obtained during the FVC maneuver. If necessary to determine whether maximum

from the flow-volume loop. Tracings are nec-

tracing (spirogram) derived electronically

provide tracings of the volume versus time

expiration. The instrument shall, in addition,

spiration and the entire maximum forced ex-

loop) which displays the entire maximum in-

umes to body temperature saturated with

ment must have a means of correcting vol-

that the resistance to airflow at 12 liters per

BTPS.

measuring vital capacity from 0 to 7 liters

whichever is greater.

±

approved by NIOSH and shall conform to the

tration of pulmonary function tests shall be

sider such fact in determining the evi-

tion tests and that the best available med-

ister such fact in determining the evi-

been met, the claims adjudicator may con-

ical evidence will be submitted in support of

claim for black lung benefits. If it is estab-

ment of the Department of Labor.

The following standards are established in

accordance with section 402(f)(2)(D) of the

were developed in consultation with the Na-

National Institute for Occupational

and medical technicians to insure that uniform

procedures are used in admin-

istering and interpreting ventilatory func-

tion tests and that the best available med-

cal evidence will be submitted in support of

claim for black lung benefits. If it is estab-

lished that one or more standards have not

been met, the claims adjudicator may con-

ider such fact in determining the evi-

dentary weight to be given to the results of

ventilatory function tests.

(1) Instruments to be used for the adminis-

tration 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 iner-

tia and offer low resistance to airflow such

that the resistance to airflow at 12 liters per

second must be less than 1.5 cm H20 liter/sec.

(iv) The instrument or user of the instru-

ment must have a means of correcting vol-

umes 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 in-

spiration and the entire maximum forced ex-

piration. The instrument shall, in addition,

provide tracings of the volume versus time

tracing (spirogram) derived electronically

from the flow-volume loop. Tracings are nec-

essary to determine whether maximum in-

spiratory and expiratory efforts have been

obtained during the FVC maneuver. If max-

imum voluntary ventilation is measured, the

tracing shall record the individual breaths

volumes versus time.

(vi) The instrument shall be capable of ac-

cumulating volume for a minimum of 10 sec-

onds 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 in-

strument 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 sec-

ond over the volume range.

(ix) The spirogram shall be recorded at a

speed of at least 20 mm/sec and a volume ex-

ursion of at least 10mm3. Calculation of the

FEV1 from the flow-volume loop is not ac-

ceptable. Original tracings shall be sub-

mitted.

(2) The administration of pulmonary func-
tion tests shall conform to the following cri-
teria:

(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 ex-

plained in simple terms to the patient who

shall be instructed to loosen any tight cloth-
ing and stand in front of the apparatus. The

subject may sit, or stand, but care should be

taken on repeat testing that the same posi-
tion be used. Particular attention shall be
given to insure that the chin is slightly ele-
vated with the neck slightly extended. The

subject shall be instructed to expire com-
pletely, momentarily hold his breath, place

the mouthpiece in his mouth and close the

mouth firmly about the mouthpiece to en-
sure no air leak. The subject will then make

a maximum inspiration from the instrument

and when maximum inspiration has been at-
tained, 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 de-

rived spirometric tracings shall be carried out.

The patient shall be observed through-
out the study for compliance with instruc-
tions. Inspiration and expiration shall be

checked visually for reproducibility. The ef-

tort shall be judged unacceptable when the

patient:

(A) Has not reached full inspiration pre-

ceding the forced expiration; or

(B) Has not used maximal effort during the

entire forced expiration; or

(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 MVVs 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 ±1 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, shall be used in the analysis.
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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). 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) of this subchapter, nor do they establish standards for determining normal alveolar gas exchange values for any particular individual. Tests must not be performed during or soon after an acute respiratory or cardiac illness. A miner who meets the following medical specifications must 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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