

Attachment 1a

Cotton Dust Standard 29 CFR 1910.1043 (h) (1) (iii)

APPENDIX D –PULMONARY FUNCTION STANDARDS FOR COTTON DUST STANDARD

The spirometric measurements of pulmonary function shall conform to the following minimum standards, and these standards are not intended to preclude additional testing or alternate methods which can be determined to be superior.

I. APPARATUS

- a. The instrument shall be accurate to within + or - 50 milliliters or within + or - 3 percent of reading, whichever is greater.
- b. The instrument should be capable of measuring vital capacity from 0 to 7 liters BTPS.
- c. The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H₂O/(liter/sec).
- d. The zero time point for the purpose of timing the FEV(1) shall be determined by extrapolating the steepest portion of the volume time curve back to the maximal inspiration volume (1, 2, 3, 4) or by an equivalent method.
- e. Instruments incorporating measurements of airflow to determine volume shall conform to the same volume accuracy stated in (a) of this section when presented with flow rates from at least 0 to 12 liters per second.
- f. The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.
- g. The instrument used shall provide a tracing or display of either flow versus volume or volume versus time during the entire forced expiration. A tracing or display is necessary to determine whether the patient has performed the test properly. The tracing must be stored and available for recall and must be of sufficient size that hand measurements may be made within requirement of paragraph (a) of this section. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume.
- h. The instrument shall be capable of accumulating volume for a minimum of 10 seconds and shall not stop accumulating volume before (1) the volume change for a 0.5 second interval is less than 25 milliliters, or (2) the flow is less than 50 milliliters per second for a 0.5 second interval.
- i. The forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV(1).(0) measurements shall comply with the accuracy requirements stated in paragraph (a) of this section. That is, they should be accurately measured to within + or - 50 ml or within + or - 3

percent of reading, whichever is greater.

j. The instrument must be capable of being calibrated in the field with respect to the FEV(1) and FVC. This calibration of the FEV(1) and FVC may be either directly or indirectly through volume and time base measurements. The volume calibration source should provide a volume displacement of at least 2 liters and should be accurate to within + or - 30 milliliters.

II. TECHNIQUE FOR MEASUREMENT OF FORCED VITAL CAPACITY MANEUVER

a. Use of a nose clip is recommended but not required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, but care should be taken on repeat testing that the same position be used and, if possible, the same spirometer. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The patient shall be instructed to make a full inspiration from a normal breathing pattern and then blow into the apparatus, without interruption, as hard, fast, and completely as possible. At least three forced expirations shall be carried out. During the maneuvers, the patient shall be observed for compliance with instruction. The expirations shall be checked visually for reproducibility from flow-volume or volume-time tracings or displays.

The following efforts shall be judged unacceptable when the patient:

1. Has not reached full inspiration preceding the forced expiration,
2. Has not used maximal effort during the entire forced expiration,
3. Has not continued the expiration for at least 5 seconds or until an obvious plateau in the volume time curve has occurred,
4. Has coughed or closed his glottis,
5. Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.)
6. Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts), and therefore not allowing back extrapolation of time 0 (extrapolated volume on the volume time tracing must be less than 10 percent of the FVC.)
7. Has an excessive variability between the three acceptable curves. The variation between the two largest FVC's and FEV(1)'s of the three satisfactory tracings should not exceed 10 percent or + or - 100 milliliters, whichever is greater.

b. Periodic and routine recalibration of the instrument or method for recording FVC and

FEV(1).(0) should be performed using a syringe or other volume source of at least 2 liters.

III. INTERPRETATION OF SPIROGRAM

- a. The first step in evaluating a spirogram should be to determine whether or not the patient has performed the test properly or as described in II above. From the three satisfactory tracings, the forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV(1).(0)) shall be measured and recorded. The largest observed FVC and largest observed FEV(1) shall be used in the analysis regardless of the curve(s) on which they occur.
- b. The following guidelines are recommended by NIOSH for the evaluation and management of workers exposed to cotton dust. It is important to note that employees who show reductions in FEV(1)/FVC ratio below .75 or drops in Monday FEV(1) of 5 percent or greater on their initial screening exam, should be re-evaluated within a month of the first exam. Those who show consistent decrease in lung function, as shown on the following table, should be managed as recommended.

IV. QUALIFICATIONS OF PERSONNEL ADMINISTERING THE TEST

Technicians who perform pulmonary function testing should have the basic knowledge required to produce meaningful results. Training consisting of approximately 16 hours of formal instruction should cover the following areas.

- a. Basic physiology of the forced vital capacity maneuver and the determinants of airflow limitation with emphasis on the relation to reproducibility of results.
- b. Instrumentation requirements including calibration procedures, sources of error and their correction.
- c. Performance of the testing including subject coaching, recognition of improperly performed maneuvers and corrective actions.
- d. Data quality with emphasis on reproducibility.
- e. Actual use of the equipment under supervised conditions.
- f. Measurement of tracings and calculations of results