blown out in six seconds, after full inspiration.

FVC means forced vital capacity, which is the volume of air that can forcibly be blown out after full inspiration.

PEF means peak expiratory flow, which is the maximal airflow during a forced expiratory maneuver.

Spirometry examination means a pulmonary function test that measures expiratory volume and airflow rates and may determine the presence and severity of lung function impairments, if such are present.

§ 37.92 Spirometry examinations required for miners.

(a) Voluntary examinations. Each operator must provide to all miners who are employed in or at any of its coal mines the opportunity to have a spirometry examination and respiratory assessment at no cost to the miner at least once every 5 years in accordance with this subpart. The examinations will be available during a 6-month period that begins no less than 3.5 years and not more than 4.5 years from the end of the last 6-month period.

(b) Mandatory examinations. Every operator must provide to each miner who begins work in or at a coal mine for the first time on or after August 1, 2014, a spirometry examination and respiratory assessment at no cost to the miner in accordance with this subpart.

(1) Initial spirometry examination. An initial spirometry examination and respiratory assessment will be provided to all miners who begin work in or at a coal mine for the first time on or after August 1, 2014 within the first 30 days of their employment or within 30 days of approval of a plan to provide spirometry examinations.

(2) Second examination. A follow-up second spirometry examination and respiratory assessment will be provided to the miner no later than 3 years after the initial spirometry examination if the miner is still engaged in coal mining.

(3) Third examination. A third spirometry examination and respiratory assessment will be provided no later than 2 years after the examinations in paragraphs §37.3(b)(2) and paragraph (b)(2) of this section if the chest radiograph shows evidence of pneumoconiosis as defined in §37.3(b)(3) or if the second spirometry test results demonstrate more than a 15 percent decline in the value of percent predicted FEV1 since the initial test. Percent predicted FEV1 will be calculated according to prediction equations published in Spirometric Reference Values from a Sample of the General U.S. Population, American Journal of Respiratory and Critical Care Medicine, 159(1):179-187, January 1999, (incorporated by reference, see §37.97). A correction factor to Caucasian reference values will be applied when testing individuals of Asian descent as specified in the ATS Technical Standards: Spirometry in the Occupational Setting, p. 987 (incorporated by reference, see §37.97).

(c) Notification. NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, NIOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner’s third examination only with the miner’s written consent, and the notice to the operator must not state the medical reason for the examination or that it is the third examination in the series. If the miner is notified by NIOSH that the third mandatory examination is due and the operator is not so notified, availability of the spirometry examination under the NIOSH-approved operator’s plan will constitute the operator’s compliance with the requirement to provide a third mandatory examination even if the miner does not take the examination.

(d) Availability of spirometry testing. The opportunity for spirometry to be available for purposes of this subpart must be indicated in an operator’s plan that has been submitted and approved in accordance with this subpart.

§ 37.93 Approval of spirometry facilities.

(a) Facilities seeking approval to provide the spirometry examinations specified under this subpart must have the ability to provide spirometry of high technical quality. Thus, NIOSH-
approved facilities must meet the requirements specified in this subpart for the following activities: Training technicians to perform the tests; conducting spirometry tests using equipment and procedures that meet required specifications; collecting the respiratory assessment form; transmitting data to NIOSH; and communicating with miners as required for scheduling, testing, and notification of results. Facilities seeking approval may apply to NIOSH using the Spirometry Facility Certification Document (Form CDC/NIOSH (M2.14), available at http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSureProgram.html.

(b) Spirometry quality assurance. A spirometry quality assurance program must be in place to minimize the rate of invalid test results. This program must include all of the following components:

(1) Instrument calibration checks. Testing personnel must fully comply with the 2005 ATS/ERS Standardisation of Spirometry guidelines for instrument calibration check procedures, pp. 322–323, including Table 3 (incorporated by reference, see §37.97). Calibration check procedures must include daily (day of testing) leak and volume accuracy checks and linearity checks according to the frequency established by the 2005 ATS/ERS guidelines. Instrument calibration check records must be maintained by the facility and available for inspection.

(2) Automated maneuver and test session quality checks. The spirometer software must automatically perform quality assurance checks on expiratory maneuvers during each spirometry testing session. Messages must alert the technician to maneuver acceptability errors and test session non-repeatability. Each spirometry test session must have the goal of obtaining 3 acceptable with 2 repeatable forced expiratory maneuvers, as defined by the 2005 ATS/ERS Standardisation of Spirometry, p. 325 (incorporated by reference, see §37.97).

(3) Ongoing monitoring of test quality. Facilities must submit spirometry results to NIOSH within 14 calendar days of testing as specified in §37.95(d) to permit NIOSH to monitor test quality and provide a report to the miner. NIOSH may provide feedback to the appropriate technician(s) along with suggestions for improvement.

(4) Quality assurance audits. NIOSH may periodically conduct audits to review examinations submitted by approved facilities and assess the quality of spirometry provided. Such audits may include a review of all spirometry examination data obtained during a specified time period or review of spirometry test data collected over time on selected miners.

(c) Noncompliance. If NIOSH determines that a facility is not compliant with the policies and procedures specified in this section that a facility is not performing spirometry examinations of adequate quality, the facility will be notified of the deficiency. The facility must promptly make appropriate arrangements for the deficiency to be rectified.

(d) Revocation of approval. If a facility fails to rectify deficiencies within 60 days of notification, NIOSH approval of the facility may be revoked. An approval which has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted by the facility to prevent a recurrence.

(e) Maintenance of records. In conducting medical examinations pursuant to this part, physicians and radiographic facilities must maintain the results and analyses of these examinations (including any hard copies or digital files containing individual data, interpretations, classifications, and images) in a manner consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

§37.94 Respiratory assessment form.

As part of the spirometry examination and concurrent with it, personnel at the facility must complete a Respiratory Assessment form (Form CDC/