§ 37.95 Specifications for performing spirometry examinations.

(a) Persons administering the spirometry examination. Each person administering spirometry examinations must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses, identified on the NIOSH Web site at http://www.cdc.gov/niosh/; A copy of the certificate of completion from a NIOSH-approved spirometry training or refresher course, with validation dates printed on the document, must be available for inspection. NIOSH will assign each person administering spirometry examinations a unique identification number, which must be entered into the spirometry system computer whenever instrument quality assurance or miner testing is done or on the Spirometry Results form (Form CDC/NIOSH (M)2.17), available at http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSure Program.html.

(b) Spirometer specifications. Spirometry testing equipment must meet the 2005 ATS/ERS Standardisation of Spirometry specifications for spirometer accuracy and precision and real-time display size and content, pp. 331–333, including Table 2 on p. 322 and Table 6 on p. 332 (incorporated by reference, see §37.97). Facilities must make available for inspection written verification from a third-party testing laboratory (not the manufacturer or distributor) that the model of spirometer being used has successfully passed its validation checks as required by the Standardization of Spirometry: 1994 Update protocol, Appendix B pp. 1128–1134, including Table C1 (incorporated by reference, see §37.97). Facilities may request such documentation from spirometer manufacturers. For each forced expiratory maneuver submitted for a miner under this part, the spirometry data file must retain a record of the parameters defined in the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see §37.97). Spirometers that provide electronic transfer of spirometry data results files must use the format, content, and data structure specified by the 2005 ATS/ERS Standardisation of Spirometry, p. 335, or a procedure for data transfer that is approved by NIOSH.

(c) Spirometry examination procedures. Administration of spirometry examinations must include the following:

1. Pre-test checklist. A short Spirometry Pre-Test Checklist (Form CDC/NIOSH (M)2.15), available at http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSure Program.html, must be administered prior to each spirometry examination to identify possible contraindications to testing, or factors that might affect results.

2. Respiratory assessment. A standardized Respiratory Assessment form (Form CDC/NIOSH (M)2.13), available at http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSure Program.html, must be completed at the initial spirometry examination and repeated at each spirometry examination.

3. Collection of anthropometric and demographic information. The miner’s standing height must be measured in stocking feet using a stadiometer (or equivalent device) each time the miner has a spirometry test. The miner’s weight must also be measured (in stocking feet). The miner’s birth date, race, and ethnicity must also be recorded. These data will be entered into the spirometry system computer and transmitted with the spirometry data file. For facilities with spirometers that do not permit electronic transfer of data files as specified in §37.96(d), the Spirometry Results form (Form CDC/NIOSH (M)2.17), available at http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSure Program.html, will be completed for each miner tested, and will report the numerical results of the highest and second highest results for the FVC and FEV1 and the highest PEF from at least three maximal, acceptable expiratory maneuvers.
(also called trials), as well as the FEV6 derived from those maneuvers reported.

(4) Examination. The spirometry examination will be conducted in accordance with test procedures defined in the 2005 ATS/ERS Standardisation of Spirometry, pp. 229–236, and the Standardisation of Lung Function Testing, Replies to Readers, pp. 1496–1498 (both incorporated by reference, see §37.97).

(i) The technician must be able to view real-time testing display screens as specified in the 2005 ATS/ERS Standardisation of Spirometry, p. 322 (incorporated by reference, see §37.97).

(ii) A miner will be tested in the standing position, but may be seated if he or she experiences lightheadedness or other signs or symptoms that raise a safety concern relating to the standing position during the spirometry test.

(d) Submission of test results. NIOSH-approved facilities must submit results of spirometry examinations electronically with content as specified in §37.96(b), pre-test screening checklists, and standardized respiratory assessments within 14 calendar days of testing a miner.

(e) Records retention. On-site records of the results will include spirometry examination reports and retention of all spirometry examinations, pre-test checklists, and standardized respiratory assessment results in electronic or printed format until notification to delete or render the information inaccessible, as described in §37.100(b)(6)(ii), is received from NIOSH.

§37.96 Spirometry interpretations, reports, and notifications.

(a) Interpretation of spirometry examinations. Interpretations will be carried out by physicians or other qualified health care professionals who have all required licensure and privileges to provide this service in their State or Territory. Interpretations must be carried out using procedures and criteria consistent with recommendations in the ATS Technical Standards: Spirometry in the Occupational Setting, pp. 967–990, and the ATS/ERS Interpretative Strategies for Lung Function Tests, p. 950, p. 956 including Table 5, and p. 957 including Table 6 (both incorporated by reference, see §37.97).

(b) Spirometry test reports at the facilities. (1) Spirometry test reports must contain, at a minimum, the miner’s age, height, gender, race, and weight, numerical values (FVC, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, FET, and PEF) and volume-time and flow-volume spirograms for all recorded expiratory maneuvers, normal reference value set used, the predicted, percent predicted and lower limit of normal values, miner position during testing (standing or sitting), dates of test and last calibration check, ambient temperature and barometric pressure (volume spirometers), and the technician’s unique identification number.

(2) NIOSH will notify the submitting facility when to permanently delete or, if this is not technologically feasible for the spirometry system used, render permanently inaccessible all files and forms associated with a miner’s spirometry examination from its electronic and physical files.

(c) Notifying miners of spirometry examination results. (1) Findings must be communicated to the miner or, if requested by the miner, to the miner’s designated physician. The health care professional at the NIOSH-approved facility must inform the miner if the spirometry examination shows abnormal results or if the respiratory assessment suggests he or she may benefit from the medical follow-up or a smoking cessation intervention.

(2) NIOSH will notify the miner of his or her spirometry examination results and the results of a comparison between current and previously submitted spirometry examinations and will advise the miner to contact a health care professional as appropriate based on the results.

(d) Submission of results. Each facility must submit spirometry results and completed forms to NIOSH within 14 days after a miner has received an examination under this subpart. If specified under a facility’s approval, it must submit spirometry results and the completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16), available at http://