Employment Standards Administration, Labor
Pt. 718, App. B

(13) Each roentgenogram made under this Appendix shall be permanently and legibly marked with the name and address of the facility at which it is made, the miner’s DOL claim number, the date of the roentgenogram, and left and right side of film. No other identifying markings shall be recorded on the roentgenogram.

(55 FR 80045, Dec. 20, 2000)

APPENDIX B TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF PULMONARY FUNCTION TESTS. TABLES B1, B2, B3, B4, B5, B6.

The following standards are established in accordance with section 402(f)(1)(D) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting ventilatory function tests and that the best available medical evidence will be submitted in support of a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be given to the results of the ventilatory function tests.

(1) Instruments to be used for the administration of pulmonary function tests shall be approved by NIOSH and shall conform to the following criteria:

(i) The instrument shall be accurate within ±50 ml or within ±3 percent of reading, whichever is greater.

(ii) The instrument shall be capable of measuring vital capacity from 0 to 7 liters BTPS.

(iii) 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.

(iv) 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.

(v) The instrument used shall provide a tracing of flow versus volume (flow-volume loop) which displays the entire maximum inspiration and the entire maximum forced expiration. The instrument shall, in addition, provide tracings of the volume versus time tracing (spirogram) derived electronically from the flow-volume loop. Tracings are necessary to determine whether maximum inspiratory and expiratory efforts have been obtained during the FVC maneuver. If maximum voluntary ventilation is measured, the tracing shall record the individual breaths volumes versus time.

(vi) The instrument shall be capable of accumulating volume for a minimum of 10 seconds after the onset of exhalation.

(vii) The instrument must be capable of being calibrated in the field with respect to the FEV1. The volume calibration shall be accomplished with a 3 L calibrating syringe and should agree to within 1 percent of a 3 L calibrating volume. The linearity of the instrument must be documented by a record of volume calibrations at three different flow rates of approximately 3 L/6 sec, 3 L/3 sec, and 3 L/sec.

(viii) For measuring maximum voluntary ventilation (MVV) the instrument shall have a response which is flat within ±10 percent up to 4 Hz at flow rates up to 12 liters per second over the volume range.

(ix) The spirogram shall be recorded at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L. Calculation of the FEV1 from the flow-volume loop is not acceptable. Original tracings shall be submitted.

(2) The administration of pulmonary function tests shall conform to the following criteria:

(i) Tests shall not be performed during or soon after an acute respiratory illness.

(ii) For the FEV1 and FVC, use of a nose clip is 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, or stand, but care should be taken on repeat testing that the same position be used. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The subject shall be instructed to expire completely, momentarily hold his breath, place the mouthpiece in his mouth and close the mouth firmly about the mouthpiece to ensure no air leak. The subject will than make a maximum inspiration from the instrument and when maximum inspiration has been attained, without interruption, blow as hard, fast and completely as possible for at least 7 seconds or until a plateau has been attained in the volume-time curve with no detectable change in the expired volume during the last 2 seconds of maximal expiratory effort. A minimum of three flow-volume loops and derived spirometric tracings shall be carried out. The patient shall be observed throughout the study for compliance with instructions. Inspiration and expiration shall be checked visually for reproducibility. The effort shall be judged unacceptable when the patient:

(A) Has not reached full inspiration preceding the forced expiration; or

(B) Has not used maximal effort during the entire forced expiration; or

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(C) Has not continued the expiration for least 7 sec. or until an obvious plateau for at least 2 sec. in the volume-time curve has occurred; or
(D) Has coughed or closed his glottis; or
(E) 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.); or
(F) Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts). Peak flow should be attained at the start of expiration and the volume-time tracing (spirogram) should have a smooth contour revealing gradually decreasing flow throughout expiration; or
(G) Has an excessive variability between the three acceptable curves. The variation between the two largest FEV1’s of the three acceptable tracings should not exceed 5 percent of the largest FEV1 or 100 ml, whichever is greater. As individuals with obstructive disease or rapid decline in lung function will be less likely to achieve this degree of reproducibility, tests not meeting this criterion may still be submitted for consideration in support of a claim for black lung benefits. Failure to meet this standard should be clearly noted in the test report by the physician conducting or reviewing the test.

(iii) For the MVV, the subject shall be instructed before beginning the test that he or she will be asked to breathe as deeply and as rapidly as possible for approximately 15 seconds. The test shall be performed with the subject in the standing position, if possible. Care shall be taken on repeat testing that the same position be used. The subject shall breathe normally into the mouthpiece of the apparatus for 10 to 15 seconds to become accustomed to the system. The subject shall then be instructed to breathe as deeply and as rapidly as possible, and shall be continually encouraged during the remainder of the maneuver. Subject shall continue the maneuver for 15 seconds. At least 5 minutes of rest shall be allowed between maneuvers.

At least three MVV’s shall be carried out. (But see §718.103(b).) During the maneuvers the patient shall be observed for compliance with instructions. The effort shall be judged unacceptable when the patient:
(A) Has not maintained consistent effort for at least 12 to 15 seconds; or
(B) Has coughed or closed his glottis; or
(C) 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.); or
(D) Has an excessive variability between the three acceptable curves. The variation between the two largest MVV’s of the three satisfactory tracings shall not exceed 10 percent.

(iv) A calibration check shall be performed on the instrument each day before use, using a volume source of at least three liters, accurate to within ±3 percent of full scale. The volume calibration shall be performed in accordance with the method described in paragraph (1)(vii) of this Appendix. Accuracy of the time measurement used in determining the FEV1 shall be checked using the manufacturer’s stated procedure and shall be within ±3 percent of actual. The procedure described in the Appendix shall be performed as well as any other procedures suggested by the manufacturer of the spirometer being used.

(v)(A) The first step in evaluating a spirogram for the FVC and FEV1 shall be to determine whether or not the patient has performed the test properly or as described in (2)(ii) of this Appendix. The largest recorded FVC and FEV1, corrected to BTPS, shall be used in the analysis.
(B) Only MVV maneuvers which demonstrate consistent effort for at least 12 seconds shall be considered acceptable. The largest accumulated volume for a 12 second period corrected to BTPS and multiplied by five or the largest accumulated volume for a 15 second period corrected to BTPS and multiplied by four is to be reported as the MVV.
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*Note: Table continues with various columns and entries.*
APPENDIX C TO PART 718—BLOOD-GAS TABLES

The following tables set forth the values to be applied in determining whether total disability may be established in accordance with §§718.204(b)(2)(ii) and 718.305(a), (c). The values contained in the tables are indicative of impairment only. They do not establish a degree of disability except as provided in §§718.204(b)(2)(ii) and 718.305(a), (c) of this subchapter, nor do they establish standards for determining normal alveolar gas exchange values for any particular individual. Tests shall not be performed during or soon after an acute respiratory or cardiac illness. A miner who meets the following medical specifications shall be found to be totally disabled, in the absence of rebutting evidence, if the values specified in one of the following tables are met:

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