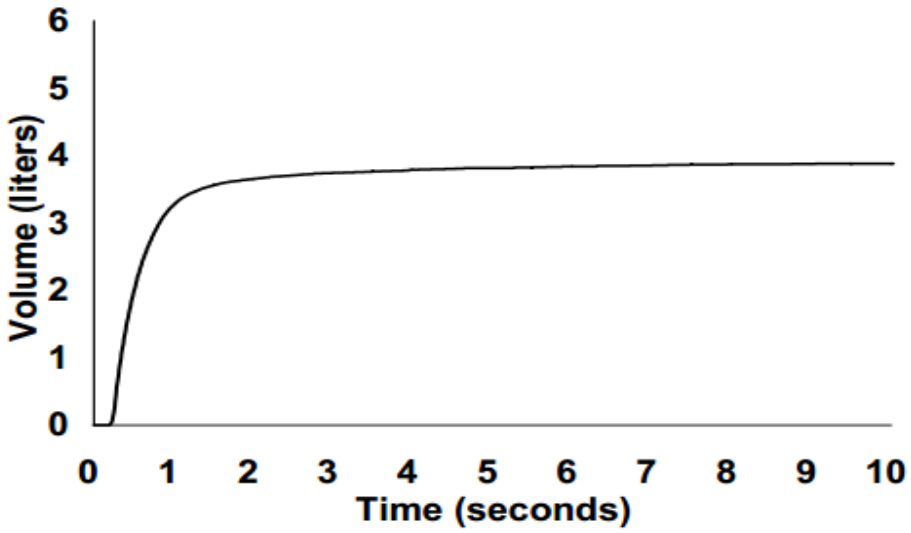
Forced Vital Capacity (FVC):

FVC is the maximal volume of air in the lungs that can be forcefully and maximally exhaled by a person after maximum inhalation. It is expressed in liters at body temperature and ambient pressure saturated with water vapor (Miller *et al.*, 2005b).

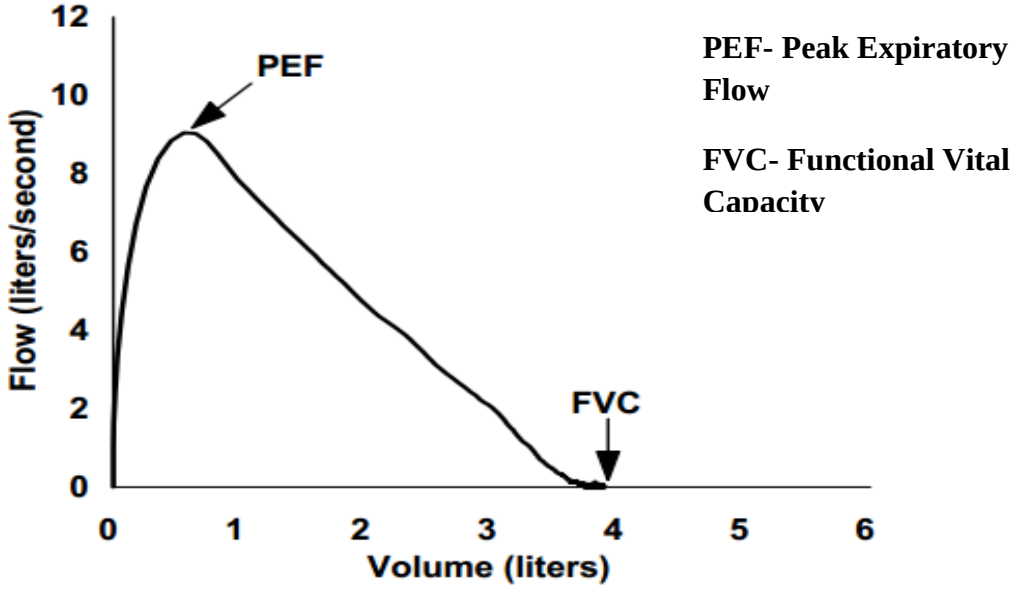
Forced Expiratory Volume (FEV) in One Second (FEV1):

FEV1 is the volume of air in the lungs that can be forcefully and maximally exhaled in the first second after a maximal inhalation. It can be described as the volume of air that is exhaled in the first second of the Forced Vital Capacity, and it is about 80% of the FVC. It is expressed in liters at body temperature and at ambient pressure saturated with water vapor ((Miller, Hankinson, Brusasco, Burgos, Casaburi, Coates, Crapo, Enright, van der Grinten, Gustafsson, Jensen, Johnson, MacIntyre, McKay, Navajas, Pedersen, Pellegrino, Viegi and Wanger, 2005b).

The outcome of spirometry, which is called a spirogram is a flow volume-time curve. A spirogram is the graphical plot of Forced Vital Capacity (FVC) in liters and time in seconds.



NORMAL VOLUME –TIME CURVE



NORMAL FLOW-VOLUME CURVE

Figure 4 Normal Volume-Time and Normal Flow-Volume Curves (Spirogram)

(Adapted From NIOSH Spirometry Training, 2003)

Figure 4 shows volume-time and flow-volume curves that are measured during spirometry. A spirogram helps to identify the FEV1, FVC and FEV1/FVC ratio of the individual's lung functions.

FEV1/FVC Ratio: This ratio most commonly contributes to the classification of different lung disorders. In elderly patients, this ratio is significantly lower because of the decreased elastic recoil of the lungs (Hyatt RE 2003).

2.3 Occupational Lung Disorders

Spirometry results help to identify the obstructive, restrictive or mixed patterns of lung disorders.

Obstructive Lung Disorders are clinically manifested as diffuse airway narrowing because of different mechanisms such as asthma (immune related) and Chronic Obstructive Pulmonary Diseases (environmental related) (Ali Altalag, 2009).

Restrictive Lung Disorders are characterized by an abnormal reduction in the lung volumes because of changes in the lung parenchyma or disorders of the pleura, chest wall or respiratory muscle weakness (Ali Altalag, 2009). **Table 4** shows different types of occupational lung disorders and their etiology and lung disease patterns. This research is focused on occupational lung diseases; therefore **Table 4** gives the classification of disease patterns on the basis of occupational lung disorders.

Table 4 Overview of Occupational Lung Disorders

Obstructive Patterns

- Occupational Asthma
- Reactive Airway Dysfunctional Syndrome (RADS)
- Chronic Emphysema
- Chronic Bronchitis (Caused by repeated infections and/or exposure to irritants such as fumes and dusts (including wood dusts and mineral fibers), oil aerosols, gases such as ozone and nitrogen dioxide, and smoke from cigarettes or exposure to fire (such as fire-fighting).

Restrictive Patterns

- Pneumoconioses (Silicosis, Asbestosis and Black Lung (Coal Worker's Pneumoconiosis)
- Hypersensitivity Pneumonitis (Exposure to Organic Dusts)
- Granulomatous Disease (Tuberculosis, Berylliosis)
- Other Health Conditions

Mixed Patterns (Obstructive and Restrictive)

- Pneumonia (Because of infections of bacteria, fungi, virus or other microorganisms in Healthcare workers, child care workers, and animal care workers)
- Pneumoconioses (Although its restrictive pattern, in advanced level it has both patterns)
- Occupational Lung Cancer (Exposure to bis-chloromethyl ether, coal tar, pitch volatiles, mustard gas, arsenic, asbestos, radium, petroleum, chromates, and uranium)

(Adopted from NIOSH Spirometry Training Guide 2003)

These lung disorder patterns can be identified with the help of spirometry results. These spirometry results can be helpful for screening as well as diagnostic purposes. **Table 5** shows the results of lung volumes that can contribute to identify the lung disease patterns.

Table 5 Spirometry Results and Lung Disease Patterns

Spirometry Results			
FVC	**FEV1**	**FEV1/FVC %**	**Interpretation**
Normal	Normal	Normal	Normal Spirometry
Low or Normal	Low	Low	Obstructive Disorders
Low	Low	Normal	Restrictive Disorders
Low	Low	Low	Combinations of Obstructive and Restrictive Disorders

(Adapted From NIOSH Spirometry Training Guide 2003, Altalag et al. 2009).

The diagnostic feature of obstructive lung disorders are decreases in FEV1/FVC ratio and decreases in FVC. While normal or an increased FEV1/FVC ratio is a charachteristic of restrictive lung disorders (NISOH 2003, Altalag et al. 2009).

Apart from measuring the FEV1 and FVC lung volumes, spirometry also measures other lung functions such as the Instantaneous Forced Expiratory Flow (FEF_{25}, FEF_{50}, FEF_{75}) and the Maximum Mid-Expiratory Flow (MMEF OR FEF_{25-75}). FEF measures the flow of the exhaled air at different levels of the Forced Vital Capacity, particularly at 25%, 50% and 75% of the Forced Vital Capacity (FVC). The Maximum Mid-Expiratory flows (MMEF) or FEF_{25-75} is the average flow during the middle half of the Forced Vital Capacity (25-75% of the FVC). These variables represent the effort-independent part of the FVC (Ali Altalag, 2009; Hancox B 2001). These

lung functions are more sensitive but non-specific in the early identifications of airway obstructions that occur at the lower lung volumes (Flenley, 1988; Pellegrino *et al.*, 2005).

Spirogram curves also help to identify lung disorders. **Figure 5** shows the comparison of the restrictive disorders and normal spirometry results. Patients with restrictive lung disorders have steep descending limb of the flow volume curve because of high lung elasticity. The width of the FVC curve and FEV1 is decreased on the descending limb of the curve and is close to the residual volume suggesting a normal or higher FEV1/FVC ratio. The peak expiratory flow (PEF) is defined as the maximum flow generated during expiration performed with maximal force and started after a full inspiration. The PEF may be increased because of increased elastic recoil of the lung that had caused an increase in the initial flow of exhaled air (Ali Altalag, 2009).

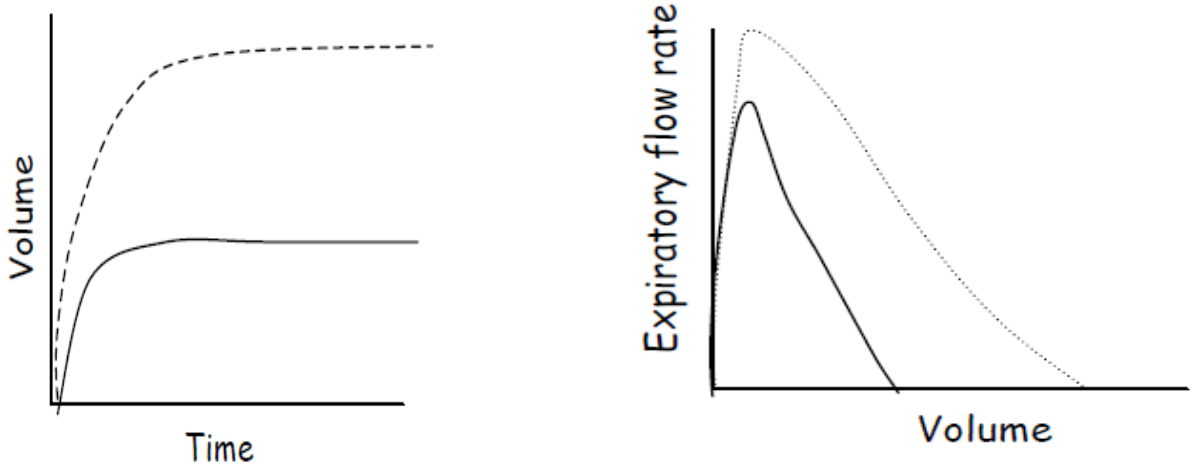


Figure 5 Comparison of Restrictive Disorder and Normal Spirogram

(Adapted from NIOSH Spirometry Training Guide, 2003)

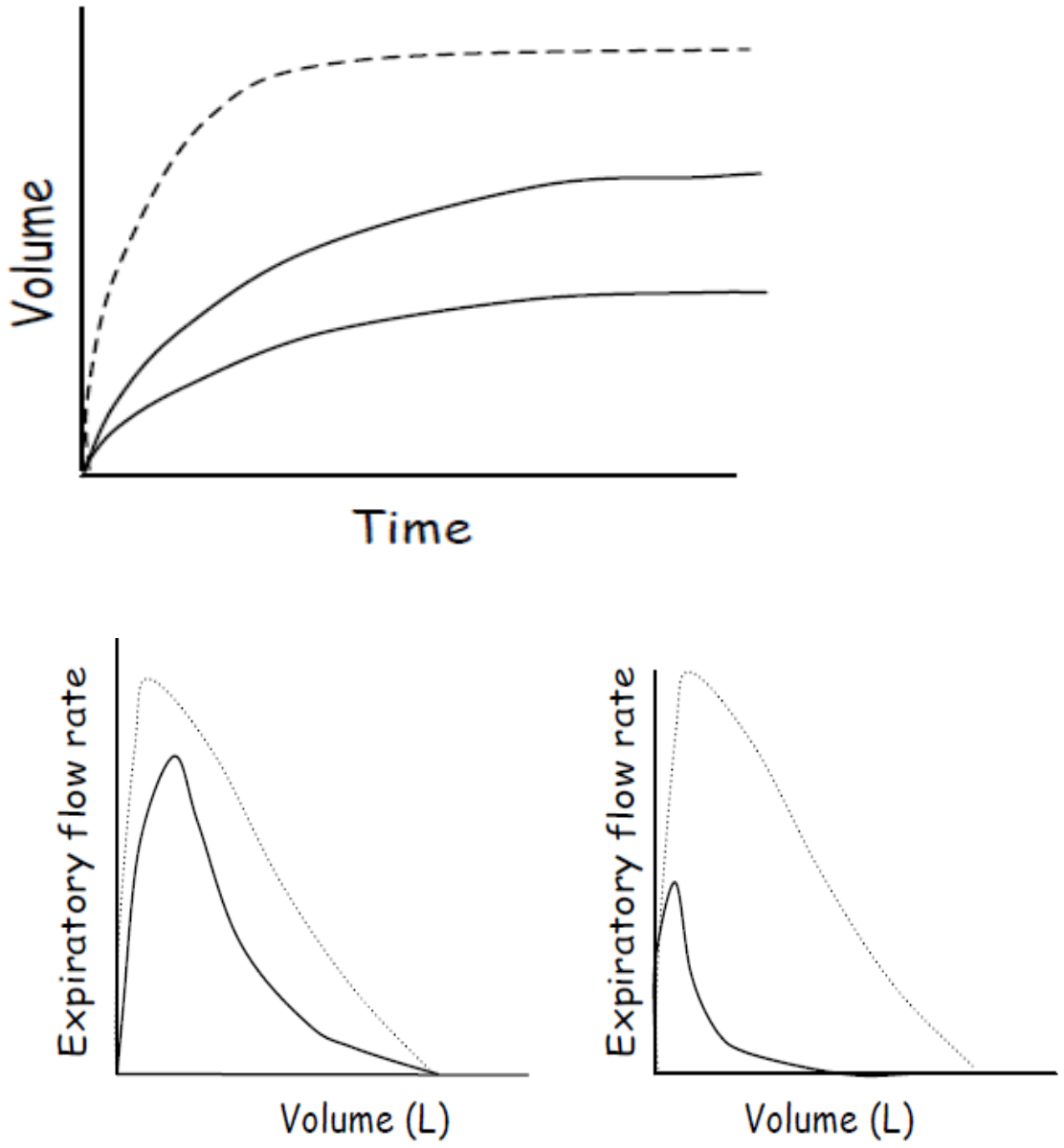


Figure 6 Comparison of Normal Spirogram and Obstructive Pattern

(Adapted from NISOH Spirometry Training Guide, 2003)

Figure 6 shows the comparison of Normal Spirogram and Obstructive Patterns of the Lung functions. The obstructive lung disorders' curve has decreased the height of PEF because of airway obstructions. **Figure 6** shows a severe obstructive pattern with a descending concave (scooped) loop in the Flow-Volume curve, and it has a significant outward concavity in the Flow -Volume Curve. The slope of the descending limb that characterizes MMEFs and FEFs is decreased due to airflow obstruction at low lung volumes (Ali Altalag, 2009).

2.4 Limitations of Spirometry

Spirometry is an important diagnostic and screening tool for lung function evaluation though it has certain limitations. Spirometry results can help to differentiate between obstructive or restrictive lung disorders, but it is not able to identify an etiology of the lung diseases. To make a diagnosis, health care professionals require additional information such as personal health and occupational histories, physical examinations, and chest-x-rays. Spirometry can identify early changes in obstructive lung disorders, but it is not sensitive for detecting in certain restrictive diseases. Restrictive diseases such as silicosis and coal workers' pneumoconiosis may be detected early in chest x-rays even though spirometry results are still normal. Because of these limitations, spirometry should not be used as the only tool for surveillance purposes (NISOH 2003). Spirometry can evaluate most of the lung volumes except the total lung capacity (TLC), functional residual capacity (FRC), and residual volume (RV) because these volumes of air are present in the lungs even after maximal exhalation (Kasper, 2005). The definite diagnosis of restrictive lung disorders requires a decrease in the Total Lung Capacity (TLC) and a decline in the RV/TLC ratio which helps to identify different types of restrictive lung disorders such as

pulmonary parenchymal disease (diseases of lung tissue) and extra-parenchymal (extra-pulmonary diseases). (Kasper, 2005).

Chapter 3. Literature Review

A literature review has been conducted to support the hypotheses in this study. Numerous review articles, original research, specific guidelines from expert committees or societies, mandatory standards and epidemiological surveys recommended specific guidelines for medical screening for respirator usage in the workplace.

3.1 Use of Spirometry for Medical Evaluation

The Bureau of Labor Statistics (BLS) and the National Institute for Occupational Safety and Health (NIOSH) conducted a voluntary survey of respirator usage among private sector firms during August 2001 to January 2002. This study provides data on the number of establishments, type of industries and respirators, employment size of the workplace and respirator program and respirators used at these various workplaces. This survey is based on the guidelines of OSHA Standards 29 CFR 1910.134- Respiratory protection, which required employers to protect the health of employees when respirator usage is necessary. This survey showed that about 281,776 establishments and around 3.3 million workers required use of respirators at their work place during the past 12 months' prior to the investigation. Of these private institutions, 267,467 used air purifying respirators, and 47,290 used air supplied respirators at the workplace. This study also suggested that out of the total number of establishments, 132,346 (47%) assessed workers' medical fitness to wear respirators, 130,648

(46.4%) facilities did not evaluate medical fitness before wearing a respirator at the workplace, and 13,598 (4.8%) establishments did not know about the medical assessments before using respirators at the workplace. Out of these 47 % establishments, methods of medical assessments utilized by these establishments included a questionnaire only 14,761 (5.2%), a questionnaire with follow-up exams as needed 64,839 (23%), physical exam only 40,950 (14.5%) and other methods 13,157 (4.7%) ((NIOSH), 2003b).

The Occupational Safety & Health Administration (OSHA) regulates the use of a respirator in the general industry, construction industry, and maritime industry. The requirements of these regulations are published in **the 29 CFR 1910.134, 29 CFR 1926.103** and **29 CFR 1915.152; 1918.102** respectively. OSHA also regulates the respiratory protection program for specific substances as shown in **Table 6.** OSHA requires the use of regular medical surveillance using chest x-ray, pulmonary function testing before starting work and also at regular intervals for these particular substances (Szeinuk, Beckett, Clark and Hailoo, 2000). **Table 6** identifies different substances and their OSHA specific respiratory protection standards.

Table 6 Substances Specific OSHA Respiratory Protection Requirements

Standards	**Substances**
29 CFR 1910.1045(n); 1926.1145;1915.1045	Acrylonitrile
29 CFR 1910.1018(n);1926.1118; 1915.1018	Arsenic (Inorganic)
29 CFR 1910.1001; 1926.1101;1915.1001	Asbestos
29 CFR 1910.1028(i); 1926.1128; 1915.1028	Benzene
29 CFR 1910.1029(j)	Coke Oven Emissions
29 CFR 1910.1043(h)	Cotton Dust
29 CFR 1910.1044(m); 1926.1144; 1915.1044	1.2-dibromo-3-chloroproprane
29 CFR 1910.1047(i); 1926.1147	Ethylene Oxide
29 CFR 1910.1048(l); 1926.1148; 1915.1048	Formaldehyde
29 CFR 1910.120(f); 1926.65	Hazardous Waste
29 CFR 1910.1025(j); 1926.62	Lead
29 CFR 1910.1017(k); 1926.1117	Vinyl Chloride

Easterling et al. 2007 conducted a survey of respiratory protection programs for firefighters in the state of Kentucky. This survey suggested that 116 out of 120 counties of Kentucky returned their self-administered 21 question survey evaluating the respiratory protection practices on the basis of OSHA recommended standards for the past 12 months. The total number of responses are from 511 fire departments from 116 counties of Kentucky. All respondents answered that they were using some respiratory protection, but only 37 % responded that they had a written respiratory respirator program. Lack of funding (48%) and lack of understanding (39%) are the major barriers to the implementation of a respiratory protection

program. Also, this survey suggested that only 23% had health care providers who can review medical questionnaires or provide physical evaluation (Easterling and Prince, 2007).

National Institute for Occupational Safety and Health (NIOSH) in 1991, conducted a review of various research and recommended individual health care workers' judgment is needed to determine the risk factors affecting the worker's fitness to wear a respirator. It recommended that health care worker's individual experience, further research and individual worker sensitivities should be considered while assessing medical fitness for wearing a respirator. NIOSH also recommended that healthcare professionals should consider the following conditions while determining the medical fitness of the workers; history of spontaneous pneumothorax, claustrophobia/anxiety reaction, use of contact lenses, moderate or severe pulmonary disease, angina pectoris, cardiac arrhythmias, history of myocardial infarction, increased blood pressure, and advanced age of workers. They also indicated that further research was required for the respiratory fitness screening program (NIOSH, 1991).

Lerner et al. 1998 in his review suggested that healthcare professionals should use OSHA recommended questionnaires and also recommended using physical examination, spirometry and cardiac screening as required according to the workers' health conditions. Apart from the history of medical conditions, he also suggested that the medical evaluation of the employees should consider the degree of chemical exposure, the type of respirator used and workers' age (Lerner, 1998).

After the introduction of the OSHA recommended questionnaire for the medical evaluation of employees for fitness to endure, the larger question raised was whether or not the questionnaire improved workers' safety. To evaluate the effectiveness of the screening with the

help of a questionnaire Pappas et al. conducted research in 1998; they evaluated the sensitivity and specificity of a 30-item self-administered questionnaire similar to the OSHA recommended questionnaire. In their study, 413 workers at the Department of Energy were cleared through the self-administered questionnaire. The result of their survey indicated that their questionnaire had 100% sensitivity in identifying employees requiring worker's restrictions, but specificity was 19% and (336/413) did not clear by questionnaire alone but eventually required a physician evaluation and spirometry. They concluded that their questionnaire was able to recognize workers required restrictions, but it was not sensitive enough to identify employees with chronic conditions. They argued that their questionnaire was insensitive and could not identify workers diagnosed with chronic lung disease. They suggested that there were limitations in their study such as population size, they used respirators infrequently and may not be a representative population using respirators regularly. They indicated that the physician evaluation is the gold standard for respirator clearance at the workplace. They also indicated that several questionnaires have been used to recognize workers who may obtain benefit from additional evaluation prior to respirator use. They advised that there was no data available to validate these instruments including the new OSHA questionnaire. Their study suggested that validations of these instruments are necessary as questionnaire responses may not precisely reflect the physician assessment (Pappas *et al.*, 1999a; Pappas *et al.*, 1999b).

The American Thoracic Society in their respiratory protection guidelines published in 1996 recommended using spirometry to assess the ventilatory function of workers before using a respirator. They suggested the use of spirometry for the workers >45 years old and who are using Self-Contained Breathing Apparatus (SCBA), any worker having respiratory symptoms or

abnormalities on the questionnaire and strongly recommended for workers > 55 years old (Harber *et al.*, 1996).

Szeinuk et al. 2000 in their clinical practice review also suggested using guidelines recommended by the American Thoracic Society (ATS, 1996) for medical evaluation for respirator use in the workplace. They additionally recommended spirometry for particular work conditions such as asbestos workers or firefighters (Szeinuk, Beckett, Clark and Hailoo, 2000).

American College of Occupational & Environmental Medicine (ACOEM) 2002 suggested the use of spirometry for medical clearance for respirator usage every one or two years when mandatory respirator use is required by OSHA. (Townsend, 2011).

National Fire Protection Association (NFPA)-2013 suggested that spirometry is an important component of the annual health evaluation of firefighters. The NFPA 1582; Standard for the comprehensive occupational medical program for fire departments recommended that spirometry is an indispensable tool for the respiratory protection program of the firefighters who are using respirators in the workplace (NFPA).

American National Standards Institute (ANSI) in their revised standards for "Respiratory Protection-Respirator Use –Physical Qualifications for Personnel" in 2006 suggested the recommendations of the American Thoracic Society for the use of spirometry for the physical evaluation of workers for respirator use and also use of spirometry as per instructions of the healthcare professionals in the assessment of the ventilatory function of workers ((AIHA):, 2006).

Belafsky et al. 2013 in their review suggested the role of the OSHA questionnaire, physical exam and use of spirometry on the basis of age, workload or pulmonary symptoms for

respirator clearance at the workplace. They also suggested that the OSHA questionnaire should be extensively utilized for the younger and lower risk workers and use of preventive screening such as spirometry for older workers, those with chronic illnesses and performing exhausting work and wearing SCBA at the workplace (Belafsky, Vlach and McCurdy, 2013).

Cohen et al. 2012 in their clinical review suggested that medical evaluation for respirator use should be considered in the perspective of the work conditions, protection programs and medical surveillance in the workplace. They also suggested that spirometry, which is not, required by OSHA, but frequently employed for respirator medical evaluations and periodic spirometry can be used for medical surveillance depending on the workplace exposures (Cohen and Birkner, 2012).

These studies suggested that using of spirometry would be useful for preventive screening and testing along with OSHA recommended questionnaires for evaluating pulmonary fitness for clearance for respirator use. Preventive screening such as spirometry would be recommended to collect baseline lung functions data before employment that requires respirator medical clearance and also early detection of potential pulmonary illnesses**. Table 7** shows suggested regulatory and academic agencies' recommendations for using spirometry for respirator clearance.

Table 7 Using of Spirometry for Respirator Medical Clearance

Agencies/Authors	Recommendations
American Thoracic Society (1996)	• >45 years old using SCABA with heavy exertion • Workers with abnormalities on questionaries' or symptomatic • Workers > 55 years old
Szeinuk (2000)	• Age-specific guidelines as American Thoracic Society recommended • Specific occupations such as firefighters or asbestos workers
American College of Occupation and Environment Medicine (2002)	• Every 1-2 years when mandated by OSHA for workplace exposures • Workers using SCABA or working under strenuous/exhaustive conditions
American National Standards Institute (2006)	• As per American Thoracic Society guidelines • Recommended by Health Care Professionals
Cohen (2012)	• Depending on occupational exposures • For medical surveillance purposes
Notational Fire Protection Agency (2013)	• Mandatory component of firefighters medical evaluation
Belfasky (2013)	• On the basis of age, workload or pulmonary symptoms • Use of SCABA

Currently, there are few medical criteria that suggest a specific level of lung function that should allow a worker to wear a respirator in the workplace. The American Thoracic Society (ATS, 1996) recommended that workers with > FEV1of 60% of predicted value be allowed to wear a respirator; National Fire Protection Agency (NFPA-1582) suggested that any firefighter with FVC or FEV1 < 70 % prevents the safe use of SCBA respirators (Hankinson *et al.*, 1999; NFPA). **Table 8** shows ATS and NFPA spirometry criteria for medical clearance for respirator use.

Table 8 Spirometric Criteria for Respirator Clearance

Agency	**Criteria**
National Fire Protection Association	Firefighter with FVC or FEV1 < 70 % prevents the safe use of SCBA respirators
American Thoracic Society	Workers with FEV1 of > 60% of predicted value be allowed to wear a respirator

3.2 Interpretation of Spirometry results

Interpretations of Spirometric values are significant and indicate whether the worker's lung function is within normal range or having pulmonary impairments. Likewise, these readings will help follow the indicated above spirometry criteria. OSHA recommends the following algorithm suggested by the American Thoracic Society, National Institute for Occupational Safety Health and American College of Environmental and Occupational Medicine. Pellegrino et al. 2005 in their article "Interpretive strategies for lung function tests" suggested the algorithm to interpret spirometry results compared with the normal range (reference values). Most commonly used and recommended reference values are based on National Health and Nutrition Examination Survey III (NHANES III) by Hankinson et al. 1999. Comparison of the worker's Spirometric value with the reference values will help to identify whether lung function is within normal range or abnormal. OSHA recommended using NHANES III reference values for occupational spirometry unless it is mandatory to use different reference values for particular standards such as the OSHA cotton dust standard. Previously Spirometric reference equations suggested by Crapo et al. (Crapo), Knudson et al. (Knudson) and Morris et al. (Morris) are used in the Pulmonary function laboratories, in the United States (Crapo R.O., 1981; Hankinson, Odencrantz and Fedan, 1999; Knudson *et al.*, 1976; Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005). **Table 9** shows the commonly used lung function prediction equations used for interpretation of spirometry results in the US.

Table 9 Commonly Used Lung Function Prediction Equations

Reference	Lung Functions	Equations	
		Males	Females
Crapo et al. 1981	FEV1	0.0414H-0.0244A-2.190	0.0342H-0.0255A-1.578
	FVC	0.0600H-0.0214A-4.650	0.0491H-0.0216A-3.590
Knudson et al.1983	FEV1	0.0665H-0.0292A-6.515	0.0665H-0.0292A-6.515
	FVC	0.0844H-0.0298A-8.782	0.044H-0.0169A-3.195
Hankinson et al. 1999 (NHANES III)	FEV1	0.5536-0.01303*Age-0.000172*Age*Age+0.00014098*Ht*Ht	0.4333-0.00361*Age-0.000194*Age*Age+0.00011496*Ht*Ht
	FVC	-0.1933+0.00064*Age-0.000269*Age*Age+0.00018642*Ht*Ht	-0.3560+0.01870*Age-0.000382*Age*Age+0.00014815*Ht*Ht

Collen et al. 2008 suggested that there is discordance between the prediction equation proposed by the Crapo, Knudson, Morris and NHANES III in the interpretation of spirometry results leading to misinterpretations of the pulmonary conditions (Collen J., 2008).

Sood et al. 2007 suggested in their article that there are differences in the interpretation of pulmonary function abnormalities using NHANES III, Crapo, and Knudson prediction equations. This research study is also focused on these different spirometry prediction equations that follow the American Thoracic Society and National Fire Protection Association criteria used

to determine if workers can safely wear respirators using these various prediction equations. This study will assess whether these criteria are consistent and reliable for determining the safe use of respirators in the workplace (Sood *et al.*, 2007).

Pellegrino et al. 2005 suggested that pulmonary function changed when they performed spirometry over a long period of time. They suggested that statically or biological changes occurred over a period differ in measurements depending on several factors, including duration of measurements and the type of patients. They also suggested that long-term variability in the pulmonary function test requires relatively large changes in the pulmonary function to indicate confidently that significant changes occurred. American Thoracic Society (ATS) 1991 suggested that in persons with relatively "normal" lung function. This requires >15% changes in FEV1 over a year duration before confidently suggesting that clinical changes occurred in that person (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005).

The American Thoracic Society/ European Respiratory Society recommended the use of FEV1 as a spirometric measurement to assess lung function over an extended period of time (Pellegrino et al. 2005). They suggested that FEV1 measured changes in both obstructive and restrictive lung diseases are not likely affected by the testing errors such as early termination, which affects the accuracy of FVC. FEV1/FVC is also not an accurate measurement of change in lung function over a period of time as it is influenced by factors that affect the FEV1 and FVC (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005).

ATS/ERS, ACOEM, and NIOSH recommended that >15 % of predicted values of FEV1 is considered a significant loss in lung function and should be carefully evaluated in that subject (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005; Townsend, 2011; Townsend and Dreger, 2005). NIOSH in their recently published study suggested that lesser changes such as 8-10 percent in FEV1 might be regarded as a significant loss in pulmonary function, in healthy workers with serial spirometry measurements (Wang ML, 2004). American College of Occupational & Environmental Medicine recently suggested that changes of 10-15% in baseline Spirometric measurements after adjusted for age should be evaluate when known chemical exposure is present at the workplace (Townsend, 2011). Age is a significant factor in declining spirometric measurements over time, and it is decreased about 0.03 L/yr on average in non-smoking adults whose age is ≥35 years ((NIOSH), 1995). **Table 10** shows the American Thoracic Society/European Respiratory Society recommendations for interpreting longitudinal changes in lung function.

Table 10 Significant Changes in Forced Expiratory Volume in One Second (FEV1) or Forced Vital Capacity (FVC) over time

	Forced Vital Capacity (FVC)	**Forced Expiratory Volume in One Second (FEV1)**
Within a Day Normal Subjects COPD Patients	 ≥ 5 % ≥ 11%	 ≥ 5 % ≥ 13%
Week to Week Normal Subjects COPD Patients	 ≥11% ≥20%	 ≥12% ≥20%
Year to Year	≥15%	≥15%

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Kreiss et al. 2012 conducted a serial spirometry study of flavor manufacturing workers in the California, and found that of 416 workers with at least two spirometry results, 40 workers (9.6%) had abnormal FEV1 declines. Abnormal FEV1 decline was more prominent among workers at the manufacturing units who were using >800 lbs /year diacetyl than manufacturing units using less diacetyl. They stated that Spirometric surveillance of flavoring workers can identify individual workers with an abnormal FEV1 decline for preventive measures, even though, the FEV1 itself remains within the normal range (Kreiss *et al.*, 2012).

3.3 Occupational sectors

3.3.1. Boat Manufacturing Workers

This study focused on boat manufacturing workers, emergency responders, and utility workers. In this research, these study populations were selected because all these workers are exposed to hazardous airborne contaminants that can affect lung function due to workplace exposure. In Florida, Boat Manufacturing is a major business, and many people are employed in this industry. A study performed by the Marine Industry Association of Florida suggested that the marine industry has contributed nearly 18.4 billion dollars to Florida's economy and employed 220,000 Floridians in 2005 and boat manufacturing facilities are an important component of the marine industry directly and indirectly. Economic impact assessment studies conducted for the National Marine Manufacturing Association by the Recreational Marine Research Center at Michigan State University for the year 2013 indicated the total annual economic impact from recreational boating in Florida is 10.35 billion dollars (NMMA Center for Knowledge, 2013). The boat building industry created 21% (9,336/43,859) directly attributed to the recreational boat industry in Florida (NMMA Center for Knowledge, 2013). The recreational

boat industry has a significant economic impact on Florida directly creating jobs. The overall effect of the recreational boating was about 121.5 billion dollars in the year 2013 in the US. The boat building industry contributed nearly 10 % (32,485/338,526) of the jobs in the United States (NMMA Center for Knowledge, 2013). Florida ranked number 1 in the US for recreational boat registrants, with 902,964 in 2011 (NMMA, 2012). Florida also ranked number one for the total expenditure on new powerboats, engines, trailers and accessories in the US (NMMA, 2012).

The most commonly used materials for boat manufacturing are fiberglass (fiber-reinforced plastic, FRP), aluminum, wood and polyethylene. **Fiber reinforced plastic (FRP)** is usually used these days in the boat manufacturing industries with the use of primarily **unsaturated polyester resins** and to a lesser amount**, epoxy resins** in which glass fibers are the primary reinforcing agents. Other chemicals also used are catalysts, curing agents, fillers, pigments, lacquers, accelerators, inhibitors and mold release agents in the boat building process (Glass, 2001). Boat manufacturing necessarily requires a spray coating of a prepared wooden mold with a polyester resin. It is followed by a lamination process where layers of catalyzed resin and fiberglass applied to a frame either manually or mechanically. Once these layers are dried, the mold is removed and then sanded, dyed and decorated to complete the boat structure (Brigham and Landrigan, 1985). Workers, exposed mainly during the manufacturing process involves an open mold method using either a hand lay-up and rolling technique or a spray technique (Glass, 2001). **Figure 7** shows gel coating and lamination procedure doing boat manufacturing processes.

Figure 7 Boat manufactures using respirators to prevent hazardous exposures while applying gel coating and during lamination procedures

In boat manufacturing industries, **styrene** is the most commonly used cross-linking material along with diluents for unsaturated polyester resins. It is the volatile chemical that are of concern, and other alternative hardeners and organic peroxides catalysts such as **methyl ethyl ketone peroxide and methyl methacrylate** (Glass, 2001). During lamination and curing about 10 -15 % of styrene evaporates into the workplace environment air (Brigham and Landrigan, 1985)(IARC,2002). There are various factors such as manufacturing units with large objects such as boats, truck parts, and open mold processes that are associated with a higher

concentration of styrene in the workplace environment (Lemasters *et al.*, 1985). A survey conducted in 12 fiberglass manufacturing plants in Washington State suggested that about 40 % of 8-hour samples contained more than 100 ppm (426 mg/m^3). (The OSHA permissible exposure limit for styrene in the workplace is 100 ppm averaged over an eight- hour work shift)

Boat manufacturing facilities have the highest workplace styrene exposures when compared to other sectors and also specific jobs such as chopper gun operators have highest workplace exposures followed by laminators and gel-coat applicators in the boat building facilities (Schumacher *et al.*, 1981). It is well recognized that workers in boat building facilities have high levels of styrene exposures (Lemasters, Carson and Samuels, 1985). Workers are most commonly exposed through inhalation of polluted air in the work environment and rarely dermal exposure through contact with liquid styrene or resins. After inhalation, styrene is rapidly absorbed into the body through the lungs and is metabolized through the Cytochrome P450 mediated monooxygenase system in the liver (IARC,2002).

Acute exposure to styrene can cause irritation of the eyes and upper respiratory tract at concentrations of approximatelly 10-100 ppm (43-426 mg/m^3) or above (IARC, 2002)(Lorimer *et al.*, 1978). Individual complaints of acute irritation of the eyes and upper respiratory tract did not occur among workers in the glass reinforced plastic industry at air limits below 24 ppm (102 mg/m3) (IARC, 2002). Several case reports and scientific research found that chronic styrene exposure at the workplace could cause pulmonary function changes and pulmonary injury.

Lorimer et al. 1976 conducted a clinical survey of 493 workers in a polymerization and extrusion facility in the United States and found that styrene is also a potential lower respiratory tract irritant as well. They found that 30 % of the non-smokers had FEV1/FVC < 75 % and 12%

of workers who had higher styrene exposures had repeated complaints of wheezing and/or chest tightness as compared to 4 % who had lower styrene exposures (Lorimer *et al.*, 1976).

Recently, Sati et. al. 2011 conducted a study to assess the effects of styrene exposure on lung function in plastic manufacturing workers in India (Sati *et al.*, 2011). They found that most of the lung volumes and in capacities (FVC, FEV1, VC, ERV, IRV, and IC) and flow rates (PEFR, $MEF_{75\%,}$ MVV) are statistically significant by ($p<0.05$) lower in workers who are exposed to styrene compared to the control group (Sati, Khaliq, Vaney, Ahmed, Tripathi and Banerjee, 2011).

Cullinan et al. 2013 found obliterative bronchiolitis (OB), a rare pulmonary disease caused by occupational exposures in six workers involved in preparing fiberglass hulls for boats. Two patients received lung transplants while one patient died while waiting for a lung transplant. Diagnosis of obliterative bronchiolitis was confirmed by either biopsies or post-mortem examinations in these patients. They concluded this rare pulmonary disease occurring among six workers applying fiberglass with styrene resins resulted from workplace exposures could be because OB. Though they are unable to identify specific agents causing the OB (Cullinan *et al.*, 2013).

Ruder et al. 2004 observed mortality patterns among 5,204 workers exposed to styrene during 1959 to 1978 at two reinforced plastic boat manufacturing facilities in the United States. They found significantly increased mortality from “Pneumoconioses and other respiratory diseases” among workers who had high styrene exposure at the workplace (Ruder *et al.*, 2004).

Wong & Trent et al. 1999 conducted a study to observe mortality from nonmalignant diseases of the respiratory, genitourinary and nervous system among workers who had styrene

exposure at the workplace. They found 15,826 workers exposed to styrene in the reinforced plastics and composites industries. They found increased mortality in workers from a non-malignant respiratory diseases, but not from genitourinary and nervous system disorders. The study also indicated that mortality was higher among workers who had short and lower styrene exposure as compared to higher styrene exposure (Wong and Trent, 1999).

Though these studies have suggested there is a correlation between chronic styrene exposure and pulmonary function changes, some studies are inconclusive and require further research into establishing a relationship. Robin et al. 1999 conducted research to evaluate the pulmonary morbidity among 751 patterns and model makers in Southeast Michigan who were exposed to hardwoods, softwoods, epoxy and polyester/styrene resins and welding and metal fumes. They found that cumulative plastics exposures were linked to wheezing, chronic bronchitis, and dyspnea, but not with pulmonary function changes (Robins *et al.*, 1990). Oner et al. 2004 found some occupational asthma caused by styrene; he evaluated 47 workers in the furniture industry who were exposed to styrene in the workplace and found only one worker with occupational asthma on the basis of spirometry findings, but this was not significant to establish a relationship between occupational asthma and styrene (Oner *et al.*, 2004).

Other potential health hazards such as **methyl methacrylate, methyl ethyl ketone peroxide, and dimethyl phthalate** are present in the boat manufacturing processes and workers are potentially exposed to these airborne contaminants. Dimethyl phthalate is a part of the immune sensitizer family of chemicals also known as acid anhydrides which are commonly used as curing agents for epoxy resins and in the manufacture of plasticizers, polyester resins, and alkyd resins. Dimethyl phthalate is mainly used as a curing agent in the boat building process (Markowitz et al. 2005). It is well established that exposure to acid anhydrides can cause

irritation of the pulmonary system and leads to occupational asthma, late respiratory distress syndrome (myalgia, malaise, fever, chills, arthralgia, cough, wheezing and dyspnea), and dyspnea, hemoptysis, pulmonary infiltrates restrictive lung disease and hemolytic anemia (Bardana and Andrach, 1983; Hagmar *et al.*, 1987).

Volkman et al. 2006 reported a case of hypersensitivity pneumonitis **(yacht maker's lung)** in a 46-year-old female worker who was involved in yacht manufacturing. She complained about respiratory symptoms such as dyspnea, chest tightness and coughing temporally related to her job duration. They suggested styrene and dimethyl phthalate likely cause of the hypersensitivity pneumonitis. Though they could not identify the specific chemical or antigen the clinical features and Spirometric and chest x- ray findings suggested hypersensitivity pneumonitis (Volkman *et al.*, 2006).

Chen et. al 2013 reported two cases of obliterative bronchiolitis (OB) in Taiwan among workers involved in FRP yacht manufacturing. Both these patients were working at a yacht manufacturing site; one patient was specifically involved in the FRP leakage proof lamination process, not gel coating process, so it was concluded that the FRP lamination process was responsible for the OB. This worker specifically used polyester resin with MEKP (as a catalyst) and styrene (as an active diluent) during his work. They suggested these agents could cause OB in these patients, but they needed more conclusive evidence to established the cause (Chen *et al.*, 2013).

Jedrychowski et al. 1981 conducted a study in 454 male workers who are exposed to styrene and methyl methacrylate and compared to control group. They found that there were no significant differences in the prevalence of chronic chest symptoms in both groups, but the

incidence of lung obstruction in exposed group was twice that of a control group in the exposed group. They also found that a large portion of workers who had lung obstruction did not have chronic chest symptoms. They concluded that chronic chest symptoms are not useful predictors of workplace exposure and spirometric evaluation of the workers should be used to identify health risks from environmental and occupational exposures (Jedrychowski, 1982).

Piirila et al. 1998 conducted a study to identify acrylate induced respiratory hypersensitivity cases in dental offices in Finland during 1992-1997. Twelve cases of respiratory hypersensitivity were found during this period. Out of these twelve cases, 9 cases of occupational asthma, 1 case of laryngitis, and 2 cases of rhinitis were identified using spirometry and work stimulation provocation test. The average duration of acrylate exposure was 22 years, and the duration of respiratory complaints was eight years (Piirila *et al.*, 1998).

Scheerpereel et al. 2004 reported two cases of hypersensitive pneumonitis in dental technicians because of inhalation of methyl methacrylate (MMA). These dental technicians were exposed to mineral dust and chemicals while performing polishing and grinding of dentures. Methyl methacrylate (MMA) is a monomer, commonly used in dental clinics. It has been established that acrylate compounds (MMA) are responsible for occupational asthma, rhinitis and laryngitis (Piirila, Kanerva, Keskinen, Estlander, Hytonen, Tuppurainen and Nordman, 1998; Scherpereel *et al.*, 2004).

These scientific research articles suggested that boat building workers are likely exposed to hazardous airborne contaminants such as styrene, methyl methacrylate, methyl ethyl ketone peroxide and dimethyl phthalate. As discussed above chronic exposure to these chemical agents can cause respiratory illnesses, and to prevent this exposure workers are required to use respirators in the workplace. The National Institute for Occupational Safety Health (NIOSH)

and the Occupational Safety & Health Administration (OSHA) recommend that personal protective equipment should be used when other control methods are not sufficient to keep the exposure limit of the hazardous contaminants at acceptable levels the workplace. The National Institute for Occupational Safety and Health (NIOSH) recommends the different types of respirators should be used at different levels of chemical exposures to protect workplace (NIOSH, 2011).

These research articles suggested that boat manufacturing workers are potentially exposed to contaminates that adversely affect pulmonary function and these workers regularly use respirators in the workplace that may have physiological effects of respirator on pulmonary function over a period. Use of spirometry for occupational health surveillance will identify workers who are exposed to chemicals exposure and are medically not fit to wear a respirator in the workplace.

3.3.2. Emergency Responders

Emergency responder compromise firefighters, police personnel, emergency medical technicians, and paramedics. They take part in any natural or industrial disaster, terrorist activity or fire in the neighborhood, and they are likely to be exposed to hazardous chemical contaminants while performing their duties. They are exposed to a mixture of chemicals, dusts, gases or vapors while performing their job in hostile environments, and often fail to wear personal protective equipment while saving the lives of others.

The range of respiratory illnesses among emergency responders were reported following the aftermath of the WTC incidents in 2001and include “WTC Cough Syndrome”, sinus, nose and postnasal irritation, reactive airway dysfunction syndrome (RADS), irritant-induced asthma

and pulmonary function abnormalities (Herbert *et al.*, 2006; Prezant *et al.*, 2008; Prezant *et al.*, 2002; Salzman *et al.*, 2004; Skloot *et al.*, 2004).

Antao et al. 2011 conducted a survey of 9,296 rescue and recovery workers (RRW) who enrolled in the WTC health registry after 9/11. This study suggested that out of 9,296 (RRW) who enrolled in this self-reported respiratory health problems survey some had shortness of breath (29.6%), wheezing (23.4%), chronic cough (15.7%), upper respiratory systems (71.6%), asthma/reactive airway dysfunction syndrome (RADS) (15.6%) and COPD (9.7%) (Antao *et al.*, 2011).

Banauch et al. 2006 performed a longitudinal pulmonary function study among firefighters who worked as rescuers at the World Trade Center collapse in 2001. They compared spirometric changes in 12,079 firefighters before and after the WTC incident over a period of years. They found that those firefighters who were exposed to WTC pollution had decreased FEV1 over a year after the incident. They found the average reduction in FEV1 was about 372 ml (95% C.I., 364-381ml, $p<0.001$) among firefighters over a period of years. They suggested this pulmonary function loss was equivalent to 12 years of aging-related changes in FEV1 (Banauch *et al.*, 2006).

Feldman et al. 2004 conducted a clinical survey of pulmonary symptoms, respirator use and pulmonary function changes of 362 firefighters who were present at the WTC collapse. They found that during the first two weeks after WTC collapse, 19% of firefighters reported not using any respirator; 50 % used a respirator only occasionally. The FEV1 and FVC were both equally decreased in firefighters after exposure at the WTC. These pulmonary function changes were higher than the referent firefighter group. They found a 60% greater decline about >450 ml in

FEV1 in firefighters who arrived at the collapse site during the first 48 hours as compared to a referent group ($p \leq 0.05$). They recommended further evaluation of the clinical features and pulmonary function changes in firefighters following the WTC incidents and recommendations to improve training in respirator usage and long-term medical evaluation of these rescue workers (Feldman *et al.*, 2004).

There were few studies conducted of police personnel who were exposed to WTC pollution and the related effects on pulmonary function changes. Kleinman et al. 2011 carried out a study on 206 emergency service unit staff without chronic pulmonary exposure who were present during the WTC incident. They compared their pulmonary function data before and after one year response to the WTC disaster and follow-up after five years following the WTC incident. They found a significant reduction in pulmonary function in 5.3% of the total subjects, and this reduction was significant among those workers who had respiratory symptoms and high-intensity exposure during the collapse. They recommended developing guidelines for efficient use of personal protective equipment (Kleinman *et al.*, 2011).

Tepper et al. 1991 conducted a study to evaluate longitudinal pulmonary function changes among 632 Baltimore City firefighters and followed them over six to ten years after a baseline spirometry study. They suggested that firefighters who never used masks in the workplace have 1.7 times greater decline in FEV1 as compared to those who used a mask during extinguishing activities (Tepper *et al.*, 1991).

Adetona et al. 2011 conducted a study to investigate the pulmonary function changes among wildland firefighters. They found no significant differences in across work shift changes on burn days compared to those with non-burn days for all the spirometric measures. They also

found that as the day progresses during the season each additional day of exposure was linked with a decline of 24 ml in pre-shift FVC and 24 ml in pre-shift FEV1 ($p<0.01$) (Adetona *et al.*, 2011).

Jacquin et al. 2011 evaluated short-term pulmonary function changes in wildland firefighters in Europe. They conducted spirometry on 108 firefighters and compared the results with baseline spirometry results. Spirometry testing performed immediately after exposure found a decline in spirometry results, and even more of a decline was seen after 24 hours but no firefighter's complained about respiratory symptoms. Three months after the season the spirometry testing performed and showed persistent declines in spirometric testing compared to baseline results. They suggested that firefighters tend to develop pulmonary impairment following wood smoke exposure, and there is no statistical difference between non-smokers and smokers (Jacquin *et al.*, 2011).

These scientific studies have suggested that emergency responders are potentially exposed to hazardous chemicals during their responses. Though they are required to use a respirator in the workplace to prevent exposure; studies indicate they are not efficiently used respirators during the responses to emergencies and exposures to contaminants likely occurred during these responses to expose to these contaminants. Spirometry will help identify the risks among these emergency responders and provide data to manage these risks and improve safety.

3.3.3. Utility Workers

A third group of workers focused in this study are utility workers. There is limited information available on occupational exposure among utility workers and workplace effects on pulmonary function. Coal is most commonly used for the generation of electricity in the United

States (US EIA,2014). These utility workers are potentially exposed to hazardous materials such as asbestos, fly ash (arsenic), coal dust, sulfur dioxide, nitrogen dioxide at power plants. These exposures may effect on respiratory function of the workers (Bridbord *et al.*, 1979). Usually affected job categories at the coal-fueled power plants are electricians, coal equipment operators, mechanic tractor operators, instrument technicians, engineers, boiler turbine operators and auxiliary equipment operators during outages as well as routine operations (Bird *et al.*, 2004).

Bar-Shai et al. 2012 conducted a study on power plant workers in Israel who were exposed to asbestos more than 15 years. They found that pulmonary function declined over a period of years in these workers. They recommended continuous monitoring of pulmonary function of employees who had asbestos exposure during their work at the power plant (Bar-Shai *et al.*, 2012).

Combustion of fossil fuel (i.e. oil, coal and natural gas) generate a large number of particulates known as fly ash, which are released into the atmosphere and workplace. It also deposited on the walls and bottom of the boiler and is known as boiler ash. During equipment maintenance, cleaning and repair workers are exposed to this boiler ash at power plants. Hauser et al. 2001 conducted a study on 118 boilermakers who are likely exposed to boiler ash while welding, grinding, cutting and burning in these boilers during construction, repair and maintenance. Several studies indicated that workers exposed to these boiler ashes have respiratory symptoms such as upper respiratory tract irritation, cough, shortness of breath and rhonchi. Hauser et al. found yearly losses in lung function associated with working as boilermakers in gas, coal, and oil-fired power plants (Hauser *et al.*, 2001; Sjoberg, 1955; Williams, 1952).

Wijngaaeden et al. 2001 conducted a study to examine the mortality pattern among electric utility workers. They evaluated 138,905 male electric utility workers who were working at least six months between 1950 and 1986 at utility companies in the US. They found that the risk of lung cancer was consistently increased among workers who are involved in different job categories that comprise utility operations in five different companies. They suggested that increases in mortality from lung cancer could be related to occupational or non-occupational risk factors. They also recommended conducting further research to identify the disease pattern and preventive measures (van Wijngaarden *et al.*, 2001).

Harbison et al. 2012 conducted a cross-sectional evaluation of pulmonary function among utility workers and compared their results with NHANES III spirometry data. They found that utility workers had a significant increase in FEV1 and FVC when compared to NHANES III population data in a univariate analysis. In this study stratification of confounding factors did not find significant increases in FEV1 and FVC except among older utility workers (Harbison, 2012).

To prevent response to airborne contaminant hazards in the workplace, utility workers commonly used a respirator during routine as well as cleaning procedures turnaround. Spirometry evaluation among these workers will help provide a medical surveillance databases for evaluating efficacy of health and safety procedures. It also can provide data for early detection of changes in pulmonary function resulting from hazardous materials exposures.

Chapter 4. Methodology

4.1 Study Participants

As discussed earlier, this research focuses on three occupational sectors in the state of Florida: boat building workers, emergency responders and utility workers. Selection of study participants is based on the following criteria:

1. He or she is working in either of the above occupational sectors

2. Age above 18 years

3. Using a regular respirator in the workplace

4. Repeatedly conducted spirometry for the medical evaluation along with a medical questionnaire.

Other data also collected for workers included age, gender, smoking history, weight, and height. Spirometry data was collected for these workers who met the selection criteria at these workplaces in the state of Florida. Review of spirometry results of these workers has been approved by the University of South Florida, Institutional Review Board (IRB) # 00001348 **(Appendix II)**.

4.2 Pulmonary Function Test

Occupational spirometry was conducted by a NIOSH-certified technician according to the recommendation of ATS/ERS criteria (Miller *et al.*, 2007; Miller *et al.*, 2005a; Miller,

Hankinson, Brusasco, Burgos, Casaburi, Coates, Crapo, Enright, van der Grinten, Gustafsson, Jensen, Johnson, MacIntyre, McKay, Navajas, Pedersen, Pellegrino, Viegi and Wanger, 2005b). Spirometry was performed using **KoKo Spirometer,** according to the American Thoracic Society/European Respiratory Society (ATS/ERS) criteria. **Figure 8** shows a computer based KoKo Spirometer that was used to conduct lung function tests among workers.

Figure 8 KoKo Spirometer to Conduct Spirometry among Workers

(Adopted from Nspire Health Inc.)

Equipment used to perform spirometry on the workers met the validation, display requirements, and quality control criteria for volume and flow measuring devices of the American Thoracic Society/European Respiratory Society recommendations. ATS/ERS suggested that the following two components should be included to validate spirometry tests:

1.) At least three acceptable curves that are free of technical errors (these curves called "acceptable").

2.) Results of FVC and FEV1 are consistent with the curves (such results are called "repeatable"). **Table-11** outline the recommended acceptability and repeatability criteria for the spirometry tests.

Table 11 Acceptability and Repeatability Criteria for Spirometry

Within-maneuver criteria
Individual Spirograms are ‘‘acceptable’’ if
They are free from artifacts such as
- A cough during the first second of exhalation
- Glottis closure that influences the measurement
- Early termination or cutoff
- Effort that is not maximal throughout
- Leak
- Obstructed mouthpiece
They have good starts
Extrapolated volume < 5% of FVC or 0.15 L, whichever is greater

Table 11 (Continued) Acceptability and Repeatability Criteria for Spirometry

Within-maneuver criteria
They show satisfactory exhalation
Duration of ≥ 6 s (3 s for children) or a plateau in the volume–time curve or if the subject cannot or should not continue to exhale
Between-maneuver criteria
After three acceptable spirograms have been obtained, apply the following
Tests
- The two largest values of FVC must be within 0.150 L of each other
- The two largest values of FEV1 must be within 0.150 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 (optional) or
The patient/subject cannot or should not continue
Save, as a minimum, the three satisfactory maneuvers

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Figure 9 shows the steps necessary to conduct the Spirometry tests on workers according to the NIOSH recommended criteria.

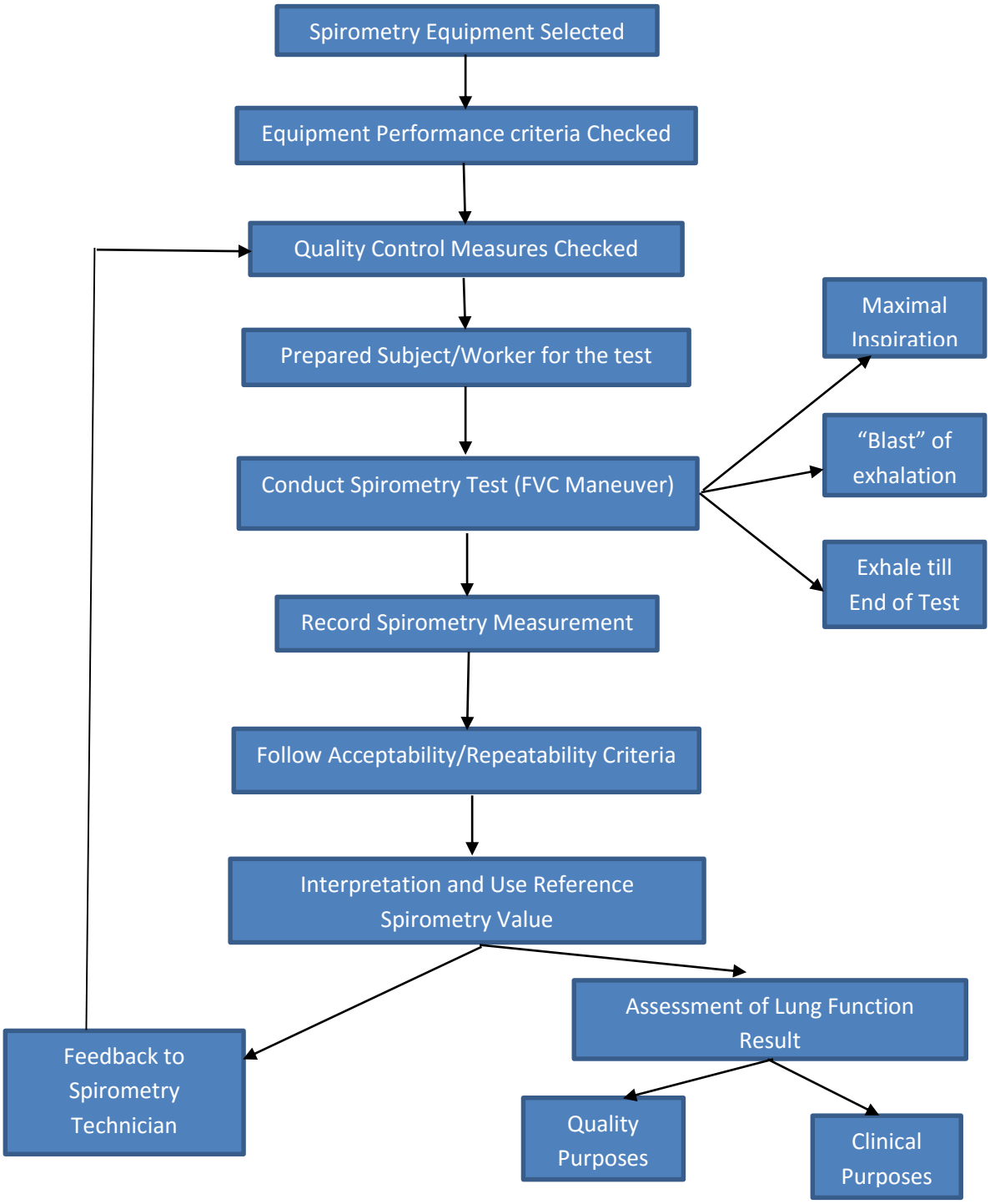

Figure 9 Steps to perform Spirometry

(Reproduced with permission of the European Respiratory Society © Eur Respir J August 2005 26:319-338; doi:10.1183/09031936.05.00034805)

4.3 Interpretation of Spirometry Results

The largest FVC and FEV1 values from all acceptable spirometric curves are reported as the reported test results even though they are derived from different curves (Miller, Hankinson, Brusasco, Burgos, Casaburi, Coates, Crapo, Enright, van der Grinten, Gustafsson, Jensen, Johnson, MacIntyre, McKay, Navajas, Pedersen, Pellegrino, Viegi and Wanger, 2005b). FEV1/FVC ratio is calculated using these values and spirometry results from all acceptable curves should be reported on the final spirometry report (Townsend, 2011). For research purposes, this study used three different reference equations from NHANES III, Crapo, and Knudson to obtain spirometry results and these results were compared using these different equations. **Appendix III** shows the spirometry report we have obtained after conducting KoKo Spirometer. This Pulmonary Function Report displays the type of protocol and reference equations and other demographic information collected for research purposes.

4.4 Spirometry Criteria for Respirator Medical Certification

This study evaluates the reliability of following two spirometric criteria recommended by Several groups for certification of suitability for wearing a respirator.

1. American Thoracic Society (ATS, 1996) Criteria: Any worker who has FEV1 > 60% of predicted value should be allowed to wear respirator.
2. National Fire Protection Agency (NFPA-1582) Criteria: Any firefighter with FVC or FEV1 <70% of predicted values prevents the safe use of SCBA respirators.

The objective of this study is to determine how many workers from different occupational sectors meet these spirometric criteria using different testing methodologies.

4.5 Longitudinal Changes

To evaluate the longitudinal changes in lung function among these workers, it used workers who had at least two spirometry tests conducted six months or more apart were included in the study. FEV1 and FVC were calculated for each worker who met the above selection criteria over a period of more than six months using NHANES III criteria. Maximum FEV1 and FVC values were used for workers who satisfied the temporal criteria for longitudinal spirometry evaluations.

4.6 Statistical Analysis

4.6.1. Kappa Statistics

Kappa Statistics (κ) was used to measure agreement between spirometric results derived from NHANES III and other equations such as Crapo and Knudson in meeting the spirometric criteria of the American Thoracic Society and National Fire Protection Association for medical certification for respirator clearance. Kappa statistics is defined as an interobserver agreement (Cohen, 1960). Kappa statistics is anticipated to provide the reader a quantitative evaluation of the magnitude of agreement between observers (Viera and Garrett, 2005). Kappa statistics is based on the difference between "Observed" agreements to chance agreements ("Expected" agreements) (Sood, Dawson, Henkle, Hopkins-Price and Quails, 2007; Viera and Garrett, 2005).

Kappa statistics for the categorical data were interpreted by guidelines suggested by Landis et al. 1977. **Table 12** suggested the guidelines for the interpretation. Generalized McNemar's test was used to measure the presence of the bias. A p value of < 0.05 for the hypothesis (H_0: $\kappa = 0$) was considered to be significant.

Table 12 Guidelines for Interpretation of Kappa Statistics

Kappa Statistics	Strength of Agreement
0.81-1.00	Very Good
0.61-0.80	Substantial
0.41-0.60	Moderate
0.21-0.40	Fair
0.00-0.20	Slight
<0.00	Poor

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4.6.2. Interclass Correlation Coefficient

When each subject is evaluated by multiple observers, to what extent is the rating between the two observers is homogenous? Interclass correlation coefficients (ICC) are used to evaluate interrater reliability in the continuous data. ICC is the assessment of the correlation between two measurements made on the same worker. ICC provides an evaluation of reliability, but many forms of ICC exist, and each is appropriate only under limited conditions (Shrout and Fleiss, 1979).

In this study ICC was calculated for the lung functions such as Forced Expiratory Volume in First Second (FEV1), Forced Vital Capacity (FVC) and FEV1/FVC ratio derived from different reference equations such as Knudson (1983), Crapo (1981) and NHANESIII (UCLA, 2014)(Winer, 1971).

The three different reference standards randomly selected interpret the lung function of each worker. Workers represent a random sample of the all possible workers.

$$\boldsymbol{Yij}=\boldsymbol{\mu}+\boldsymbol{\beta i}+\boldsymbol{\varepsilon ij}$$

$\boldsymbol{\beta i}\sim(\mathbf{0},2)$ random subject effect

$\boldsymbol{\varepsilon ij}\sim(\mathbf{0},2)$ experimental error

Interclass Correlation Coefficients calculated using the repeated measure analysis (PROC MIXED) method using the SAS 9.4 Software package where

1. Output estimates of variance components (part of standard output) to a dataset
2. Use the estimates to calculate ICC

4.6.3. Percentage Change in Lung Function

To analyze longitudinal lung function changes for each worker, this study calculated the percent change in FEV1 and FVC over time. The following formula is used to calculate the percentage change in lung function.

Absolute Change in Lung Function = Current Year Lung Function – Previous Highest Lung Function

Percent Change = Absolute Change in Lung Function / Previous Highest × 100

Percentage change in lung function of normal subject is provided by the National Institute for Occupational Safety and Health (NIOSH). (NIOSH, 2003).

To evaluate factors that are affecting the distribution of long-term changes in FEV1 and FVC among workers, we performed a multivariate linear regression analysis to measure the outcomes of percent changes in FEV1 or FVC. Linear regression analysis is the procedure that estimates the linear coefficients of the linear equation, involving one or more independent variables (continuous or categorical) that best predict the outcomes of the dependent variable (continuous) which should be quantitative (Alexopoulos, 2010; Hidalgo and Goodman, 2013).

Multivariable or multiple linear regression model is defined as a

$$y = \alpha + x_1\beta_1 + x_2\beta_2 + \ldots\ldots\ldots x_k\,\beta_k + \varepsilon$$

Where y is a continuous dependent variable, x is a single predictor in the simple regression model, and x1, x2 … xk are the predictors in the multivariable model.

In our statistical analysis, the outcomes of Percentage Change in lung functions are affected by various independent variables such as smoking, occupation sector, race, gender, height and duration of exposure. Some of the response variables were binary in this study. In this study, analysis of variance for percentage changes in lung functions conducted through a generalized linear model (GLM).

4.6.4. Longitudinal Repeated Measure Analysis

Classical multiple regression models considered the units of analysis as independent explanations. One consequence of failing to identify hierarchical structures is that standard errors of regression coefficients will be underestimated, leading to an overstatement of statistical significance. Standard errors for the coefficients of higher-level predictor variables will be the most affected by ignoring grouping (Rasbash et al. 2015). If this study used only statistical techniques that ignore the clustering –e.g. multiple regression – the standard errors and confidence intervals that are obtained from analysis will be un realistic and may conclude that there are real effects when the analysis was simply looking at random variation. Also in this study workers had repeated measure lung function data. One of the advantage of using multilevel modeling in this study is to deal with data in which the times of measurements vary from subject to subject. Multilevel models recognize the presence of such data hierarchies by allowing for residual components at each level in the hierarchy. Multilevel modelling is an increasingly popular method to modelling hierarchically structured data, overtaking traditional regression techniques in predictive accuracy (Gelman et al. 2006).

To evaluate changes in lung function within a subject over a period of years where lung functions were not measured at regular time points. In this study lung functions measured at irregular time intervals, here modeling time as a linear predictor of the lung function changes. It is a situation where multilevel modeling excels for the analysis of the lung function data with irregularly spaced time points. Both intra-individual and inter-individual lung function changes

among workers provide different but significant information about the lung function changes. Traditional linear regression models are only able to evaluate either intra-individual or inter-individual changes in the statistical model, while Multilevel modeling (MLM) provides more powerful statistical analysis because it allows assessment of both types of changes simultaneously in a single model (Holden *et al.*, 2008; Laird and Ware, 1982). The multilevel model with time as a linear effect is described in following equations:

Model

Level 1:

It measures intra-individual changes in the longitudinal multilevel model (MLM) (Singer JD, 2003).

Level 1 of the MLM contains N prediction equations, where N represents the number of participants. This model is mathematically explained as:

$$\text{Lung Function (y)}_{it} = \pi_{0i} + \pi_{1i}(\text{Age}_{it}) + e_{it}$$

Where lung function $(y)_{it}$ is the criterion variable for the i -th individual (i = 1, …,N) at the t -th time point (t = 1, …, T), π_{0i} is the intercept for the i -th individual, ! 1 i is the slope of the i -th individual, and e_{it} is the error in predicting the i -th individual at the t -th time point. In this model, Time_{it} is the only explanatory variable. When time is used as an explanatory variable in the level 1 model, the model can be conceptualized as a longitudinal model (Raudenbush SW, 2002)

Explanatory variables in the MLM can be time varying or time invariant. Covariates such as gender, race or group status (treatment/control) are time invariant variables because they don't change as time passes, while time-varying variables such as age and height which changes as time passes require multiple measurments to be used in the model (Singer JD, 2003).

Level 2:

At Level 2, the individual change coefficients are modeled as dependent variables with time-invariant predictors. For example, the intercept and slope of the N individuals might be modeled by the smoking and occupation group (Holden, Kelley and Agarwal, 2008). Level 2 is mathematically derived in the following equations:

Level 2 (Person):

$$\pi_{0i} = \beta_{00} + \beta_{01}(\text{Smoking}_i) + r_{0i}$$

$$\pi_{1i} = \beta_{10} + \beta_{11}(\text{Smoking}_i) + r_{1i}$$

Where, β_{00} and β_{01} are the intercepts (fixed effects) for the intercept and slope, respectively, and r_{0i} and r_{1i} are the unique effects for the i -th individual on the intercept and slope, respectively.

Substituting Level 2 model into level 1 model we get the following single equation

$$\text{Lung Function} = \beta_{00} + \beta_{01}(\text{Smoking}) + \beta_{10}(\text{Age}) + \beta_{11}(\text{Smoking x Age}) + [r_{0i} + r_{1i}(\text{Age}) + e_{it}]$$

The random components of the model are placed in the Squared [ ] brackets. This model contains both the fixed and random effects.

The multilevel model as discussed above is used to characterize lung function changes among workers as intra-individual or inter-individual or both.

4.6.5 Model Comparisons

As discussed above different models for the same data can be developed. To determine which model is the best fit for the data, we can use different model comparison techniques. Deviance statistics are used when models are nested within one another and identical data is used (Holden, Kelley and Agarwal, 2008). Deviance statistics are used in most multilevel model programs and are included in their output or can be obtained indirectly from the output. If models are not nested, deviance statistics are not an appropriate method for model comparisons. The Akaike Information Criterion (AIC) or Bayesian Information Criterion (BIC) statistics can be used when models are non-nested. AIC or BIC can be used to compare two different models whether they are nested or non-nested as long as identical data are used (Holden, Kelley and Agarwal, 2008). A smaller AIC/BIC, indicates a model better fit for the data. The AIC and BIC concurrently reflect error and frugality, so a model that has a smaller error term might not be considered “better” because additional frugality were required to achieve that level of fit. Additional caution should be added when using the AIC and BIC statistics for model comparisons because utilization of these statistics is subjective. Complications arise during the utilization of these statistics when the AIC and BIC show contradictory results. Thus, the AIC and BIC should only be used when models are not nested, given the exact procedures are available in certain conditions (Singer JD, 2003).

Our models are non-nested and use identical data. This research compared different multilevel models using the AIC and BIC. We used the smallest AIC and BIC to select our model for the multilevel modeling for the longitudinal lung function analysis.

4.6.6. Statistical Software Package

All statistical analyses were conducted using a SAS 9.4 software package.

Chapter 5. Using Spirometry as a Screening Tool

5.1 Data Source

Pulmonary function test results of the workers from different occupations are included on the basis of the American Thoracic Criteria as discussed in the Chapter 4. 337 workers who met the study criteria listed in this study were used to evaluate employees who met the spirometry recommendations to wear respirators.

5.2 Results

Study population demographics used for the analysis of the use of spirometry as a screening tool between different spirometric criteria are described in **Table 13**. The study population was primarily male (approximately 87 %), mainly Caucasian (approximately 83 %) and about 35 % had a smoking history. The average age of the study population is about 40 years, and the average height of the population is about 69 inches.

Table 13 Summary of Study Populations

Total Number	**337**	**100%**
Gender		
Male	**296**	**87.83382789**
Female	**41**	**12.16617211**
Smoking History		
Yes	**120**	**35.60830861**
No	**217**	**64.39169139**
Race		
Caucasian	**282**	**83.67952522**
African-American	**24**	**7.121661721**
Hispanic	**31**	**9.198813056**
Occupations		
Boat Manufacturing	**122**	**36.20178042**
First Responders	**129**	**38.27893175**
Utility Workers	**86**	**25.51928783**
Age		
≤ 54 years old	**307**	**91.10**
≥ 55 years old	**30**	**8.90**

5.2.1 National Fire Protection Association Criteria

This research used the NFPA spirometry criteria (FEV1 or FVC ≥70) for the screening functions to wear respirators in the workplace**. Table 14** and **15** indicate the summary of the workers who met the spirometry criteria. Also data were compared using different spirometric reference equations. A small number of employees with FEV1 (14, 4.15%) and FVC (9, 2.67%) were not able to pass the spirometry screening criteria but had already passed the OSHA recommended questionnaire.

Table 14 Number of workers who met the National Fire Protection Association (FEV1) Criteria to wear Respirators

FEV1 ≥70 (Total Number = 337)		
	Pass	**Fail**
NHANES III (1999)	323 (95.84%)	14 (4.15%)
Crapo et al. 1981	318 (94.36%)	19 (5.63%)
Knudson et al. 1983	322 (95.54%)	15 (4.45%)

Table 15 Number of workers who met the National Fire Protection Association (FVC) Criteria to wear Respirators

FVC ≥70 (Total Number = 337)		
	Pass	**Fail**
NHANES III (1999)	328 (97.32%)	9 (2.67%)
Crapo et al. 1981	325 (96.43%)	12 (3.5%)
Knudson et al. 1983	330 (97.92%)	7 (2.07%)

5.2.2. American Thoracic Society Criteria

This study also used other criteria (FEV1 ≥ 60) recommended by the American Thoracic Society for screening purposes to wear respirators. A small percentage of the workers who had been cleared by the OSHA approved questionnaire failed to pass the screening criteria to wear respirators. **Table 16** presents the number of employees who failed to meet standards recommended by the ATS.

Table 16 Number of workers who met the American Thoracic Criteria to wear Respirators

FEV1 ≥60 (Total Number = 337)		
	Pass	Fail
NHANES III (1999)	332 (98.51%)	5 (1.48%)
Crapo et al. 1981	330 (97.92%)	7 (2.07%)
Knudson et al. 1983	331 (98.21%)	6 (1.78%)

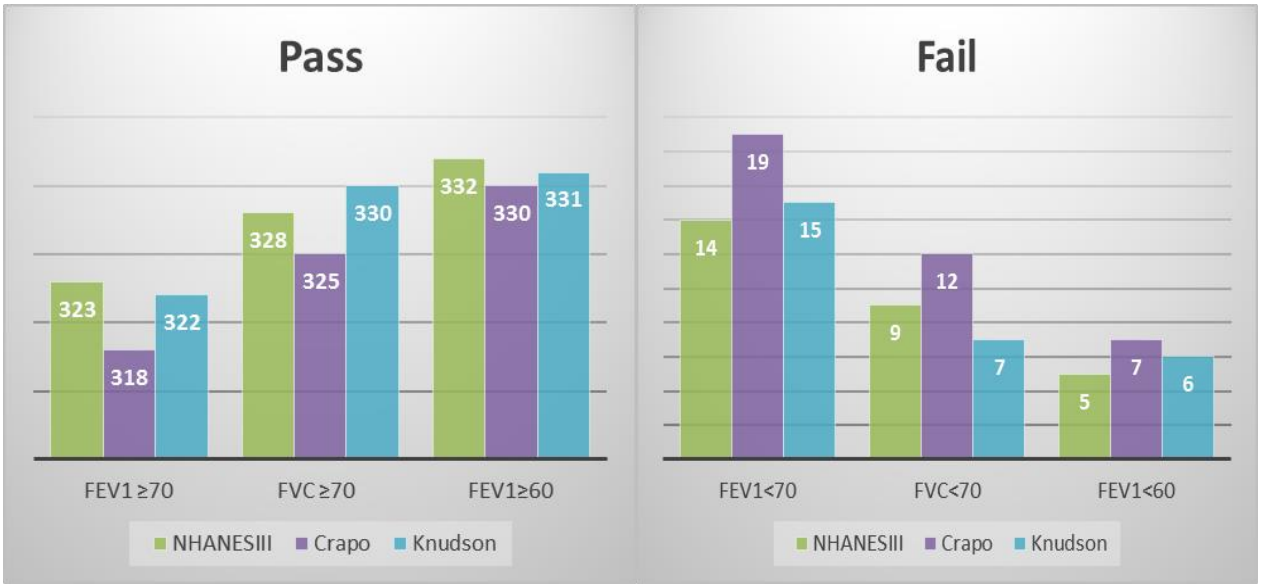

Figure 10 Comparison of Different Spirometric Criteria to wear Respirators

Figure 10 outlines the comparison of different screening spirometric criteria used to certify suitable to wear a respirator in various occupations.

5.3 Multivariate Analysis

Multivariate logistic regression analysis was conducted to determine the effect of various predictors on the outcome of the passing the spirometry screening criteria. **Table 17-19** shows the impact of individual factors on the result of passing the spirometric screening criteria using different spirometric equations. In this study the effects of various factors such as gender, worker's age, smoking history, occupation type, race and height were evaulauated for passing of respirator screening criteria. For different spirometric equations, various factors are statistically significant.

Table 17 Logistic Regression Analysis for different Spirometric Criteria using NHANES III Reference Equation
(Bolded Values are Statistically Significant)

NFPA Criteria		
FEV1 ≥70 NHANES III		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	5.368	(0.288, 100.053)
Smoking History (Non-Smoking Vs. Smoking)	2.114	(0.732, 6.106)
Race		
African-American Vs Caucassian	0.565	(0.128,2.496)
Hispanic Vs Caucassian	3.293	(0.189,57.375)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.353	(0.097,1.284)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	2.336	(0.564,9.668)
Utility Workers Vs Boat Manufacturing Workers	2.426	(0.675,8.726)
Height	1.055	(0.873,1.274)
FVC ≥70 NHANES III		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	3.988	(0.220,72.164)
Smoking History (Non-Smoking Vs. Smoking)	2.982	(0.835,10.650)
Race		
African-American Vs Caucassian	0.293	(0.063,1.351)
Hispanic Vs Caucassian	2.107	(0.126,35.111)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.644	(0.115,3.615)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	1.011	(0.218,4.683)
Utility Workers Vs Boat Manufacturing Workers	1.395	(0.311,6.264)
Height	1.083	(0.869,1.349)
ATS Criteria		
FEV1 ≥60 NHANES III		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	2.622	(0.148,46.537)
Smoking History (Non-Smoking Vs. Smoking)	0.742	(0.172,3.197)
Race		
African-American Vs Caucassian	0.419	(0.066,2.654)
Hispanic Vs Caucassian	1.986	(0.116,33.916)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.286	(0.049,1.683)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	2.742	(0.477,15.764)
Utility Workers Vs Boat Manufacturing Workers	9.08	(0.635,129.807)
Height	1.077	(0.835,1.389)

Table 18 Logistic Regression Analysis for different Spirometric Screening Criteria Using Knudson Reference Equation (Bolded Values are Statistically Significant)

NFPA Criteria		
FEV1 ≥70 Knudson		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	2.021	(0.111,36.637)
Smoking History (Non-Smoking Vs. Smoking)	2.152	(0.747,6.1960
Race		
African-American Vs Caucassian	**0.185**	**(0.054,0.626)**
Hispanic Vs Caucassian	1.561	(0.089,27.273)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.335	(0.091,1.238)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	3.376	(0.640,17.804)
Utility Workers Vs Boat Manufacturing Workers	1.598	(0.484,5.274)
Height	0.95	(0.781,1.156)
FVC ≥70 Knudson		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	1.068	(0.056,20.400)
Smoking History (Non-Smoking Vs. Smoking)	0.82	(0.204,3.292)
Race		
African-American Vs Caucassian	**0.09**	**(0.022,0.372)**
Hispanic Vs Caucassian	0.735	(0.046,11.885)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.339	(0.053,2.179)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	2.142	(0.361,12.719)
Utility Workers Vs Boat Manufacturing Workers	2.139	(0.357,12.799)
Height	0.939	(0.726,1.214)
ATS Criteria		
FEV1 ≥60 Knudson		
Predictor	**Odds Ratio**	**95% Confidence Interval**
Gender (Females Vs Males)	1.821	(0.103,32.261)
Smoking History (Non-Smoking Vs. Smoking)	1.02	(0.256,4.063)
Race		
African-American Vs Caucassian	0.259	(0.053,1.261)
Hispanic Vs Caucassian	1.44	(0.086,24.080)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.313	(0.053,1.845)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	2.633	(0.468,14.801)
Utility Workers Vs Boat Manufacturing Workers	8.954	(0.632,126.827)
Height	1.003	(0.782,1.287)

Table 19 Logistic Regression Analysis for Different Spirometric Screening Criteria Using Crapo Reference Equation
(Bolded Values are Statistically Significant)

NFPA Criteria		
FEV1 ≥70 Crapo	**Odds Ratio**	**95% Confidence Interval**
Predictor		
Gender (Females Vs Males)	8.005	(0.405,158.261)
Smoking History (Non-Smoking Vs. Smoking)	**3.337**	**(1.221,9.119)**
Race		
African-American Vs Caucassian	**0.158**	**(0.047,0.533)**
Hispanic Vs Caucassian	0.3009	(0.170,53.352)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	**0.31**	**(0.098,0.983)**
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	1.441	(0.341,6.086)
Utility Workers Vs Boat Manufacturing Workers	0.688	(0.235,2.015)
Height	1.139	(0.951,1.365)
NFPA Criteria		
FVC ≥70 Crapo	**Odds Ratio**	**95% Confidence Interval**
Predictor		
Gender (Females Vs Males)	6.974	(0.348,132.808)
Smoking History (Non-Smoking Vs. Smoking)	1.654	(0.548,4.991)
Race		
African-American Vs Caucassian	**0.088**	**(0.026,0.303)**
Hispanic Vs Caucassian	2.195	(0.123,39.057)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	0.381	(0.086,1.693)
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	1.217	(0.261,5.679)
Utility Workers Vs Boat Manufacturing Workers	0.849	(0.227,3.173)
Height	1.15	(0.930,1.422)
ATS Criteria		
FEV1 ≥60 Crapo	**Odds Ratio**	**95% Confidence Interval**
Predictor		
Gender (Females Vs Males)	2.225	(0.120,41.288)
Smoking History (Non-Smoking Vs. Smoking)	1.481	(0.400,5.476)
Race		
African-American Vs Caucassian	0.245	(0.050,1.207)
Hispanic Vs Caucassian	1.243	(0.076,20.315)
Age		
Workers ≥ 55 Years Old Vs Workers ≤54 Years Old	**0.197**	**(0.043,0.902)**
Occupation		
Emergency Responders Vs Boat Manufacturng Workers	2.02	(0.364,11.199)
Utility Workers Vs Boat Manufacturing Workers	3.121	(0.527,18.483)
Height	1.018	(0.799,1.298)

5.4 Discussion

This research evaluates the use of spirometry as a screening tool in addition to the OSHA recommended questionnaire for clearance to wear respirators in the workplace. In this study, data were collected from the occupations where workers used a respirator regularly to prevent workplace exposure. Statistical analyses were conducted to find the study population's demographics and employees who met these spirometry criteria.

A small percentage of workers (14, 4.15%) failed the spirometry criteria to wear a respirator. The National Fire Protection Association (NFPA) uses FEV1 and FVC for screening purposes. The number of workers who did not meet FEV1 or FVC criteria is approximately similar. These results show that the OSHA recommended questionnaire did not identify a small percentage of workers who are not able to wear a respirator.

Similar results were also found while using the American Thoracic Society criteria for the screening purposes. The American Thoracic Society uses only FEV1 as compared to the NFPA, that uses FEV1 and FVC for screening purposes.

Though the OSHA allows the use of a questionnaire for the respiratory protection program, physical examination and screening tools such as spirometry help to identify the workers who are at risk for cardiopulmonary stress as well as mortality. Currently, there are no standardized guidelines available for the spirometry criteria as well as the inclusion of the screening tool spirometry in the respirator protection program. Other factors such as a type of respirator use, work conditions and heat, and other stressors while screening for respirator use should be considered.

The results of the effects of the passing screening criteria suggest that race, workers' age, and smoking history are significant factors, and can affect the outcome of the certification process. Certain factors such as gender, height and occupation did not statistically significantly affect the odds ratio for achieving certification. The range of confidence intervals depend upon the sample size and the standard deviations of the study groups (Bender and Lange, 2007). Large sample sizes provide strong confidence and narrower confidence intervals in the statistical analysis. The wider confidence intervals in the results reflect a smaller sample size. If the distribution is large in the sample size, the results are not certain, and the confidence interval becomes wider (du Prel *et al.*, 2009). These results suggested a smaller sample size affected the statistical significance of comparisons. Though these factors are statistically not significance in this study, they are influencing the passing the spirometry screening criteria. These results suggest that these factors are statistically not significant, but clinically they are relevant because of the smaller sample size and high diversity of the sample (du Prel, Hommel, Röhrig and Blettner, 2009).

Chapter 6. Use of Different Spirometry Reference Values

The goal of this research is to see is whether the use of different spirometry reference values has any effect on the outcome of meeting the different spirometry screening criteria to wear a respirator. As discussed earlier the focus of this study was on commonly used reference equations of NHANES III (1999), Crapo et al. 1981 and Knudson et al. 1983.

6.1 Agreement between NHANES III and Crapo Reference Equations

This study analyzed the 337 workers using the NHANES III and the Crapo reference equations to compare the spirometry compliance criteria (Crapo R.O., 1981; Hankinson, Odencrantz and Fedan, 1999). **Figures 11-13** shows the agreement between the NHANES III and the Crapo spirometry reference equations to screen for respirator compliance using different recommended criteria. For comparing the various compliance criteria, the level of agreement between the NHANES III reference standard with the Crapo reference standard is varied from the good ($\kappa = 0.76$) to very good ($\kappa = 0.85$) as shown in **Table 20.**

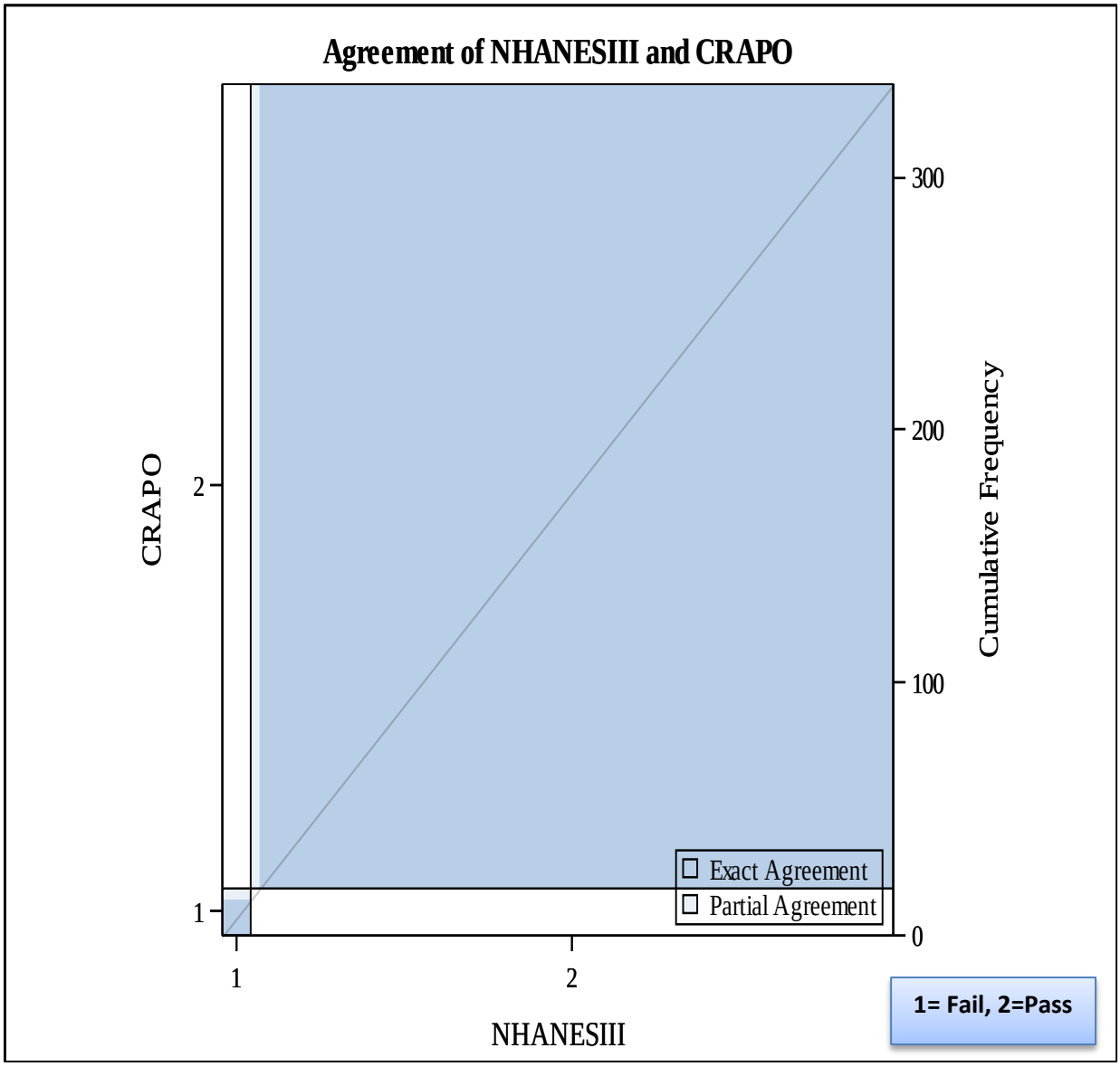

Figure 11 Agreement Chart for comparing the NFPA Criteria (FEV1 ≥70) using two different NHANESIII and Crapo Spirometry Reference Equations for respirator compliance

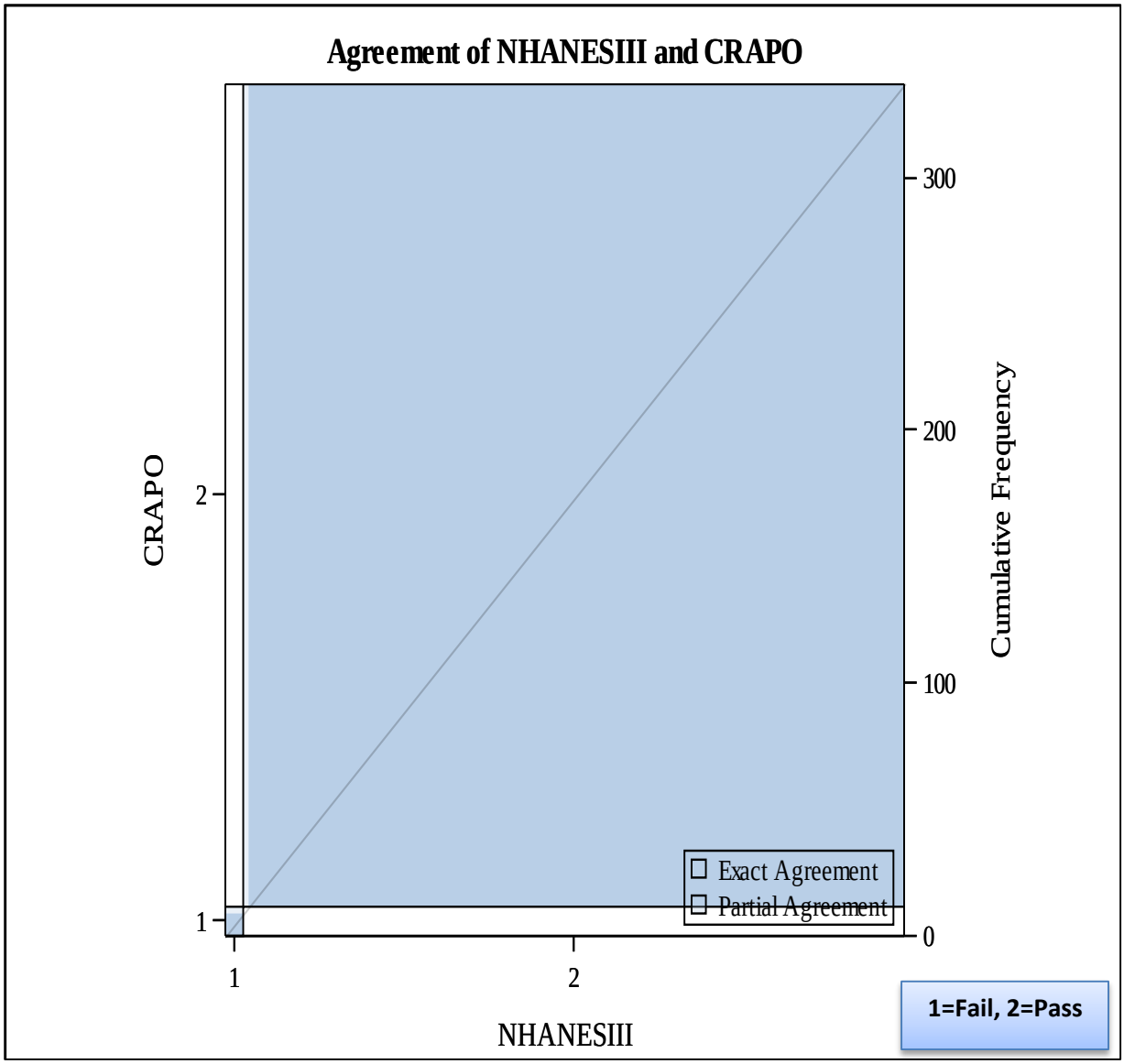

Figure 12 Agreement Chart for comparing the NFPA criteria (FVC ≥70) using two different NHANESIII and Crapo Spirometry Reference Equations for respirator compliance

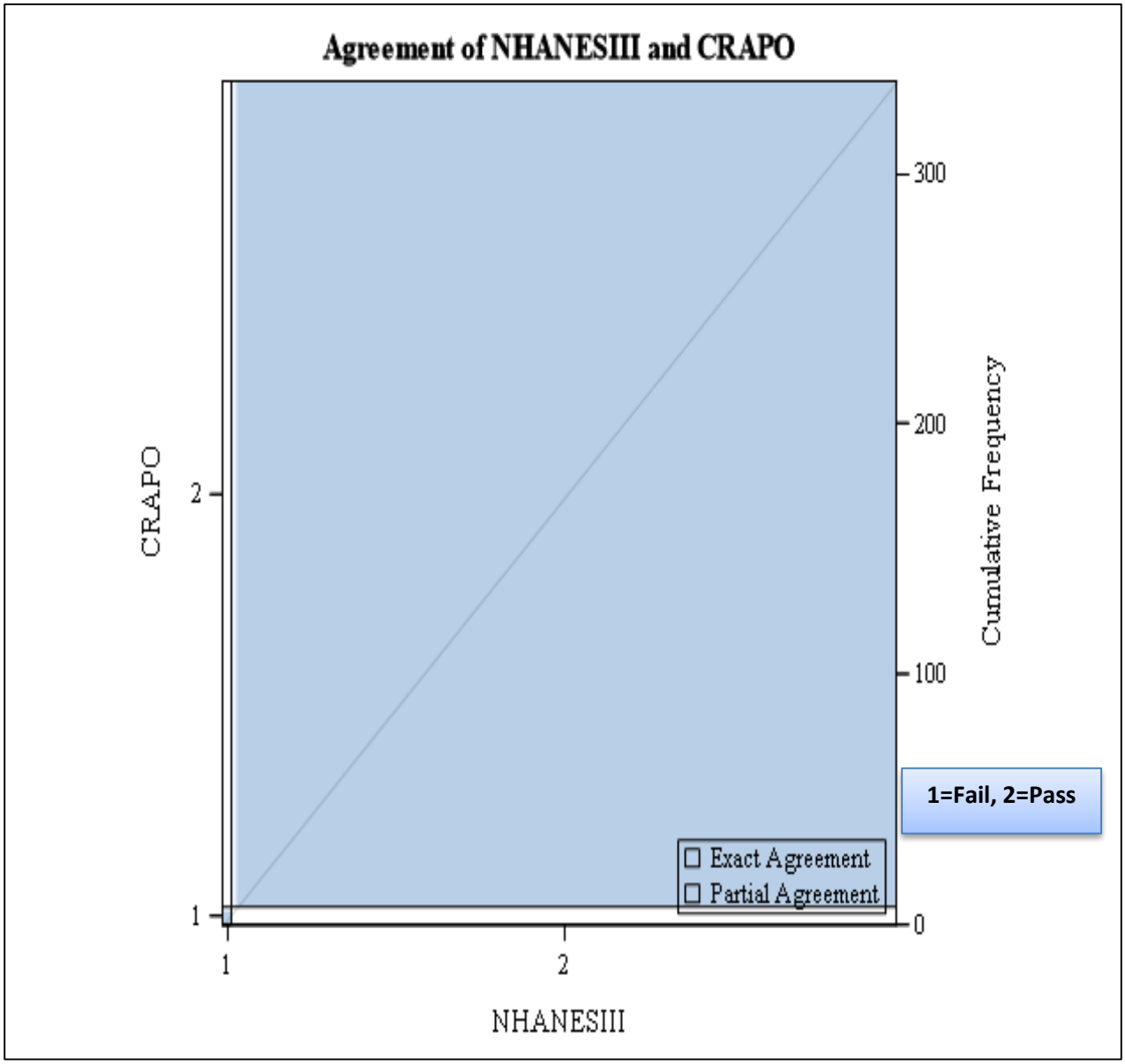

Figure 13 Agreement Chart for the comparing the ATS Criteria (FEV1≥60) using two different NHANESIII and Crapo Spirometry Reference Equations for respirator compliance

Table 20 Agreement between the NHANES III and the Crapo Standards for the respirator screening criteria

Compliance Criteria	Kappa Statistics*	Generalized McNemar's Test	p-Value
NFPA Criteria (FEV1 <70)	0.8409 (0.7042-0.9775)	p>0.0253	P<0.001
NFPA Criteria (FVC < 70)	0.8526 (0.6885-1.00)	p>0.0833	P<0.001
ATS Criteria (FEV1 >60)	0.8304 (0.5994 – 1.00)	p>0.1533	P<0.001

***Numbers in Parentheses indicate the 95% Confidence Intervals**

6.1.1 Discussion

The American Thoracic Society/European Respiratory Society in 2005 recommended use of the NHANES III reference standards to diagnose occupational lung diseases in the United States, although it suggested that other reference standards may be used if there are valid reasons for choice of these standards (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005). Alternative respiratory reference standards are used in certain mandatory conditions such as Knudson 1976 standard utilized by the cotton industry and other industries used for medical surveillance of workers in this occupational setting (Knudson, Slatin, Lebowitz and Burrows, 1976). Sood et al. 2007 suggested that caution should be used when

Crapo reference standards are used to establish impairment of lung functions among patients (Crapo R.O., 1981; Sood, Dawson, Henkle, Hopkins-Price and Quails, 2007).

This research evaluated the outcome of passing the spirometric screening criteria for respirator protection programs using two different respiratory standards. This study analyzed the agreement between the NHANES III and the Crapo reference standards. The agreement charts shown in the Figures 11-13 suggest there is a significant agreement between the two spirometry reference standards. The path of the rectangles in the Figures 11-13 are above the 45° diagonal indicating meaningful bias for passing the compliance criteria. Agreement charts were used to characterize the degree of agreement between the two reference standards used to interpret spirometry screening results. The major advantage of using agreement charts it is a visual demonstration of the level of agreement while other available methods are based on the summary statistics or model approach. It also allows a characterization an understanding of the degree of disagreement affecting two observers/standards. The main disadvantage of the agreement chart is that it is limited to ordinal scale variables where various categories on nominal scales may influence the outcome of the visual illustrations of understanding between the observers if they presented in different ways (Bangdiwala and Shankar, 2013).

The kappa statistics for the NFPA compliance criteria is very good between the NHANES III and the Crapo standards while ATS criteria have kappa statistics in the range of good agreement between the NHANESIII and the Crapo standards. The agreement between these two standards is higher because they are used for screening purposes to wear a respirator as compared to diagnosis purposes. These results suggest that using either of the reference standards does not affect the outcome of the spirometry screening for respirator protection use. The results of this

study suggest that decreasing the spirometric criteria to wear a respirator causes more discordance between the two reference standards.

6.2 Agreement between the NHANES III and the Knudson reference standards

In order to compare the spirometry compliance criteria, the study analyzed the 337 workers using the NHANES III and the Knudson reference equations (Hankinson, Odencrantz and Fedan, 1999; Knudson *et al.*, 1983). **Figures 14-16** outline the agreement chart between the NHANES III and the Knudson spirometry reference equations to screen for respirator compliance using different recommended criteria. For comparing the various compliance criteria, the level of agreement between the NHANES III reference standard and the Knudson reference standard is very good ($\kappa = 0.83$ to 0.96) as shown in **Table 21.**

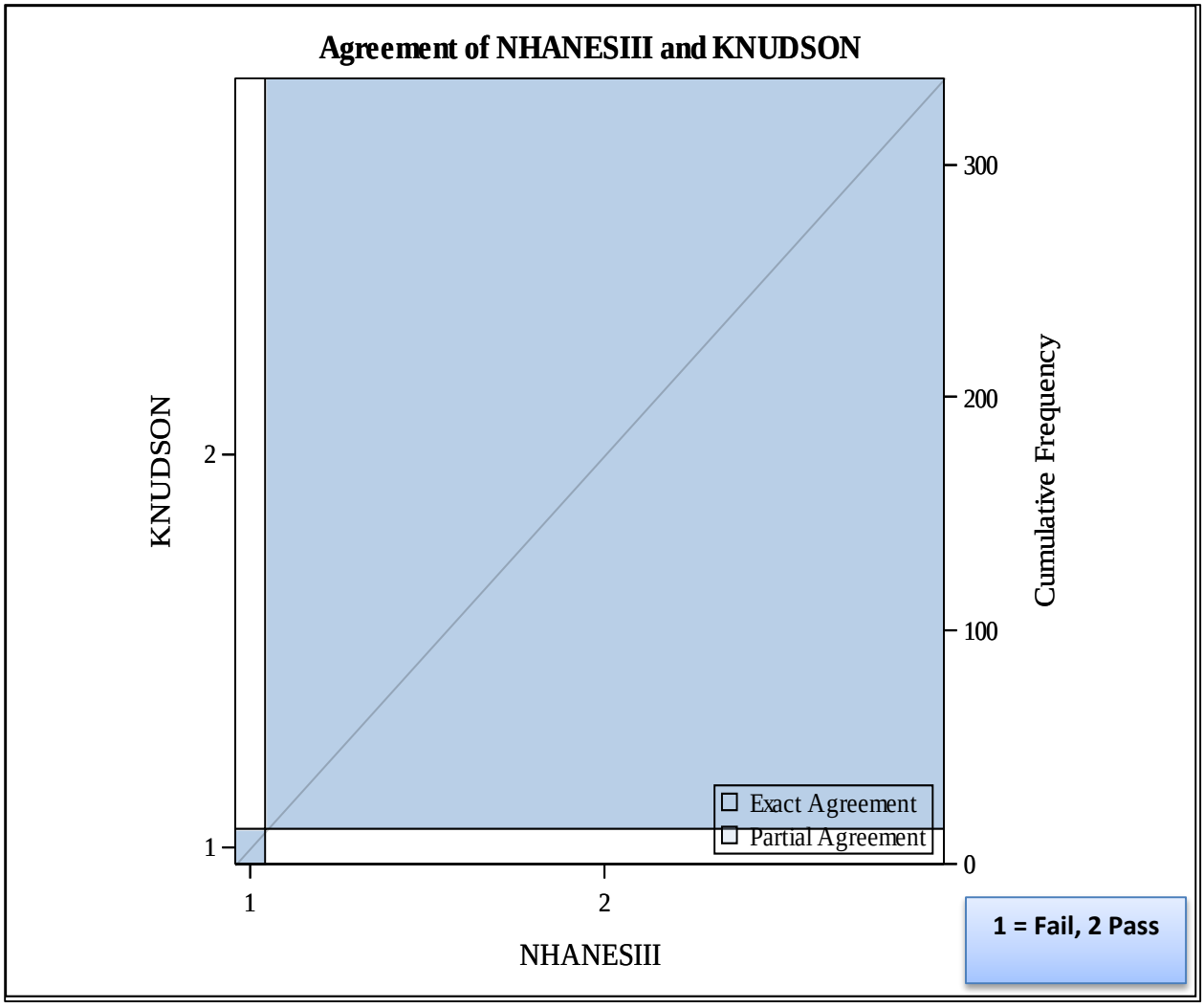

Figure 14 Agreement between the NHANES III and the Knudson Reference Standards for the NFPA Criteria (FEV1≥70)

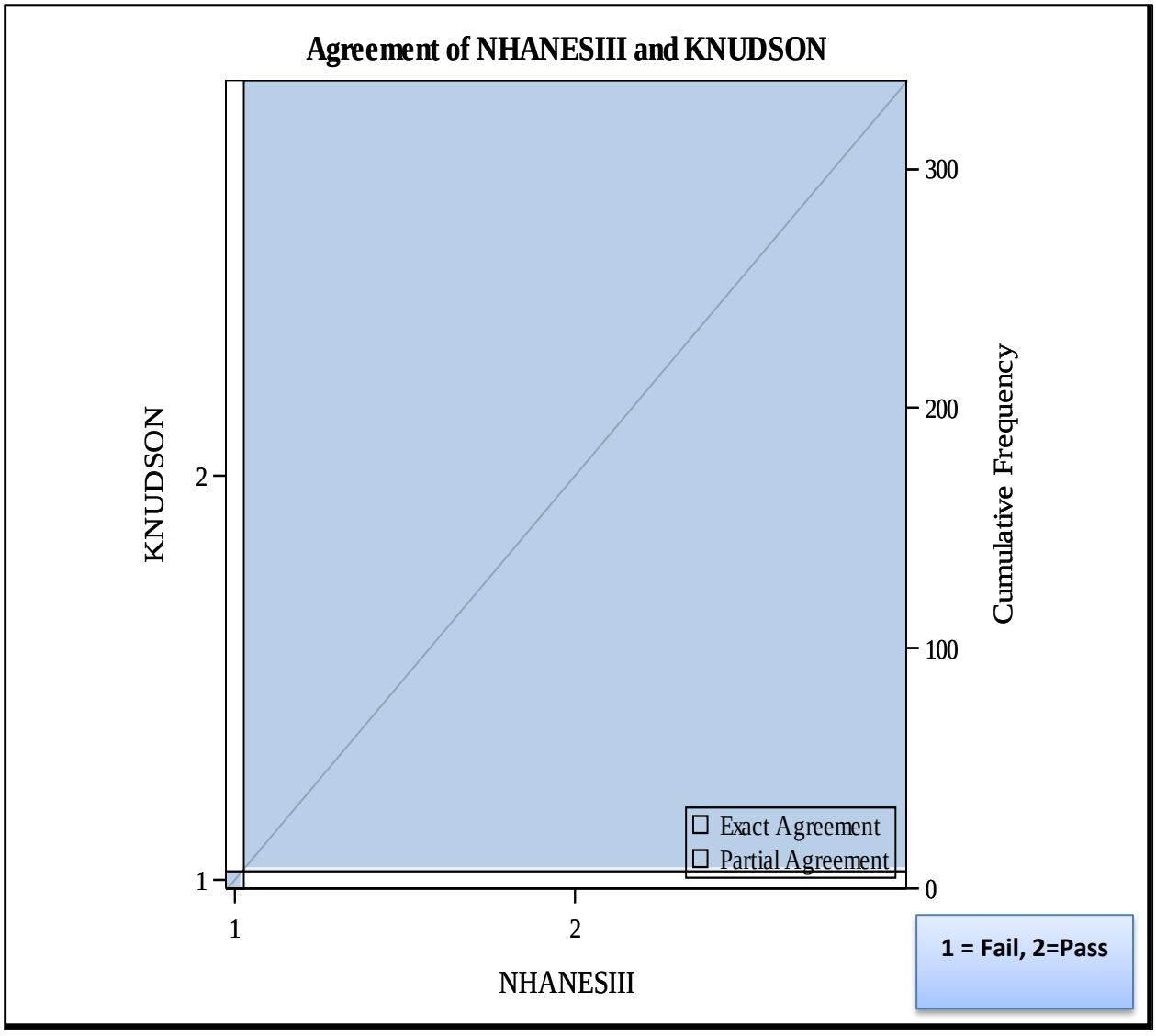

Figure 15 Agreement between the NHANES III and the Crapo for the NFPA Criteria (FVC ≥ 70)

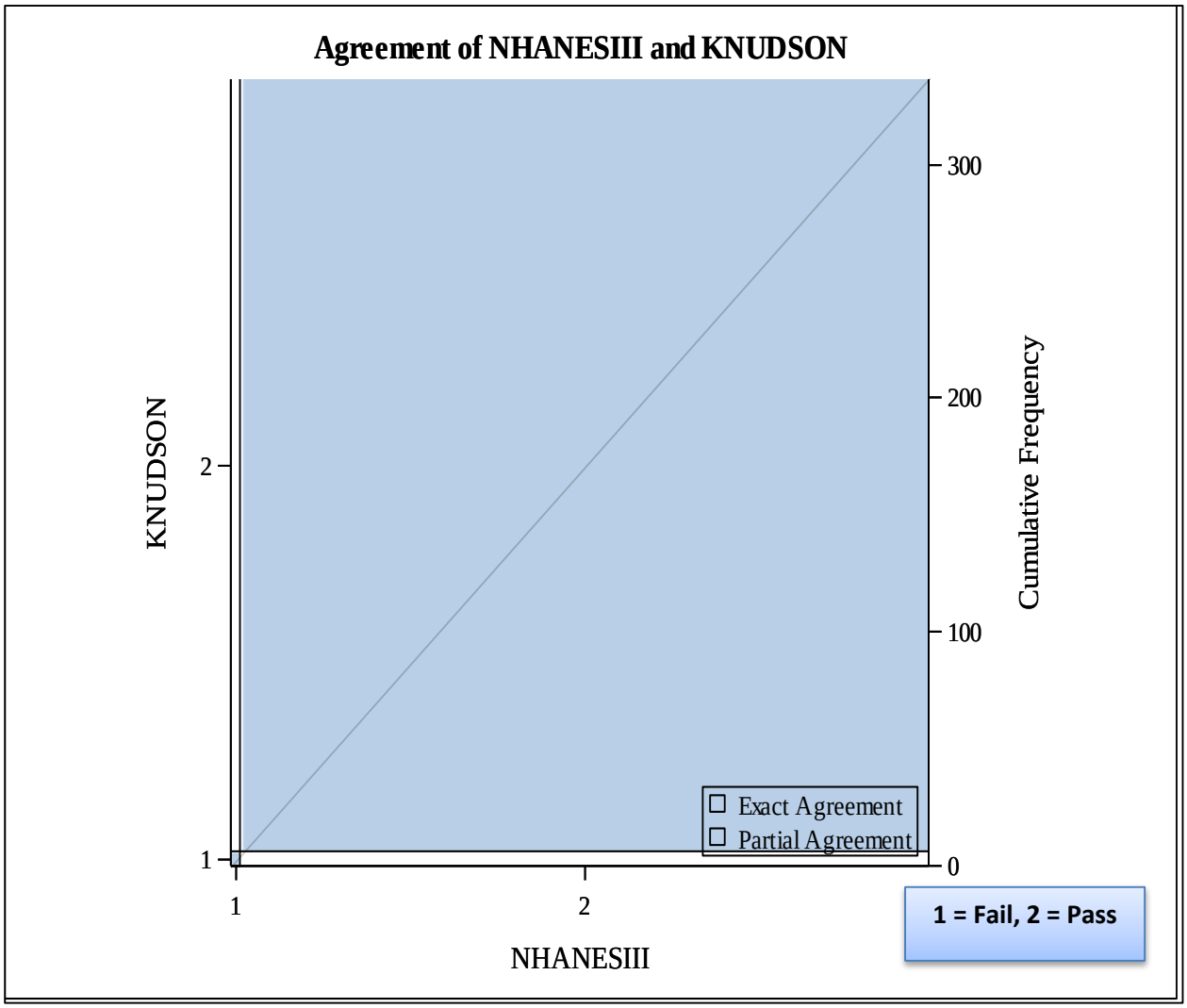

Figure 16 Agreement Chart of the NHANES III and the Crapo Reference Standards for the ATS Criteria (FEV1 ≥ 60)

Table 21 Agreement between the NHANES III and the Knudson reference standards for the respirator screening criteria

Compliance Criteria	Kappa Statistics*	Generalized McNemar's Test	p-value
NFPA Criteria (FEV1 <70)	0.96(0.89-1.00)	p>0.3173	p <0.001
NFPA Criteria (FVC <70)	0.87(0.69-1.00)	p>0.1573	p <0.001
ATS Criteria (FEV1 >60)	0.90(0.72-1.00)	p>0.3173	p <0.001

***Numbers in parentheses indicate the 95% Confidence Intervals**

6.2.1 Discussion

The American Thoracic Society/ European Respiratory Society (ATS/ERS) in 2005 recommended the NHANES III reference standards because it was derived from a large and random population, across varied age ranges and included Caucasian, African-Americans, and Mexican-Americans in the population. Also, this study had rigorous quality control and statistically sound variables to derive reference standards for lung functions. Sood et al. 2007 suggested that there is discordance in the interpretations of spirometry results between the NHANES III standards and other reference standards. In their research, Sood et al. 2007 suggested disagreement between NHANES III and various other reference standards because of biological variation, statistical imprecision or different techniques need to measure lung functions among study populations (Sood, Dawson, Henkle, Hopkins-Price and Quails, 2007).

This research compared the use of Knudson reference standards instead of NHANES III reference standards to interpret spirometry results for screening purposes to wear a respirator. We found substantial agreement between the NHANES III and Knudson reference used standards to interpret spirometry screening for respirator protection programs. The path of the rectangles in the **Figures 15-16** are on the 45° diagonal, suggesting the high correlation between the two standards used for passing the spirometry screening criteria. **Figure 17** shows the path pf the rectangle lies above the 45° diagonal, suggesting meaningful bias towards passing the spirometry selection criteria.

6.3 Interclass correlation coefficient

Reliability assessment is used to evaluate the reproducibility of measurement among study subjects, diagnostic tests and laboratory assay. For continuous data, an interclass correlation coefficient (ICC) is the best measure of the reliability of the quantitative measures (Li Lu, 2007). In this study, interpretation of lung function of workers using different spirometry reference standards was utilized. An ICC was calculated for these different reference standards for the assessment of lung functions and are shown in **Table 22**.

Table 22 Interclass Correlation Coefficients (ICC) for different reference Standards (NHANES III vs. Knudson vs. Crapo Reference Standards)

Lung Functions	Interclass Correlation Coefficient (ICC)
Forced Expiratory Volume in First Second (FEV1)	0. 27783
Forced Vital Capacity (FVC)	0.87452
FEV1 / FVC Ratio	0.80436

6.3.1 Discussion

Interclass correlation coefficients, as discussed above, are the relative measurement of the reliability of the research data. It is a ratio of variance derived from ANOVA (Chinn and Burney, 1987; Weir, 2005). It is unitless and theoretically it is more similar to a R^2 from regression models as compared to a Pearson coefficient (r) (Rousson *et al.*, 2002). The ICC can theoretically range from 0 to 1, where 0 shows no reliability, whereas 1.0 suggests perfect reliability (Weir, 2005). The ICC can extend beyond the ranges of 0 to 1.0, but it is uncommon (LAHEY, 1983).

This study found the ICC for interpretation of the FEV1 between the three reference standards is 0.27; it suggested that there may not be significant repeatability for the analysis of the FEV1 lung function. While ICC for FVC was 0.87, it suggested that good reproducibility between these standards. Also for the FEV1/FVC ratio the ICC is 0.80, it suggested that there is good reproducibility between these standards for the interpretation of lung function. It clearly suggested that assessment of the lung functions using different reference standards can affect the outcome of the occupational lung disease diagnosis.

Chapter 7. Longitudinal Lung Function Changes

7.1 Workers' Characteristics

Workers' who had two spirometry tests conducted at least six months apart from different occupations were included in this research study. Occupational Health Surveillance of the 175 workers for longitudinal lung function changes found 77 (44%) from the boat manufacturing industry, 52 (29.7%) first Responders, and 46 (26.3%) of utility workers had longitudinal decrease in lung function. Cigarette smoking history for these workers shows that 74 (42.2%) had smoking history and 101 (57.8%) did not have a smoking history. Of these 175 workers were mostly Caucasian 152 (86.8%), while 8 (4.57%) African-American, and 15 (8.57%) were Hispanic workers. **Table 23** outlines the demographics of these workers who were evaluated for longitudinal lung function changes.

Through occupational health surveillance of these workers we have collected their base age, current age, current Forced Vital Capacity (FVC), Previous Highest FVC, Forced Expiratory Volume in First Second (FEV1), Previous Highest FEV1, Current FEV1/FVC and Previous Highest FEV1/FVC. On the basis of current and previous highest lung functions, we have calculated the percentage change in FVC, FEV, and FEV1/FVC. **Table 24** shows the height of workers, age, base age, current and previous highest lung functions, percentage change lung functions and duration of time between the two lung function tests. The average length between

two spirometry tests conducted on workers is 1.5 years, the average height of these workers is 69.26 inches, and current median age is about 41 years old.

Table 23 Workers' Demographics for Longitudinal Lung Function Analysis

Total Number of Workers	175 (100%)
Occupation	
Boat Manufacturing	77(44%)
First Responders	52(29.7%)
Utility Workers	46(26.3%)
Smoking History	
Yes	74(42.2%)
No	101(57.8%)
Gender	
Male	151 (86.3%)
Female	24(13.7%)
Race	
Caucasian	152 (86.8%)
African-American	8(4.57%)
Hispanic	15(8.57%)

Table 24 Workers' Lung Function Characteristics for Longitudinal Changes

	Mean	St. Dev	Minimum	Maximum
Height (in)	69.26857	3.502361	60	79
Age	41.97143	9.522163	20	65
Base Age	40.38857	9.475794	19	64
Current FVC	4.9844	1.25741	1.89	9.05
Previous Highest FVC	4.6268	0.946546	2.21	7.18
Current FEV1	3.962	1.047408	1.33	7.4
Previous Highest FEV1	3.685771	0.787281	1.61	5.38
Percentage Change FEV1	12.92547	13.17831	0	55.82822
Percentage Change FVC	13.04979	12.61847	0	57.277
Current FEV1/FVC	1.240914	5.912163	0.55	79
Previous FEV1/FVC	0.797257	0.068367	0.47	0.99
Percentage Change FEV1/FVC	64.77838	810.2412	0	10721.92
Duration	1.582857	1.012986	1	6

The average current Forced Vital Capacity (FVC) is 4.98 L, and the average Previous Highest FVC is 4.62 L while the average Current Forced Expiratory Volume in First Second (FEV1) is 3.96 L and the average Previous Highest FEV1 is 3.68 L.

7.2 Longitudinal Lung Function Analysis

Multivariate Regression Analysis was conducted by constructing linear regression models including multiple response variables such as smoking history, occupation types, race, gender, height and duration between two spirometry tests modeled jointly to evaluate the outcome of Percentage Changes in Lung Function (FEV1 or FVC). This study also used a univariate regression analysis to assess the effect of independent variables on the outcome of percentage changes in Lung Function (FEV1 or FVC). The parameter estimates identify the magnitude of the effect each independent variable has on either increasing or decreasing effects on percentage changes in lung functions. Statistically significant predicting variables were defined as having a p-Value < 0.05.

7.2.1 Percentage Changes in FEV1

The results of the linear regression analysis for FEV1 are shown in **Table 25** and **26**. (Bolded values are statistically significant).

Table 25 Prediction of Percentage Changes in FEV1 from Univariate Regression Analysis

Univariate Correlation			Comparison	Estimate	Standard Error	t value	P value
	R Square	P Value					
Smoking	**0.181918**	**<.0001**	Smoking Vs Non Smoking	**11.34526**	**1.8291622**	**6.2**	**<.0001**
Occupation	**0.170906**	**<.0001**	First Responders Vs Boat Manufacturing	**12.96923**	**2.24905664**	**5.77**	**<.0001**
			Utility Workers Vs Boat Manufacturing	**5.156187**	**2.44289368**	**2.11**	**0.0362**
Race	0.020195	0.173	African-American Vs Caucasian	-3.7653438	4.75919066	-0.79	0.4299
			Hispanic Vs Caucasian	2.4761533	5.74398365	0.43	0.6669
Gender	0.000644	0.7388	Male Vs Female	0.9695622	2.90332931	0.33	0.7388
Height	0	0.9993	Height	0.0002595	0.28607	0	0.9993
Duration	0.0192	0.0677	Duration	-1.80096	0.97956	-1.84	0.0677

Table 26 Prediction of Percentage Changes in FEV1 from Multivariate Regression Analysis

Multivariate Correlation			Comparison	Estimate	Standard Error	t value	P value
	R Square	p value					
	0.325156	**<.0001**					
Smoking			Smoking Vs Non Smoking	**9.746172**	**1.76633515**	**5.52**	**<.0001**
Occupation			First Responders Vs Boat Manufacturing	**10.32479**	**2.15631533**	**4.79**	**<.0001**
			Utility Workers Vs Boat Manufacturing	2.9500062	2.4428848	1.21	0.2289
Race			African-American Vs Caucasian	-4.7365173	4.10176961	-1.15	0.2499
			Hispanic Vs Caucasian	-1.3639382	5.07876956	-0.27	0.7886
Gender			Male Vs Female	2.3799268	3.37895421	0.7	0.4822
Duration				NS			
Height				NS			

(*NS=Not Significant)

The results in **Table 25** suggest that smoking with the parameter estimate of 11.34 independently can affect the percentage change in FEV1 over a period of about 1.5 years. The individual occupation also has an effect on the percentage change in FEV1 over the period of time. First Responders with a parameter estimates of 12.96 and utility workers with a parameter estimates of 5.15 when compared to boat manufacturing workers shows changes in the percentage of FEV1 over a period of about 1.5 years. The analysis did not find that race, gender, height and duration between two spirometry tests was about 1.5 years a statistically significant factor that affected the outcomes of percentage changes in FEV1 over a period. In this study, these factors were jointly and compared a multivariate analysis to evaluate combined effects on the percentage changes in FEV1 over a period. We found that smoking with a parameter estimates of 9.74 affected the percentage changes in FEV1. Also, first responders with a parameter estimate of 10.32 suggested changes in FEV1 when compared to Boat manufacturing workers. However, the results of multilevel modeling suggest that this is the result of outliers in the first responder group rather than an effect of the group.

These results suggested that smoking is a statistically significant factor that can affect the percentage changes in FEV1 over time. Also, occupations can affect the percentage changes in FEV1. The results suggested that first Responders and utility workers were more likely to show changes in percentage lung function over time. The American Thoracic Society in their new guidelines recommended that FEV1 that exceed more than 15 % change over one year period is considered biologically significant change in lung function requiring further evaluations of these workers (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005). The results did not find more than a 15 % change in smoking and different

occupational factors, but these factors suggested that statistically significant and affected modest lung function changes over a period of almost 1.5 years.

7.2.2 Percentage Changes in FVC

The results of the linear regression analysis for FEV1 are shown in **Table 27** and **28**. (Bolded values are statistically significant). **Table 27** shows the factors affecting the percentage changes in FVC over a time. The independent factors influencing the percentage changes in FVC were assessed as they were evaluated for the Percentage Changes in FEV1. The results were that smoking significantly affected the percentage changes in FVC over a time. Smoking affected a parameter estimate of 11.19 for the percentage changes in FVC. Also, results suggested that type of occupation can affect the FVC changes over a time. First responders show percentage changes in FVC with a parameter estimate of 10.85 and Utility workers display the percentage changes in FVC with a parameter estimate of 5.65 as compared to boat manufacturing workers. However, the results of multilevel modeling suggest that this is the result of outliers in the first responder group rather than an effect of the group.

Table 27 Prediction of Percentage Changes in FVC from Univariate Regression Analysis

Univariate Correlation			Comparison	Estimate	Standard Error	t value	P value
	R Square	P Value					
Smoking	**0.193305**	**<.0001**	Smoking Vs Non Smoking	**11.19812**	**1.73922302**	**6.44**	**<.0001**
Occupation	**0.124308**	**<.0001**	First Responders Vs Boat Manufacturing	**10.85969**	**2.21320165**	**4.91**	**<.0001**
			Utility Workers Vs Boat Manufacturing	**5.653526**	**2.40394849**	**2.35**	**0.0198**
Race	0.012662	0.3343	African-American Vs Caucasian	-1.3034124	4.57449487	-0.28	0.776
			Hispanic Vs Caucasian	3.7253801	5.52106977	0.67	0.5007
Gender	0.000252	0.8349	Male Vs Female	-0.5803357	2.78053519	-0.21	0.8349
Height	0.0005	0.7728	Height	-0.07919	0.27385	-0.29	0.7728
Duration	**0.035**	**0.0132**	Duration	**-2.32991**	**0.93035**	**-2.5**	**0.0132**

Table 28 Prediction of Percentage Changes in FVC from Multivariate Regression Analysis

Multivariate Correlation			Comparison	Estimate	Standard Error	t value	P value
	R Square	p value					
	0.295219	<.0001					
Smoking			Smoking Vs Non Smoking	**9.752497**	**1.7284053**	**5.64**	**<.0001**
Occupation			First Responders Vs Boat Manufacturing	**8.098644**	**2.11001114**	**3.84**	**0.0002**
			Utility Workers Vs Boat Manufacturing	3.0528878	2.39042689	1.28	0.2033
Race			African-American Vs Caucasian	-2.8003076	4.01368921	-0.7	0.4863
			Hispanic Vs Caucasian	-0.7606787	4.96970931	-0.15	0.8785
Gender			Male Vs Female	1.1146585	3.30639538	0.34	0.7365
Height				NS			
Duration				NS			

(*NS= Not Significant)

In this study multivariate analysis was conducted to evaluate the combined effects of factors such as smoking history, height, type of occupation, race, gender and durations on the percentage changes in FVC over a period of time. The results of the multivariate analysis suggested that smoking is a significant factor affecting the percentage changes in FVC over a time. Multivariate analysis also indicated that occupation sectors have a significant effect on the percentage changes in FVC. First responders were compared to boat manufacturing workers with a parameter estimate of 8.09 that shows changes in FVC. Other occupation types, race, gender, height and duration between two spirometry results are not statistically significant.

As discussed earlier the results are statistically significant but not more than 15 % change as recommended by the American Thoracic Society. The results of this study suggest that smoking and different occupational sectors modestly affect lung function changes over a period of about 1.5 years.

7.2.3 Discussion

In this study percentage changes in lung function, FEV1 and FVC were calculated over a period of about 2 years. A Linear regression analysis was conducted to evaluate the effect of confounding factors on the lung function changes. Analysis of percentage changes of FEV1 and FVC suggested that smoking and occupation type significantly affect the lung function changes over a period of about 2 years among workers. It suggested that increase in pack-years of smoking can increase in the percentage changes which suggested decrease in FEV1 and FVC over a period of about 2 years. Also, emergency responders and utility workers as compared to

boat manufacturing workers show increases in percentage changes in FEV1 and FVC over a period of time. The American Thoracic Society recommended certain percentage changes in FEV1 and FVC occur because of aging and physiological changes but if the change > 15 % over a period of time (year to year changes). This suggest that workers are affected by occupational lung disease (Pellegrino, Viegi, Brusasco, Crapo, Burgos, Casaburi, Coates, van der Grinten, Gustafsson, Hankinson, Jensen, Johnson, MacIntyre, McKay, Miller, Navajas, Pedersen and Wanger, 2005).

In this study, smoking is a significant factor affecting the percentage changes in FEV1 and FVC. Xu et al. 1992 suggested that longitudinal lung function declines in FEV1 may occur over a period of time because of cigarette smoking during adult life (Xu *et al.*, 1992). It suggests that workers that have a smoking history can affect their lung function changes over a period of time. In this study results indicated that apart from smoking history, occupation type was also a significant contributor to changes in lung function. Emergency responders and utility workers have shown significant changes in percentage changes in FEV1 and FVC over a period of almost 2 years when compared to boat manufacturing workers. These results suggested that occupational exposure among emergency responders and utility workers is contributing factor to changes in lung function. Although results are not > 15 % as recognized by the American Thoracic Society, to rule out occupational lung disorders. These findings indicated that moderate lung function changes were found among these workers because of smoking and occupational risk factors. Outcomes of this study suggested that though workers using respirators to prevent occupational exposure had modest changes in lung function other confounding factors contributing to their lung function changes over a period of 2 years.

7.3 Repeated Lung Function Analysis

In this study, multilevel models were created to evaluate the longitudinal repeated lung function analysis of the workers over a period of about 2 years. **Tables 29** and **30** present the results of the lung function changes that help understand interindividual, intraindividual or both effects on lung function changes among workers. In this study effect of different factors such as age, smoking history, occupational sectors, gender, height and race were evaluated longitudinally to characterize lung function changes.

Results suggested that aging is a significant factor in declining FEV1 and FVC. However, aging is a well-recognized confounding factor in longitudinal declining pulmonary function. Aging contributes to a decline of -0.042 L and -0.045 L in FEV1 and FVC over time. In this study, smoking was associated with a decline in FEV1 and FVC of -0.30 L and -0.56 L respectively. A lack of statistical significance for smoking effect might be a results workers comprising a smaller sample size in this study

Table 29 Repeated Lung Function Changes (FEV1)

		FEV1 (L)			
Variables		**Estimate**	**95%CI**	**Standard Error**	**p Value**
Age		**-0.04228**	**(-0.06553,-0.01893)**	**0.0118**	**0.0005**
Smoking History	Yes	-0.3022	(-1.1432,0.5387)	0.426	0.479
	No	0	-	-	-
Occupations	Boat Manufacturing Workers	-0.4005	(-1.5405,0.7396)	0.5775	0.489
	First Responders	-0.2723	(-1.5771,1.0325)	0.661	0.6809
	Utility Workers	0	-	-	-
Gender	Male	0.6662	(0.3135,1.0189)	0.1787	0.0003
	Female	0	-	-	-
Race	Caucassian	0.2589	(-0.07496,0.5927)	0.1691	0.1277
	African-American	-0.2314	(-0.7687,0.3059)	0.2722	0.3965
	Hispanic	0	-	-	-
Height		**0.09603**	**(0.06194,0.1301)**	**0.01727**	**<0.0001**

Table 30 Repeated Lung Function Changes (FVC)

		FVC (L)			
Variables		**Estimate**	**95%CI**	**Standard Error**	**p Value**
Age		**-0.04524**	**(-0.07271,-0.01776)**	**0.01392**	**0.0014**
Smoking History	Yes	-0.5614	(-1.5528,0.4300)	0.5022	0.2653
	No	0	-	-	-
Occupations	Boat Manufacturing Workers	-0.1396	(-1.4840,1.2049)	0.6811	0.8379
	First Responders	-0.3227	(-1.8612,1.2158)	0.7794	0.6794
	Utility Workers	0	-	-	-
Gender	Male	0.7126	(0.2974,1.1279)	0.2104	0.0009
	Female	0	-	-	-
Race	Caucassian	0.3488	(-0.04424,0.7418)	0.1991	0.0816
	African-American	-0.4673	(-1.099,0.1653)	0.3205	0.1467
	Hispanic	0	-	-	-
Height		**0.1295**	**(0.08937,0.1697)**	**0.02034**	**<0.0001**

Study results show that workers from certain occupations show declining lung functions with age. Boat manufacturing workers shows a decline of -0.40 L in FEV1 and -0.13L in FVC with age. Also, First responders display a decline of -0.27 L in FEV1 and -0.32L in FVC over time. Utility workers show no changes in lung function over time. These results suggested that boat manufacturing workers and first responders who use a respirator regularly at the workplace have a longitudinal decline in the lung function. Though these findings show a decline in pulmonary functions in boat manufacturing workers and first responders, they are not statistically significant. A lack of statistical significant among these workers may result from sample sizes for these workers for analysis.

This study shows a positive correlation with height and pulmonary function changes. Change in the height of workers in this study were associated with changes of 0.09 L in FEV1 and 0.12 L in FVC over a period of about 2 years. The study suggested that increased height is correlated related with increased surface area of the lungs. It might the rise in lung functions in these workers (Bhatti *et al.,* 2014).

Chapter 8. Conclusion

The objectives of this study were to;

1.) Characterize the use of spirometry as a screening tool for medical certification of workers who use a respirator in different occupation sectors;

2.) Evaluate the effects of individual characteristics on the passing of the spirometry screening criteria;

3.) Analyze the differences between spirometric equations for assessing outcome of spirometry screening criteria;

4.) Calculate longitudinal lung function changes of workers for various occupational health surveillance and compliance purposes.

Medical certification to wear a respirator is a significant activity conducted by health professionals. It as an integral part of OSHA required respiratory protection programs. This medical certification is also a challenge for healthcare professionals. Respirator medical evaluations should be conducted in the context of workplace exposure evaluations and occupational medical surveillance programs. Periodic chest radiography and spirometry have been used for occupational medical surveillance purposes based on occupational work exposures (Cohen and Birkner, 2012). Although, OSHA does not require medical screening for a respirator

protection program. In this study, spirometry was used as a screening tool to select the workers who have been cleared by the OSHA recommended questionnaire. Prior to this study, the limited information was available to Florida workers who wear respirators, their medical certification, and health surveillance. This study indicates a small percentage of workers failed to pass the spirometric criteria recommended by the American Thoracic Society (ATS) and National Fire Protection Association (NFPA). In this study, about 5 % of workers have already been cleared by the OSHA questionnaire, but failed to pass the spirometry screening criteria. Other factors such as worker's age, respirator types, occupational exposure and heavy workload at the workplace should be considered. Other screening tools such as spirometry should be used for medical certification purposes (Belafsky, Vlach and McCurdy, 2013). One of the main objectives of this study was to identify the role of using screening tool such as a spirometry for medical certification purposes. This results suggest that spirometry is a useful tool to determine the workers who are not eligible to wear a respirator on the basis of their lung function capacity.

Using different spirometric equations to interpret results can affect the outcome of passing the screening lung function criteria. Previous studies have established the significant discordance between different spirometric reference equations for interpreting respiratory illness (Collen J., 2008; Sood, Dawson, Henkle, Hopkins-Price and Quails, 2007). This study also affirmed these results and suggested that the outcome of the passing of the spirometry screening test is affected by using the different spirometry reference equations. This study also analyzed the effects of various factors such as workers' age, race, occupation type, smoking behavior, and height on passing the spirometric screening criteria. This study suggested that these factors play a significant role in the outcome of the passing the criteria. These factors are statistically significant and, also clinically relevant. Currently, there is no recordkeeping mechanism in place

to evaluate the direct correlation of respirator use and cardiopulmonary illness or related death. Recommendations from regulatory and academic agencies for respiratory screening are based on worker's age, health conditions, workplace exposures and their use of physically demanding respirators. It leads to a gap in recommended respiratory screening for young workers with healthy conditions and using light respirators at the workplace. Migrant and seasonal workers, volunteer firefighters who do not have access to health care and increasing health care cost, make access difficult for workers to use preventive screening such as spirometry. The Affordable Care Act allows certain preventive health services at no cost. Certain provisions should make spirometry available for workers who could not previously afford the preventive screening such as spirometry and this preventive screening may help early identification of occupational respiratory illness among workers. Also, changes in lifestyle and increased prevalence of chronic diseases in the US populations may affect respirator medical clearance (Belafsky, Vlach and McCurdy, 2013). This study suggested that the use of spirometry as a screening tool is necessary to identify the workers who have already been passed on the basis of the OSHA questionnaire.

Occupational health surveillance has been conducted over the years for the tracking of occupational injuries, illnesses, hazards and exposures at the workplace. This information helps to improve worker's health and safety through developing new preventive measures. Occupational health surveillance is a preventive activity to screen and monitor workers' health for hazardous exposures and specific task requirements. Although not recommended by OSHA, Longitudinal Spirometry evaluations can be useful as a part of a respirator medical surveillance program (Cohen and Birkner, 2012). Longitudinal lung function analysis is recommended for workers, as it can establish baseline lung function before starting the job that requires the use of a respirator and also, it helps in early detection of possible lung disorders. The objective of the

longitudinal spirometry evaluation is to identify the pulmonary function that may be declining faster than expected over time (Townsend, 2011). Longitudinal spirometry evaluation is necessary for many healthy workers whose baseline pulmonary function is above average (>100%). These workers start their job with above average lung function and show significant declining in their lung function over time without affecting their lower limit of normal (LLN) and it is considered their lung function changes are “abnormal” (Townsend, 2011).

The American Thoracic Society recommends evaluation of percentage changes in lung function over a period of time. In this study analysis of percentage changes in FEV1 and FVC suggested that smoking behavior and occupational type of worker significantly affected the percentage changes in lung function. Though lung function percentage changes did not exceeding 15 % recommended guideline, this study shows modest changes in lung function percentage changes. The lung function changes are biologically and statistically significant and clinically relevant to worker’s health. ACOEM suggested that confirmed decline of FEV1 of 10 % to 15% as compared to baseline lung function, require further medical evaluation (Townsend, 2011).

These results suggested that though workers are using a respirator in the workplace to prevent occupational exposures. They are showing a decline in their lung function over time. Smoking is a significant confounding factor in declining lung function but other information is needed to verify that factors such as proper training and usage of respirators by employees at the workplace are effective. These results suggest that compliance and physiological effects of using a respirator are also an important factor in preventing changes in their lung function. The findings of this study may have been affected by time constraint. In particular, the analysis on the spirometry results was limited to data collected no longer than four years.

Repeated lung function evaluations included in this study helps to characterize crude changes in lung function over time. Boat manufacturing workers and firefighters show decline in their lung function over time. Though these numbers are not statistically significant because of a small sample size, these results demonstrate clinically relevant lung function changes among workers from these occupational sectors. Aging is a significant confounding factor affecting the decline of the lung function among workers. Smoking is also an important confounding factor influencing the loss of lung function over time though it is not statistically significant because of a small sample size.

This study has some limitations. This study did not have access to medical data of the workers to establish pulmonary diseases among those workers who have lost significant lung functions. Secondly, the sample size is the small, particularly in occupational subgroups that may results in non-significant results in the study. Another limitation of this study is we could not evaluate and correlate the OSHA questionnaire data with the spirometry criteria to pass the respirator use medical certification. The findings of this study may have been affected by the decision to analyze the spirometry results of the workers with limited years of follow-up.

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Appendix I

Sample Written Respiratory Protection Program

SAMPLE RESPIRATORY PROTECTION PROGRAM AS PER 29CFR1910.134 RESPIRATORY PROTECTION STANDARD

The sample respiratory protection program is intended to serve employers as an example written respiratory protection program which is required by the Respiratory Protection Standard. A central component of the requirements of the standard is the development of a written program.

The intent of this sample program is to provide small employers with an easy-to-use format for developing a written respiratory protection program. Each employer will need to adjust or adapt the sample program for their specific use.

The information contained in this publication is not considered a substitute for the OSHA Act or any provisions of the OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standards in its entirety for specific compliance requirements

RESPIRATORY PROTECTION PROGRAM

PURPOSE

The purpose of this respirator program is to establish standard operating procedures to ensure the protection of all employees from respiratory hazards through proper selection and use of respirators. This program applies to all employees who are required to wear respirators during normal operations, non-routine tasks, or emergency operations such as a spill of a hazardous substance.

RESPONSIBILITIES

Program Administrator Duties

This facility has designated _____ as the program administrator to oversee the respiratory protection program. Duties of the program administrator include:

- Identifying work areas, processes or tasks that require workers to wear respirators, and evaluating hazards
- Selection of respiratory protection options
- Monitoring respirator use to ensure that respirators are used in accordance with their certifications
- Arranging for and/or conducting training
- Ensuring proper storage and maintenance of respiratory protection equipment

- Conducting or arranging for fit testing
- Administering the medical surveillance program
- Maintaining records required by the program
- Evaluating the program
- Updating written program as needed

Supervisors Duties

Supervisors are responsible for ensuring that the respiratory protection program is implemented in their particular areas. In addition to being knowledgeable about the program requirements for their own protection, supervisors must also ensure that the program is understood and followed by the employees under their charge. Duties of the supervisor include:

- Ensuring that employees under their supervision (including new hires) have received appropriate training, fit testing, and medical evaluation
- Ensuring the availability of appropriate respirators and accessories
- Being aware of tasks requiring the use of respiratory protection
- Enforcing the proper use of respiratory protection when necessary
- Ensuring that respirators are properly cleaned, maintained, and stored according to the respiratory protection plan
- Ensuring that respirators fit well and do not cause discomfort
- Continually monitoring work areas and operations to identify respiratory hazards
- Coordinating with the program administrator on how to address respiratory hazards or other concerns regarding the program

Employees Duties

Each employee has the responsibility to wear his or her respirator when and where required and in the manner in which they were trained. Employees must also:

- Care for and maintain their respirators as instructed and store them in a clean sanitary location
- Inform their supervisor if the respirator no longer fits well, and request a new one that fits properly

- Inform their supervisor or the Program administrator of any respiratory hazards that they feel may not be adequately addressed in the workplace and of any other concerns that they have regarding the program

PROGRAM ELEMENTS

Respirator Selection

Respirators are selected on the basis of the hazards to which the employees are exposed and in accordance with OSHA requirements. Only NIOSH certified respirators will be selected and used.

The Program Administrator will conduct a hazard evaluation for each operation process, or work area where airborne contaminants may be present in routine operations or during an emergency. ***The hazard evaluation will include***:

- Identification of the hazardous substances used in the workplace, department or work process;
- Review of work processes to determine where potential exposures to these hazardous substances may occur; and
- Exposure monitoring to quantify potential hazardous exposures.

The results of the hazard evaluation are located _____ ***(Insert location/department)*** for employee review.

The program administrator will revise and update the hazard assessment as needed (i.e., any time work process changes which may potentially affect exposure).

General requirements

- The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability.

- The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.

- The employer shall identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Where the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be IDLH.

- The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

Respirators for Immediately Dangerous to Life and Health (IDLH) atmospheres

- The employer shall provide the following respirators for employee use in IDLH atmospheres:
    - A full facepiece pressure demand SCBA certified by NIOSH for a minimum service life of thirty minutes, or
    - A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.
- Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.
- All oxygen-deficient atmospheres shall be considered IDLH. Exception: If the employer demonstrates that, under all foreseeable conditions, the oxygen concentration can be maintained within the ranges specified in Table II of this section [29 CFR 1910.134(d), i.e., for the altitudes set out in the table], then any atmosphere-supplying respirator may be used.

Respirators for atmospheres that are not IDLH

- The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.

NIOSH Certification

All respirators must be certified by the National Institute for Occupational Safety and Health (NIOSH) and shall be used in accordance with the terms of that certification. Also, all filters, cartridges, and canisters must be labeled with the appropriate NIOSH approval label. The label must not be removed or defaced while it is in use.

Voluntary Respirator Usage

This company will provide (or allow employee-owned) respirators to employees for voluntary usage for the following work processes:

- _____
- _____
- _____

The Program Administrator will provide all employees who voluntarily choose to wear either of the above respirators with a copy of Appendix D of the standard. (Appendix D details the requirements for voluntary use of respirators by employees.) Employees choosing to wear a half facepiece air purifying respirators (APR) must comply with the procedures for medical evaluation, respirator use, and cleaning, maintenance and storage.

The Program Administrator shall authorize voluntary use of respiratory protective equipment as requested by all other workers on a case-by-case basis, depending on specific workplace conditions and the results of the medical evaluations.

Respirator Filter & Canister Replacement/Change Schedule

An important part of the Respiratory Protection Program includes identifying the useful life of canisters and filters used on air purifying respirators. Each filter and canister shall be equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or

If there is no ESLI appropriate for conditions a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before the end of their service life.

Cartridges/Filters shall be changed based on the most limiting factor below:

- Prior to expiration date
- Manufacturer's recommendations for use and environment
- After each use
- When requested by employee
- When restriction to air flow has occurred as evidenced by increased effort by user to breathe normally

Medical Evaluation

Employees who are required to wear respirators must be medically evaluated before being permitted to wear a respirator on the job. Employees are not permitted to wear respirators until a physician has determined that they are medically able to do so.

A licensed health care professional at _____ ***(Name of healthcare provider)*** will provide the medical evaluation to employees. Medical evaluation procedures are as follows:

- The medical evaluation will be conducted using medical questionnaire provided in Appendix C of 29 CFR 1910.134 Respiratory Protection Standard. _____ ***(Name of responsible person or department)*** will provide a copy of this questionnaire to all employees requiring medical evaluation.

- To the extent feasible, the company will assist employees who are unable to read the questionnaire. When this is not possible the employee will be sent directly to the health care professional for assistance and medical evaluation.

- All affected employees will be given a copy of the medical questionnaire to fill out, along with a stamped and addressed envelop for mailing the questionnaire to the health care professional. Employees will be permitted to fill out the questionnaire on company time.

- Follow up medical exams will be provided to employees as required by the OSHA standard, and/or as deemed necessary by the health care professional.

- All employees will be allowed the opportunity to speak with the health care professional about their medical evaluation if they so request.

- The program administrator will provide the health care professional with a copy of this program and a copy of OSHA's respiratory protection standard. For each employee requiring evaluation, the health care professional will be provided with information regarding the employee's work area or job title, proposed respirator type and weight, length of time required to wear the respirator, expected physical work load (light, moderate, or heavy), potential temperature and humidity extremes, and any additional protective clothing required.

- After an employee has received clearance to wear a respirator, additional medical evaluations will be provided under any of the following circumstances:

    - The employee reports signs and/or symptoms related to their ability to use a respirator, such as shortness of breath, dizziness, chest pains, or wheezing;
    - The health care professional or supervisor informs the Program Administrator that the employees needs to be reevaluated;
    - Information from this program, including observations made during fit testing and program evaluation, indicates a need for reevaluation; and
    - A change occurs in workplace conditions that may result in an increased physiological burden on the employee.

NOTE: All examinations and questionnaires are to remain confidential between the employee and the physician.

Fit Testing Procedures

_____ ***(Name of responsible person or department)*** will ensure that fit-test will be administered using an OSHA-accepted qualitative fit test (QLFT) or quantitative fit test (QNFT) protocol. The OSHA-accepted QLFT and QNFT protocols are contained in Appendix A of the Respiratory Standard (1910.134).

_____ **(Company Name)** requires employees to be fit tested at the following times and with the same make, model, style, and size of respirator that they will be using.

- Before being allowed to wear any respirator with a tight-fitting facepiece and at least annually thereafter;
- Whenever a different respirator facepiece (size, style, model, or make) is used;
- Whenever visual observations of changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight; and
- Upon employee notification that the fit of the respirator is unacceptable.

The company has established a record of the fit tests administered to employees including:

- The name or identification of the employee tested;
- Type of fit test performed;
- Specific make, model, style, and size of respirator tested;
- Date of test; and
- The pass/fail results

Use of Respirators

General Use Procedures

Employees will use their respirators under conditions specified by this program, and in accordance with the training they receive on the use of each particular model. In addition, the respirator shall not be used in a manner for which it is not certified by NIOSH or its manufacturer.

All employees shall conduct user seal checks each time that they wear their respirator. Employees shall use either the positive or negative pressure check (depending on which test works best for them) specified in Appendix B-1 of the Respiratory Protection Standard.

All employees shall be permitted to leave the work are to maintain their respirator for the following reasons: to clean their respirator if the respirator is impeding their ability to work, change filters or cartridges, replace parts, or to inspect respirator if it stops functioning as intended. Employees should notify their supervisor before leaving the area.

Employees are not permitted to wear tight fitting respirators if they have any condition, such as facial hair, facial scars, or missing dentures that prevents them from achieving a good seal. Employees are not permitted to wear headphones, jewelry, or other articles that may interfere with the facepiece to face seal.

Emergency Procedures

The following work areas have been identified as having foreseeable emergencies: ***(FILL IN AS REQUIRED)***

- _____
- _____

- _____

Emergency escape respirators are located: _____ ***(Insert Location)***.

Immediately Dangerous to Life or Health (IDLH) Procedures

The Program Administrator has identified the following area(s) as presenting the potential for IDLH conditions: ***(FILL IN AS REQUIRED)***

-
-

Respirator Malfunction

For any malfunction of a respirator (e.g., such a breakthrough, facepiece leakage, or improperly working valve), the respirator wearer should inform his or her supervisor that the respirator no longer functions as intended, and go to a safe area to maintain the respirator. The supervisor must ensure that the employee receives the needed parts to repair the respirator, or is provided with a new respirator.

Maintenance and Care Procedures

In order to ensure continuing protection from the respirators being use, it is necessary to establish and implement proper maintenance and care procedures and schedules. A lax attitude toward maintenance and care will negate successful selection and fit because the devices will not deliver the assumed protection unless they are kept in good working order.

Cleaning & Disinfecting

Our company provides each respirator user with a respirator that is clean, sanitary, and in good working order. We ensure that respirators are cleaned and disinfected _____ ***(Indicate Frequency, e.g., Daily, Weekly, etc.)*** or as often as necessary to be maintained in a sanitary condition. Respirators are cleaned and disinfected using the procedures specified in Appendix

B-2 of the standard or manufacturer's recommendations.

Respirators are cleaned and disinfected:

- As often as necessary when issued for the exclusive use of one employee;
- Before being worn by different individuals;

- After each use for emergency use respirators; and
- After each use for respirators used for fit testing and training.

Storage

Storage of respirators must be done properly to ensure that the equipment is protected and not subject to environmental conditions that may cause deterioration. We ensure that respirators are stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture,, and damaging chemicals. They are packed and stored in _____ ***(Indicate methods use for storage and location)***, in accordance with any applicable manufacturer's instructions.

Emergency respirators are stored:

- To be accessible to the work area;
- In compartments marked as such; and
- In accordance with manufacturer's recommendations.

Respirator Inspection

All respirators will be inspected after each use and at least monthly. Should any defects be noted, the respirators will be taken to the program administrator or supervisor. Damaged respirators will be either repaired or replaced.

Respirators shall be inspected as follows:

- All respirators used in routine situations shall be inspected before each use and during cleaning;
- All respirators maintained for use in emergency situations shall be inspected at least monthly and in accordance with manufacturer's recommendations, and shall be checked for proper function before and after each use; and
- Emergency escape-only respirators shall be inspected before being carried into the workplace for use.

Respirator inspections shall include the following:

- A check of respirator function, tightness of connections, and the condition of the various parts including, but not limited to, the facepiece, head straps, valves, connecting tube, and cartridges, canisters or filters; and
- Check of elastomeric parts for pliability and signs of deterioration**.**

The following checklist will be used when inspecting respirators:

- Facepiece:
  - cracks, tears, or holes
  - facemask distortion

    - cracked or loose lenses/faceshield
- Headstraps:
    - breaks or tears
    - broken buckles
- Valves:
    - residue or dirt
    - cracks or tears in valve material
- Filters/Cartridges:
    - approval designation
    - gaskets
    - cracks or dents in housing
    - proper cartridge for hazard
- Air Supply Systems:
    - breathing air quality/grade
    - condition of supply hoses
    - hose connections
    - settings on regulators and valves

Training

_____ **(Name of responsible person or department)** will be responsible to provide training to respirator training to respirator users or their supervisors on the contents of the Respiratory Protection Program and their responsibilities under it, and on the OSHA Respiratory Protection Standard. Workers will be trained prior to using a respirator in the workplace. Supervisors will also be trained prior to using a respirator in the workplace or prior to supervision of employees that must wear respirators.

The training will cover the following topics:

- The _____ ***(Company Name)*** Respiratory Protection Program
- The OSHA Respiratory Protection Standard
- Respiratory hazards encountered and their health effects
- Proper selection and use of respirators
- Limitations of respirators
- Respirator donning and user seal (fit) checks
- Fit testing
- Emergency use procedures

- Maintenance and storage
- Medical signs and symptoms limiting the effective use of respirators

Employees will be retrained annually or as needed (e.g., if they need to use a different respirator). Employees must demonstrate their understanding of the topics covered in the training utilizing a hands-on exercise and a written test. Respirator training will be documented by the Program Administrator and the documentation will include the type, model, and size of respirator for which each employee has been trained and fit tested.

Program Evaluation

The program administrator will conduct periodic evaluations of the workplace to ensure that the provisions of this program are being implemented. The evaluation will include regular consultations with employees who use respirators and their supervisors, site inspections, air monitoring and review of records.

Identified problems will be noted and addressed by the Program Administrator. These findings will be reported to management, and the report will list plans to correct deficiencies in the respirator program and target dates for the implementations of those corrections.

Documentation and Recordkeeping

A written copy of this program and the OSHA standard is kept in the Program Administrator's office and is available to all employees who wish to review it.

Also maintained in the Program Administrator's office are copies of training and fit test records. These records will be updated as new employees are trained, as existing employees receive refresher training, and as new fit tests are conducted.

The Program Administrator will also maintain copies of the medical records for all employees covered under the respirator program. The completed medical questionnaire and the physician's documented findings are confidential and will remain at ***(Location, e.g., clinic)***. The company will only retain the physician's written recommendation regarding each employee's ability to wear a respirator.

(Company Name)

VOLUNTARY AND REQUIRED RESPIRATOR USE	
RESPIRATOR	**DEPARTMENT/PROCESS**
[Example: Filtering facepiece (dust mask)]	*[Voluntary use for warehouse workers]*
[Example: Half-facepiece APR or PAPR with P100 filter]	*[Prep and Assembly]* *[Voluntary use for maintenance workers when cleaning spray booth walls or changing spray booth filter]*

(Company Name)

HAZARD ASSESSMENT

(Date)

Department	**Contaminants**	**Exposure Level (8 hrs TWA)**	**PEL**	**Controls**
[Example: e.g., Prep: sanding]	*wood dust*	*2.5 - 7.0 mg/m³*	*5 mg/m³ (TLV = 1 mg/m³)*	*Local exhaust ventilation for sanders, Half-*

				facepiece APR with P100 filter.
[Example: e.g., Prep: cleaning]	*methylene chloride* *methanol* *acetone*	*70 ppm* *150 ppm* *400 ppm*	*25 ppm* *125 ppm (STEL)* *200 ppm* *1,000 ppm*	*Local exhaust ventilation (LEV) to be installed for cleaning stations. Continuous flow SAR hood until then needed for respiratory protection. Will reevaluate after LEV installation.*

Appendix II

IRB Approval Letter

UNIVERSITY OF SOUTH FLORIDA

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

August 24, 2010

Giffe Johnson, MPH, PhD
Environmental and Occupational Health
13201 Bruce B. Downs Blvd., MDC 56
Tampa, FL 33612

RE: **Expedited Approval** for Initial Review
IRB#: Pro00001348
Title: Occupational Health Monitoring Database Development

Dear Dr. Johnson:

On 8/24/2010, the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol**.** Please note that your approval for this study will expire on 08/24/2011.

Approved Items:
Protocol Document(s):

Study Protocol.doc	6/9/2010 3:50 PM	0.01

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent

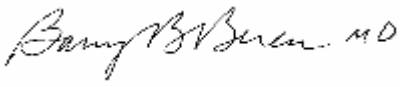
procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45 CFR 164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,



USF Institutional Review Board

Cc: Sarah Croker
USF IRB Professional Staff

Appendix III

Sample Pulmonary Function Report

Pulmonary Function Report

CEORAM
CEORAM

Screener Report

Patient Information

Name: [redacted]
ID: [redacted]
Birthdate: [redacted]
Height at test (in): 76.0
Sex: Male
Smoking history (pk-yrs):
Weight at test (lb): 205.0
Age at test: 36
Predicted set: Hankinson (NHANES III)

Comments:
Diagnosis:

Interpretation

Possible EARLY OBSTRUCTIVE PULMONARY IMPAIRMENT. This is suggested by the reduced FEF 25-75 with a normal FVC and FEV1. This finding can be due to a mild degree of small airway disease and/or the earliest stages of emphysema. This may be reversible in nature; therefore, REPEAT TESTING FOLLOWING BRONCHODILATOR ADMINISTRATION IS RECOMMENDED. This interpretation is valid only upon physician review and signature.

Site:
Physician:
Technician: Alan Allison, RRT

Effort protocol: ATS/ERS 2005

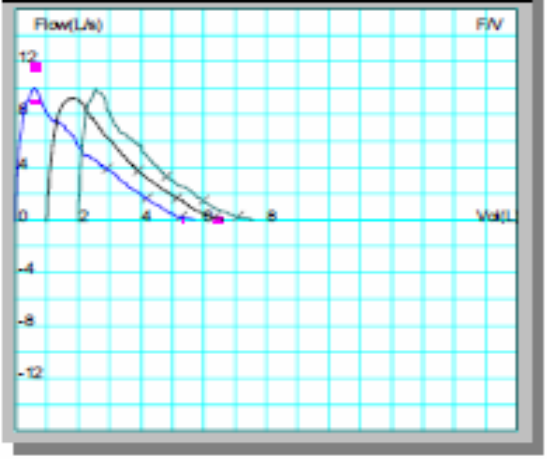
Test date/time: 07/17/13 08:50:40 AM
Number of efforts performed: 3

Results

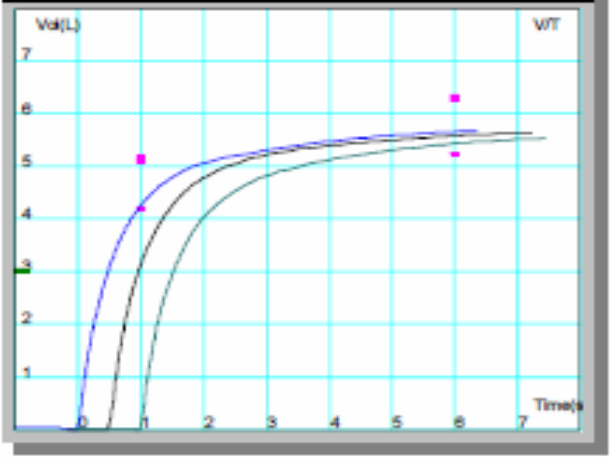
Result	Pred	Best	%Prd		%Prd		%Prd
FVC (L)	6.43	5.67	88%	5.62	87%	5.53	86%
FEV1 (L)	5.12	4.26	83%	4.26	83%	=4.03	79%
FEV1/FVC	0.81	0.75	93%	0.76	94%	0.73	90%
FEF25-75% (L/s)	4.76	3.41	72%	3.45	73%	2.98	63%
PEFR (L/s)	11.65	10.05	86%	9.22	79%	9.71	83%
Vext %	—	1.31	—	1.98	—	1.39	—

Test comments:

FVC Flow vs. Volume



FVC Volume vs. Time



Appendix IV

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1. Table 3 – Use of Spirometry, Table 11- Acceptability and Repeatability Criteria for Spirometry, Figure-9 Steps to perform Spirometry

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Kay

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2. Table 10. Significant Changes in Forced Expiratory Volume in One Second (FEV1) or Forced Vital Capacity (FVC) over time

Series:
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
Interpretative strategies for lung function tests
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3. Table 12- Guidelines for Interpretation of Kappa Statistics

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