ATTACHMENT A

Legislative Authority

Section 21
Occupational Safety and Health Act
and
Appendix D to 29 CFR 1910.1043
Pulmonary Function Standards for Cotton Dust Standard

Occupational Safety and Health Act

Section 21. Training and Employee Education

- (a) The Secretary of Health and Human Services, after consultation with the Secretary and with other appropriate Federal departments and agencies, shall conduct, directly or by grants or contracts (1) education programs to provide an adequate supply of qualified personnel to carry out the purposes of this Act, and (2) informational programs on the importance of and proper use of adequate safety and health equipment.
- 29 USC 670.
- **(b)** The Secretary is also authorized to conduct, directly or by grants or contracts, short-term training of personnel engaged in work related to his responsibilities under this Act.
- **(c)** The Secretary, in consultation with the Secretary of Health and Human Services, shall (1) provide for the establishment and supervision of programs for the education and training of employers and employees in the recognition, avoidance, and prevention of unsafe or unhealthful working conditions in employments covered by this Act, and (2) consult with and advise employers and employees, and organizations representing employers and employees as to effective means of preventing occupational injuries and illnesses.
- **(d)(1)** The Secretary shall establish and support cooperative agreements with the States under which employers subject to this Act may consult with State personnel with respect to --
 - **(A)** the application of occupational safety and health requirements under this Act or under State plans approved under section 18; and
 - **(B)** voluntary efforts that employers may undertake to establish and maintain safe and healthful employment and places of employment. Such agreements may provide, as a condition of receiving funds under such agreements, for contributions by States towards meeting the costs of such agreements.
- **(2)** Pursuant to such agreements the State shall provide on-site consultation at the employer's worksite to employers who request such assistance. The State may also provide other education and training programs for employers and employees in the State. The State shall ensure that on-site consultations conducted pursuant to such agreements include provision for the participation by employees.
- **(3)** Activities under this subsection shall be conducted independently of any enforcement activity. If an employer fails to take immediate action to eliminate employee exposure to an imminent danger identified in a

consultation or fails to correct a serious hazard so identified within a reasonable time, a report shall be made to the appropriate enforcement authority for such action as is appropriate.

- **(4)** The Secretary shall, by regulation after notice and opportunity for comment, establish rules under which an employer --
 - **(A)** which requests and undergoes an on-site consultative visit provided under this subsection;
 - **(B)** which corrects the hazards that have been identified during the visit within the time frames established by the State and agrees to request a subsequent consultative visit if major changes in working conditions or work processes occur which introduce new hazards in the workplace; and
 - **(C)** which is implementing procedures for regularly identifying and preventing hazards regulated under this Act and maintains appropriate involvement of, and training for, management and non-management employees in achieving safe and healthful working conditions, may be exempt from an inspection (except an inspection requested under section 8(f) or an inspection to determine the cause of a workplace accident which resulted in the death of one or more employees or hospitalization for three or more employees) for a period of 1 year from the closing of the consultative visit.
- **(5)** A State shall provide worksite consultations under paragraph (2) at the request of an employer. Priority in scheduling such consultations shall be assigned to requests from small businesses which are in higher hazard industries or have the most hazardous conditions at issue in the request.

Appendix D to §1910.1043—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 ± 50 milliliters or within ± 3 percent of reading, whichever is greater.
- b. 1. Instruments purchased on or before May 14, 2020 should be capable of measuring vital capacity from 0 to 7 liters BTPS
- 2. Instruments purchased after May 14, 2020 should be capable of measuring vital capacity from 0 to 8 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 H_2 O/(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. 1. Instruments purchased on or before May 14, 2020 that incorporate measurements of airflow to determine volume shall conform to the same volume accuracy stated in paragraph (a) of this section I when presented with flow rates from at least 0 to 12 liters per second.
- 2. Instruments purchased after May 14, 2020 that incorporate measurements of airflow to determine volume shall conform to the same volume accuracy stated in paragraph (a) of this section I when presented with flow rates from at least 0 to 14 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. 1. Instruments purchased on or before May 14, 2020 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 the volume accuracy

requirements of paragraph (a) of this section I. 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.

- 2. Instruments purchased after May 14, 2020 shall provide during testing a paper tracing or real-time display of flow versus volume and volume versus time for the entire forced expiration. Such a tracing or display is necessary to determine whether the worker has performed the test properly. Flow-volume and volume-time curves must be stored and available for recall. Real-time displays shall have a volume scale of at least 5 mm/L, a time scale of at least 10 mm/s, and a flow scale of at least 2.5 mm/L/s, when both flow-volume and volume-time displays are visible. If hand measurements will be made, paper tracings must be of sufficient size to allow those measurements to be made within the volume accuracy requirements of paragraph (a) of this section I. 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. 1. Instruments purchased on or before May 14, 2020 shall be capable of accumulating volume for a minimum of 10 seconds and shall not stop accumulating volume before (i) the volume change for a 0.5-second interval is less than 25 milliliters, or (ii) the flow is less than 50 milliliters per second for a 0.5 second interval.
- 2. Instruments purchased after May 14, 2020 shall be capable of accumulating volume for a minimum of 15 seconds and shall not stop accumulating volume before the volume change for a 1-second interval is less than 25 milliliters.
- i. The forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV $_1$) measurements shall comply with the accuracy requirements stated in paragraph (a) of this section. That is, they should be accurately measured to within ± 50 ml or within ± 3 percent of reading, whichever is greater.
- j. 1. Instruments purchased on or before May 14, 2020 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.
- 2. Instruments purchased after May 14, 2020 must be capable of having its calibration checked in the field and be recalibrated, if necessary, if the spirometer requires the technician to do so. The volume-calibration syringe shall provide a volume displacement of at least 3 liters and shall be accurate to within \pm 0.5 percent of 3 liters (15 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 worker who shall be instructed to loosen any tight

clothing and stand in front of the apparatus. The worker 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 ensure that the chin is slightly elevated with the neck slightly extended. The worker 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 and no more than eight forced expirations shall be carried out. During the maneuvers, the worker shall be observed for compliance with instruction. The expirations shall be checked visually for technical acceptability and repeatability from flow-volume or volume-time tracings or displays. The following efforts shall be judged technically unacceptable when the worker:

- 1. Has not reached full inspiration preceding the forced expiration,
- 2. Has not used maximal effort during the entire forced expiration,
- 3. Has not tried to exhale continuously for at least 6 seconds and the volume-time curve shows no change in volume (<0.025 L) for at least one second,
 - 4. Has coughed in the first second or closed the 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 150 milliliters or 5 percent of the FVC, whichever is greater.), and
- 7. Has an excessive variability between the acceptable curves. The difference between the two largest FVCs from the satisfactory tracings shall not exceed 150 milliliters and the difference between the two largest FEV $_1$ s of the satisfactory tracings shall not exceed 150 milliliters.
- b. Calibration checks of the volume accuracy of the instrument for recording FVC and FEV_1 shall be performed daily or more frequently if specified by the spirometer manufacturer, using a 3-liter syringe. Calibration checks to ensure that the spirometer is recording 3 liters of injected air to within ± 3.5 percent, or 2.90 to 3.10 liters, shall be conducted. Calibration checks of flow-type spirometers shall include injection of 3 liters air over a range of speeds, with injection times of 0.5 second, 3 seconds, and 6 or more seconds. Checks of volume-type spirometers shall include a single calibration check and a check to verify that the spirometer is not leaking more than 30 milliliters/minute air.

a. The first step in evaluating a spirogram should be to determine whether or not the worker has performed the test properly or as described in section II of this appendix. From the three satisfactory tracings, the forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV $_1$) 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. [Reserved]

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 repeatability of results.
- b. Instrumentation requirements, including calibration check procedures, sources of error, and their correction.
- c. Performance of the testing including worker coaching, recognition of improperly performed maneuvers and corrective actions.
 - d. Data quality with emphasis on repeatability.
 - e. Actual use of the equipment under supervised conditions.
 - f. Measurement of tracings and calculations of results.

[43 FR 27394, June 23, 1978; 43 FR 35035, Aug. 8, 1978, as amended at 45 FR 67340, Oct. 10, 1980; 50 FR 51173, Dec. 13, 1985; 51 FR 24325, July 3, 1986; 54 FR 24334, June 7, 1989; 61 FR 5508, Feb. 13, 1996; 63 FR 1290, Jan. 8, 1998; 65 FR 76567, Dec. 7, 2000; 70 FR 1142, Jan. 5, 2005; 71 FR 16672, 16673, Apr. 3, 2006; 71 FR 50189, Aug. 24, 2006; 73 FR 75586, Dec. 12, 2008; 76 FR 33609, June 8, 2011; 77 FR 17782, Mar. 26, 2012; 84 FR 21490, May 14, 2019]