

Spirometry in Occupational Health—2020

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Spirometry in the occupational health setting plays a critical role in the primary, secondary, and tertiary prevention of workplace-related lung disease. Recognizing the central role of spirometry in workplace respiratory programs, the American College of Occupational and Environmental Medicine (ACOEM) developed three spirometry position statements in the past two decades, which summarized advances of particular relevance to occupational health practice. However, since these statements were published, there have been important developments in federal regulations and in official American Thoracic Society recommendations which affect occupational spirometry testing. This 2020 ACOEM guidance statement incorporates these spirometry testing changes into its recommendations to provide current information for all users of spirometry test results, from those who perform or supervise testing to those who only interpret or review results.

Spirometry, the most frequently performed pulmonary function test (PFT), is the cornerstone of occupational respiratory evaluation programs. In the occupational health setting, spirometry plays a critical role in the primary, secondary, and tertiary prevention of workplace-related lung disease.^{1,2} The primary aim of workplace spirometry is to identify workers who should have further evaluation for possible disease. Consistency over time of testing techniques, equipment, and interpretation approaches are essential in occupational testing since workers are often evaluated over decades of employment. Testing is required by some regulations based on employee work exposures and

testing may also be used to assess the presence of impairment in symptomatic workers. Used for both screening and clinical evaluations, spirometry tests are performed in a variety of venues ranging from small clinical practices to large testing facilities and multiple plant medical departments within an industry.

Physicians and other health care professionals may conduct spirometry tests themselves, supervise others conducting the tests, or be involved only in interpreting test results. Whatever their level of involvement in the actual testing, spirometry users need to be aware that spirometry differs from many other medical measurements since it depends on multiple factors for its results to be valid. If subject effort is flawed, equipment is not accurate, or technicians fail to elicit maximal cooperation and effort, results can be falsely *elevated* or *reduced*. If uncorrected, these problems may profoundly impact conclusions that are drawn about a worker's pulmonary function with potentially adverse consequences for workers (Table 1).

Recognizing the central role of spirometry in workplace respiratory programs, the American College of Occupational and Environmental Medicine (ACOEM) developed three spirometry position statements in the past two decades, which summarize advances of particular relevance to occupational health practice.^{1,3,4}

However, since these statements were published, there have been a number of developments which affect occupational spirometry testing. First, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) issued an Official Technical Statement on Standardization of Spirometry 2019 Update,⁵ as well as a correction,⁶ and explanation of an error made in the 2005 Spirometry Statement.⁷ Second, the US Occupational Safety and Health Administration (OSHA) issued its *Best Practices Guidance on Spirometry Testing in Occupational Health Programs*.⁸ Third, the ATS issued Official Technical Standards on Occupational Spirometry Testing² and on Standardized Pulmonary Function Reports.⁹ Fourth, OSHA promulgated the Respirable Crystalline Silica Standards for construction (29 CFR 1926.1153) and for general industry (29 CFR 1910.1053) and maritime (29 CFR 1915.1053).^{10,11} Fifth, in 2014, the US Mine Safety and Health Administration added spirometry to coal miner medical surveillance exams,¹² and in 2016, the National Institute for Occupational Safety and Health (NIOSH) began approving clinics to test coal miners as part of the Coal Worker Health Surveillance Program (CWHSP).^{13,14} Effective July 15, 2019, OSHA updated the Cotton Dust Standard (29 CFR 1910.1043), the landmark regulation in which OSHA first specified how

TABLE 1. Spirometry in Occupational Health—2020 Topics

1. Equipment Performance
 - (a) Spirometer Specifications and Validation Testing Recommendations
 - (b) Spirometer Accuracy Checks
 - (c) Avoid Sensor Errors during Subject Tests
2. Conducting Tests
 - (a) Technician Training
 - (b) Conducting the Test
 - (c) Testing Goal for a Valid Test
 - (d) Reporting Results
 - (e) Quality Assurance (QA) Reviews
3. Comparing Results with Reference Values
 - (a) Reference Values
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 - (c) Interpretation Algorithm
4. Longitudinal Interpretation
 - (a) Spirometry Testing Quality and Test Variability
 - (b) Frequency and Duration of Testing
 - (c) Determination of Abnormally Reduced or Highly Variable FEV₁
5. Further Evaluation of Spirometric Abnormalities
6. Recordkeeping

FEV₁, Forced Expiratory Volume in One Second; LLN, Lower Limit of Normal; A, Quality Assurance.

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TABLE 2. Major Spirometry Developments Since Publication of ACOEM’s 2011 Statement⁴

1. Effective July 15, 2019, OSHA updated the Cotton Dust Standard (29 CFR 1910.1043), the landmark regulation in which OSHA first specified how occupational spirometry testing must be conducted.¹⁵
2. OSHA issued Best Practice Guidance for Occupational Spirometry Testing.⁸
3. NIOSH-approved spirometry courses for technicians are required by the Cotton Dust Standard,¹⁵ Respirable Crystalline Silica Standards,^{10,11} and the NIOSH Coal Worker Health Surveillance Program (CWHSP),¹³ and recommended by OSHA Guidance.⁸
4. NIOSH maintains a list of spirometers approved for use in the CWHSP.¹⁷
5. NIOSH released spirometry training videos.¹⁸
6. OSHA and NIOSH promulgate record-keeping requirements,^{10,13,15,16} and ATS and OSHA make record-keeping recommendations.^{2,8}
7. ATS/ERS states that “There is no requirement for minimum FET” (length of exhalation).⁵ Subjects who are young, have small thoracic cavities, or have restrictive impairment often have spirometry maneuvers with plateaus and repeatable results, but with exhalation times less than 6 s.^{5,6,8,9} Such maneuvers are now recognized as acceptable and can be used to meet requirements for a valid test.
8. ATS/ERS confirms that the occupational spirometry testing protocol which records only maximal expiration meets the requirements of the 2019 Update of the ATS/ERS Spirometry Standards.¹⁹⁻²¹ This permits occupational settings to maintain essential consistency in their testing procedures over time.
9. ATS/ERS confirms that for occupational spirometry testing in the United States, the use of the NHANES III²² spirometry reference values is in full compliance with the 2019 Update of the ATS/ERS Spirometry Standards.¹⁹⁻²¹ Since consistency over time is essential, NHANES III remains the required or recommended reference value set for occupational testing in the United States.^{2,8,9,15}
10. A 0.88 scaling factor, applied to NHANES III²² Caucasian reference values for FVC and FEV₁, is recommended or required when testing Asian-American workers.^{2,8,15} However, the Caucasian FEV₁/FVC reference values are not adjusted.
11. Spirometry abnormality is assessed using the 5th percentile LLN, but values close to the LLN should be interpreted with caution.⁹
12. Especially for workers with initial FEV₁ above 100% of predicted, longitudinal evaluation of FEV₁ can be used as a tool to determine whether more evaluation for possible disease is indicated.²
13. ATS recommends further medical evaluation steps when screening abnormalities are found.²

ACOEM, American College of Occupational and Environmental Medicine; ATS, American Thoracic Society; CWHSP, Coal Worker Health Surveillance Program; ERS, European Respiratory Society; nnnnnnnnn Occupational Safety and Health Administration; LLN, Lower Limit of Normal; NHANES III, National Health and Nutrition Examination Study, Round III; NIOSH, National Institute for Occupational Safety and Health.

occupational spirometry testing must be conducted.¹⁵ And finally, OSHA has issued a Letter of Interpretation regarding responsibility for maintaining medical records under the Silica and Respiratory Protection Standards.¹⁶ Table 2 summarizes these major developments since publication of the last ACOEM spirometry statement in 2011.

ACOEM has developed this 2020 statement to incorporate these spirometry testing changes into its recommendations. The goal of this statement is to provide

comprehensive current information for all users of spirometry test results, from those who perform or supervise testing to those who only interpret or review results. The document allows those with specific interests to review those sections that are relevant to them. As shown in Table 1, six major topics are covered in this statement: (1) Equipment Performance; (2) Conducting Tests; (3) Comparing Results with Reference Values; (4) Evaluating Results over Time; (5) Further Evaluation of Spirometric Abnormalities; and (6) Recordkeeping.

Major recommendations are summarized at the end of the document in ACOEM Recommendations—2020. To assist readers in understanding the material, particularly in sections on Equipment Performance and Conducting Tests, Fig. 1 presents a spirogram from a valid test, to compare with the flawed test results shown in Figs. 2 and 3, as discussed below.

EQUIPMENT PERFORMANCE

Four elements contribute to accurate spirometer performance: (1) ATS/ERS^{5,7}

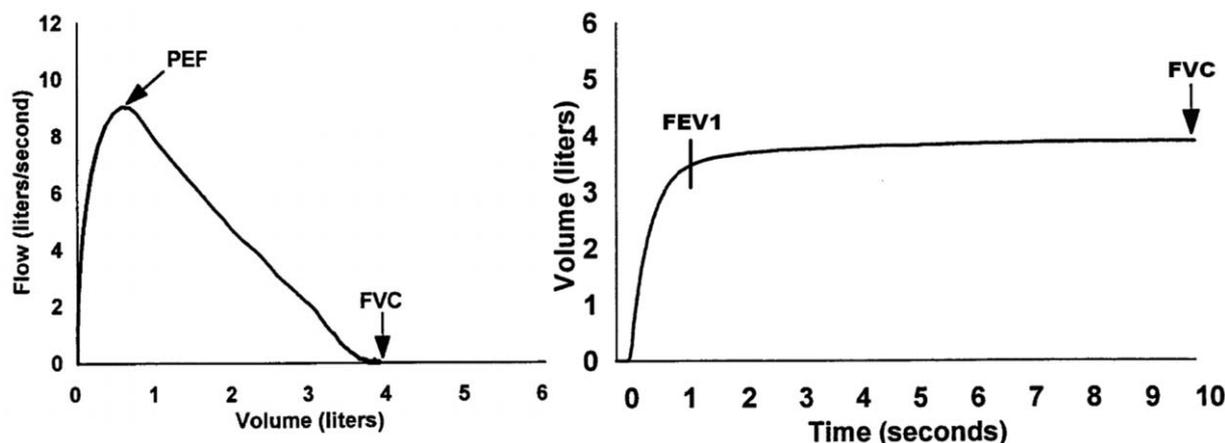


FIGURE 1. Valid test. Flow-volume curve (left) emphasizes *start* of test, rising *immediately* to a sharp peak and smoothly descending to zero flow. Volume-time curve (right) emphasizes *end* of test, initially rising rapidly, and then gradually flattening out and reaching 1 second of no visible volume change, at the FVC plateau. To permit effective subject coaching, ATS/ERS recommends using spirometers that show both graphical displays real-time and of sufficient size to clearly reveal technical errors.^{5,7}

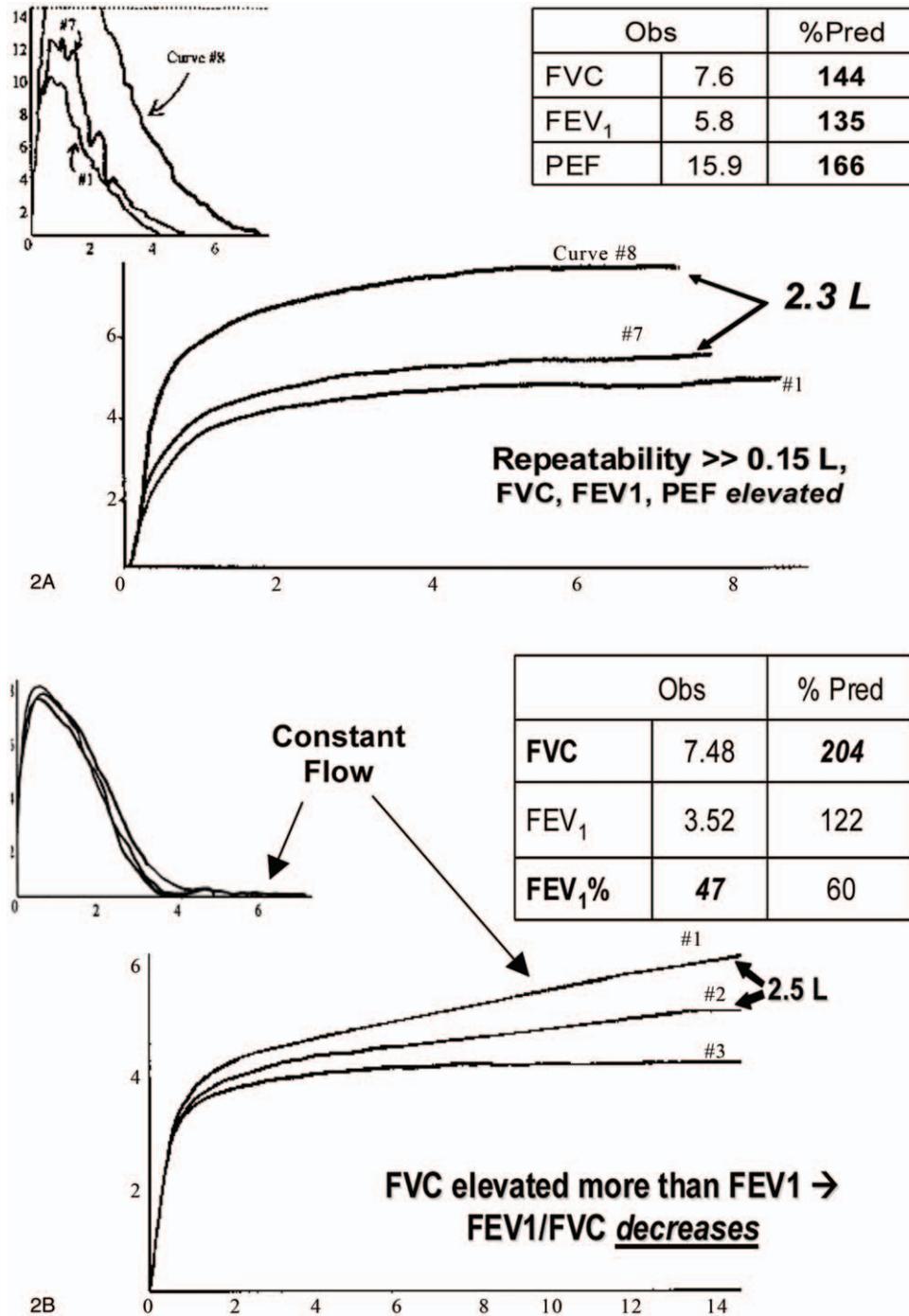
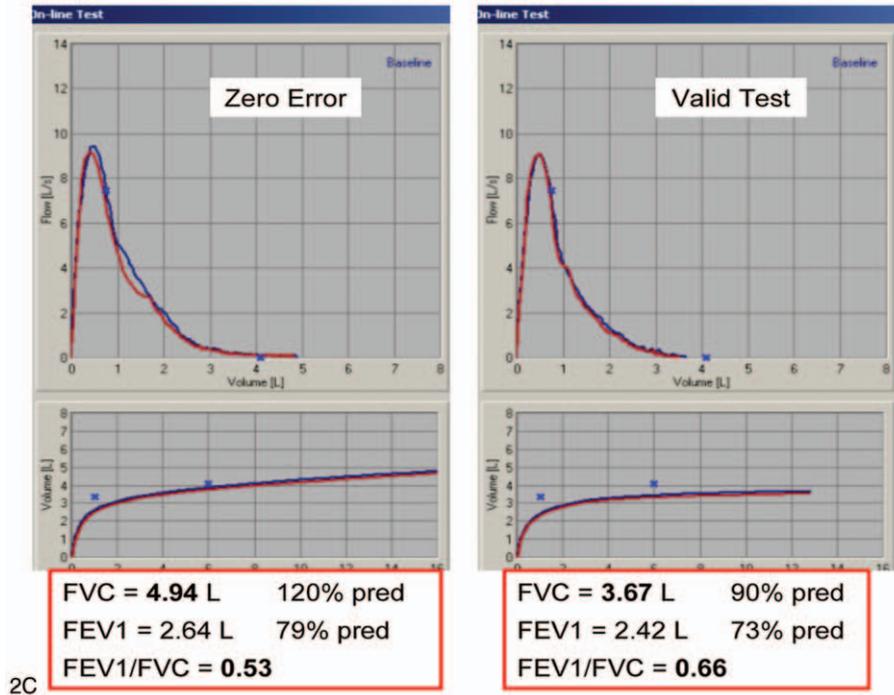
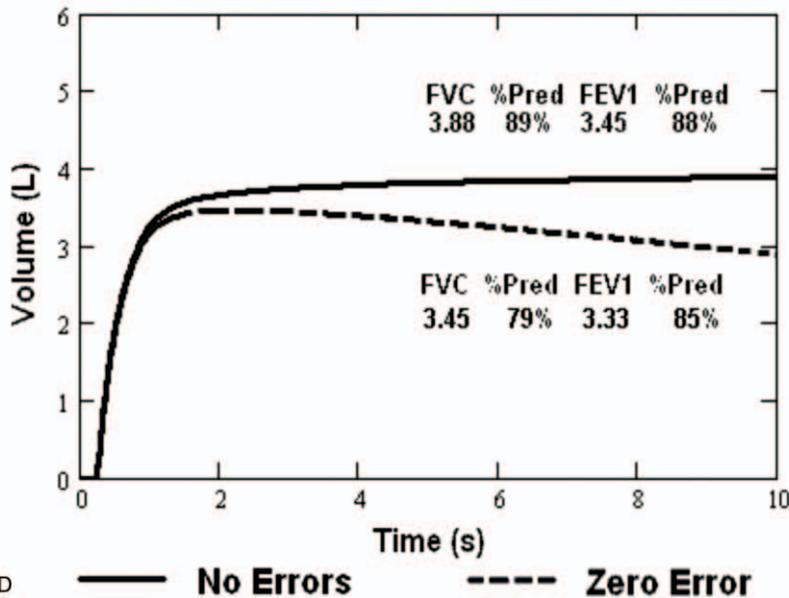


FIGURE 2. (A). Sensor contaminated or blocked by condensation, mucus, or fingers. DISCARD THIS CURVE. The last curve (#8) shows the impact of blockage or contamination of the sensor after the 7th maneuver was recorded. The FVC and FEV₁ values are falsely increased on curve #8, exceeding values from the earlier maneuvers (curves #1 and #7) by more than 0.40 L. Technicians must replace the sensor if it becomes contaminated during the test. Based on "Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals." OSHA 3637-2013.⁸ **FIGURE 2.** (B) Error: Inconsistent Zero-Flow Errors Causing Flows to be Over-Recorded. DELETE THIS TEST. This spirometer's zero-flow reference point was set at different incorrect levels before the first two maneuvers, causing the volume-time curves (top figure) to be played apart and extended tails to be drawn to the right on the flow-volume curves (bottom figure). FVC is increased more than FEV₁, falsely reducing the FEV₁/FVC and probably leading to an erroneous "obstructive impairment" pattern. Block sensor when the spirometer is zeroed and hold sensor still during subject testing to avoid this problem. Based on "Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals." OSHA 3637-2013.⁸



2C



2D

FIGURE 2. (C) Error: Zero-Flow Error Causing Flows to be Under-Recorded. DELETE THIS TEST. FVC is much more reduced than FEV₁, falsely increasing the FEV₁/FVC and possibly masking true airways obstruction. Block the sensor when the spirometer is zeroed and hold sensor still during subject testing to avoid this problem. Based on "Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals." OSHA 3637-2013.⁸ **FIGURE 2.** (D) Error: Consistent Zero-Flow Error Causing Flows to be Over-Recorded (left). DELETE THIS TEST. This spirometer's zero-flow reference point was set only once per test, before a complete set of maneuvers. The test on the left shows a zero-flow error, while the test on the right shows valid results; both tests were recorded by the same subject. The zero-flow error on the left produced erroneous but consistent results for all maneuvers, elevating the FVC more than the FEV₁ and falsely reducing the FEV₁/FVC. This zero-flow error may erroneously indicate an "obstructive impairment" pattern. Consistency of the flawed curves on the left may make this error difficult to detect, but technicians should watch out for extended tails that are drawn to the right on the flow-volume curves (top figure), and volume-time curves that climb at a constant rate without reaching a plateau, until the spirometer terminates data collection (bottom figure). Block the sensor when the spirometer is zeroed and hold sensor still during subject testing to avoid this problem. Based on "Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals." OSHA 3637-2013.⁸ OSHA; Occupational Safety and Health Administration.

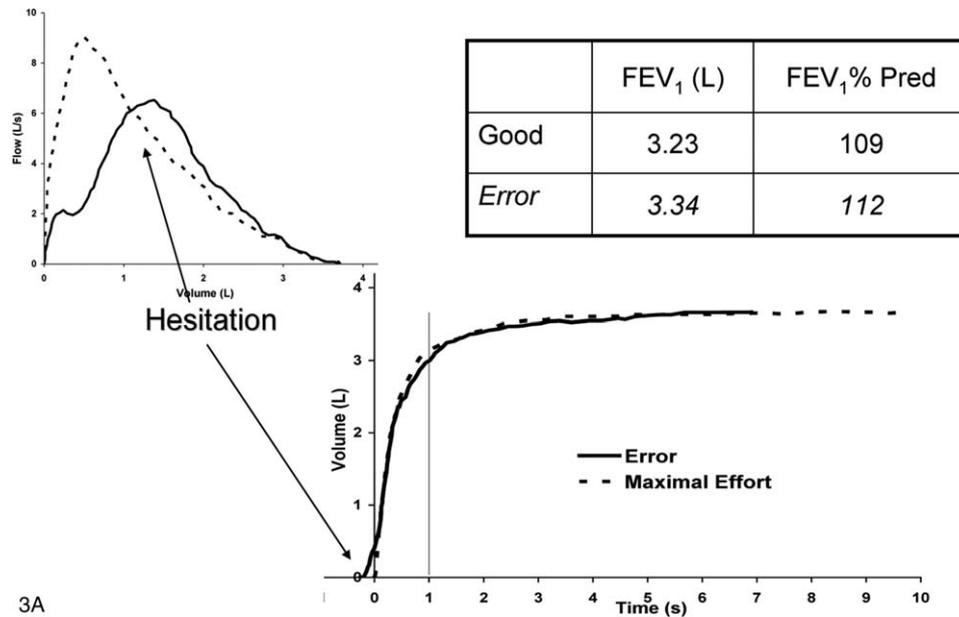


FIGURE 3. (A) Error: Excessive Hesitation (solid curves). Discard this curve. Because the worker's initial blast is delayed, the peak of the flow-volume curve (top figure) is displaced to the right, and a gradually climbing tail is seen at the start of the volume-time curve (bottom figure). Coach the worker: "blast out as soon as you are ready." Based on "Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals." OSHA 3637-2013.⁸

and ISO²³ recommend minimum performance-based standards for spirometers of all types; (2) prototype spirometers and their software should undergo validation testing, preferably by an independent testing laboratory, to demonstrate they meet these specifications^{5,7}; (3) spirometer users should perform daily accuracy checks (ie, "calibration checks") of the spirometer so that defective spirometers can be removed from service until they are repaired^{5,7}; and (4) if sensor errors develop during subject testing, users need to recognize the errors and delete the resulting invalid tests even if not labeled as errors by the spirometer's software.^{5,24}

Though these elements of accurate spirometer performance have not changed significantly since 2011, increasing attention has been paid to their implementation. The OSHA Guidance document endorses these elements as best practice for assuring accurate equipment performance and presents a list of recommended features for newly purchased spirometers.⁸ In nonmandatory Appendix B, the OSHA Respirable Crystalline Silica Standards recommend following these elements in occupational spirometry testing.¹⁰ But even though general comments about desirable spirometer properties are available, until now there has been little information about specific manufacturers and models of spirometers that might be appropriate for the occupational health setting.

As NIOSH developed requirements for its clinics approved for spirometry testing

of coal miners, NIOSH evaluated documentation submitted by manufacturers for inclusion in its CWHSP. As discussed below, though the list of spirometers approved by NIOSH for their CWHSP is not exhaustive and includes some program-specific requirements, it does provide some possible concrete guidance for spirometer selection by clinics for whom no specific recommendations have been available previously. NIOSH requires that spirometers used in its CWHSP meet the criteria listed below, as presented in an online NIOSH table of spirometers approved for CWHSP.¹⁷

ATS/ERS, ACOEM, and OSHA recommend that facilities performing occupational spirometry tests maintain a procedure manual documenting the details of equipment type, spirometer configuration, manufacturer's guidelines, calibration log, service and repair records, personnel training, and standard operating procedures.^{5,8} *Such a manual will permit troubleshooting if problems with anomalous test results arise.*

Spirometer Specifications and Validation Testing Recommendations

ACOEM⁴ and OSHA^{8,10,15} recommend or require selecting spirometers that meet the ATS/ERS recommendations for occupational testing.⁷ In addition, NIOSH operates the CWHSP to conduct mandated surveillance of working US coal miners' respiratory health. As part of CWHSP, spirometry is performed upon entry into the

coal mining workforce and periodically throughout the miner's coal mining career. NIOSH approves facilities to test miners and has established requirements for the spirometers used at these facilities. Spirometers used in NIOSH-approved clinics *must*¹⁷:

1. Comply with ATS performance standards for accuracy and precision and real-time display size.⁷
2. Meet NIOSH requirements for the content of spirometry test reports.
3. Produce output data in standardized electronic spirometry data file format which allows NIOSH to reconstruct individual spirometry curves for quality review of the coal miner spirometry test.

Though the third item is specific to NIOSH's coal miner clinic requirements, meeting the first two criteria means that the spirometer meets ATS/ERS recommendations, as recommended or required by ACOEM⁴ and OSHA.^{8,10,15} Specifically, NIOSH criteria include¹⁷:

1. Obtaining written verification documenting spirometer validation testing by a third-party laboratory. The letter should be obtained from the spirometer manufacturer and indicates that a spirometer model prototype measured at least 21 of the 24 ATS waveforms with acceptable accuracy and precision.⁷ In 2019, the ATS/ERS recommended using ISO standard waveforms²³ to evaluate spirometers.⁵

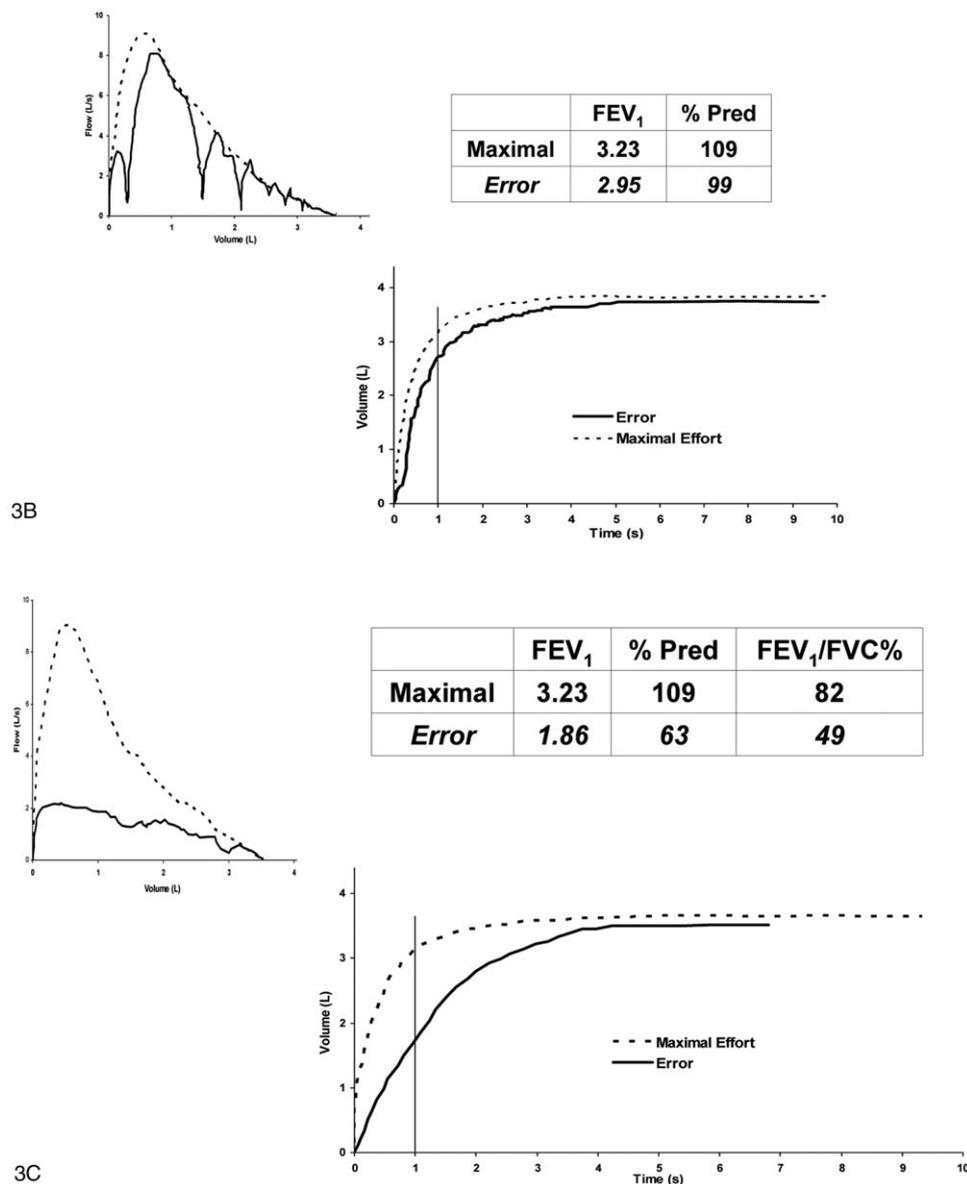


FIGURE 3. (B) Error: Cough in 1st Second (solid curves). DISCARD THIS CURVE. Because cough in the first second repeatedly interrupts the airflow early in the expiration, the flow-volume curve (top figure) clearly shows steep changes (interruptions) in the flow rate, while the volume-time curve (bottom figure) shows only subtle steps in the first second. A drink of water may solve this problem. Based on *"Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals."* OSHA3637-2013.⁸ **FIGURE 3.** (C) Error: No Blast (solid curves). This worker failed to blast out initially, so the expiratory speed was never rapid. The flow-volume curve (top figure) is very small and has no sharp peak, and the volume-time curve (bottom figure) shows a slanted start of expiration. Such a weak push reduces the FEV₁ and FEV₁/FVC, and may be caused by the worker trying to "save" air so that they can exhale for many seconds. This error causes false spirometer interpretations of "obstructive impairment." Coach "blast out hard and fast" to solve this problem. Based on *"Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals."* OSHA 3637-2013.⁸

- The spirometry system has a dedicated calibration check routine consistent with the 2005 ATS/ERS recommendations.^{2,5,7,8}
- Graphical displays meeting a minimum size requirement provide real-time volume-time and flow-volume curves during the test to enhance technician coaching.^{4,5,7,8}
- The spirometer software automatically performs quality assurance checks on expiratory maneuvers during each spirometry test.^{2,5,9} "However, technicians should be trained not to rely exclusively on these quality-control prompts, since technical errors may occur that are not among those recognized by the software."²⁵
- The spirometer can: (a) store values from at least eight maneuvers within one testing session; and (b) the spirometry software can save and recall curves and results from at least three acceptable maneuvers and preferably from all curves.^{8,9}
- The spirometry data file retains results for all parameters defined in the 2005 ATS/ERS recommendations.⁷

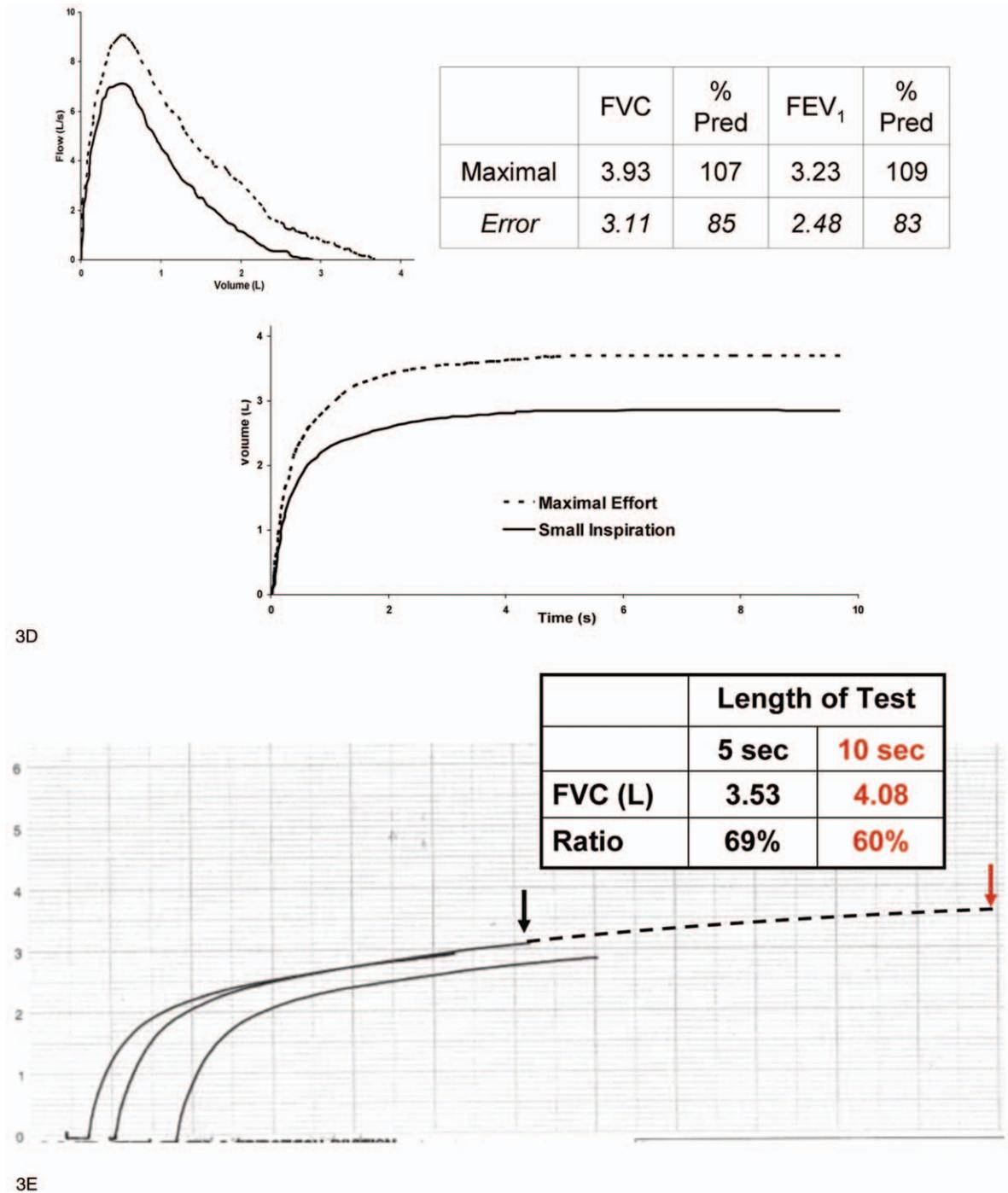


FIGURE 3. (D) Error: Sub maximal Inspiration (solid curves). The solid volume-time curve (bottom figure) resulted from a worker failing to inhale maximally before the forced expiration. The solid curve is considerably lower than the dashed curve that was drawn when the worker inhaled maximally before the forced expiration, and this very low curve is not “acceptable.” An incomplete inspiration can give the appearance of reduced FEV₁ and FVC, and may cause false spirometer interpretations of “restrictive impairment.” Coach the worker: “fill your lungs.” Based on “*Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.*” OSHA 3637-2013.⁸ **FIGURE 3.** (E) Error: Early Termination (solid curves). When expiration stops before the volume-time curve flattens into a 1-second plateau, the FVC may not be fully recorded. The solid lines show expirations for a subject with airways obstruction who terminated the exhalations early. Such incomplete recordings falsely increase the FEV₁/FVC and may cause the spirometer interpretation to be “normal” even when airways obstruction is present. The dashed line shows the increase in FVC that would have occurred with only 5 more seconds of expiration for this subject. The resulting higher FVC and the lower, more accurate FEV₁/FVC would trigger a correct interpretation of “airways obstruction.” (Note: though not shown here, subjects should try to exhale to a 1-second plateau when possible. However, curves longer than 15 seconds should not be recorded.⁵) Coach “keep blowing until I tell you to stop.” Based on “*Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.*” OSHA 3637-2013.⁸

25 yr 62" WF	Observed	% Pred
FVC	3.76 L	107 %
FEV1	3.30	112 %
FEV1/FVC	88%	105%
Time (FET)	4.5 sec	--

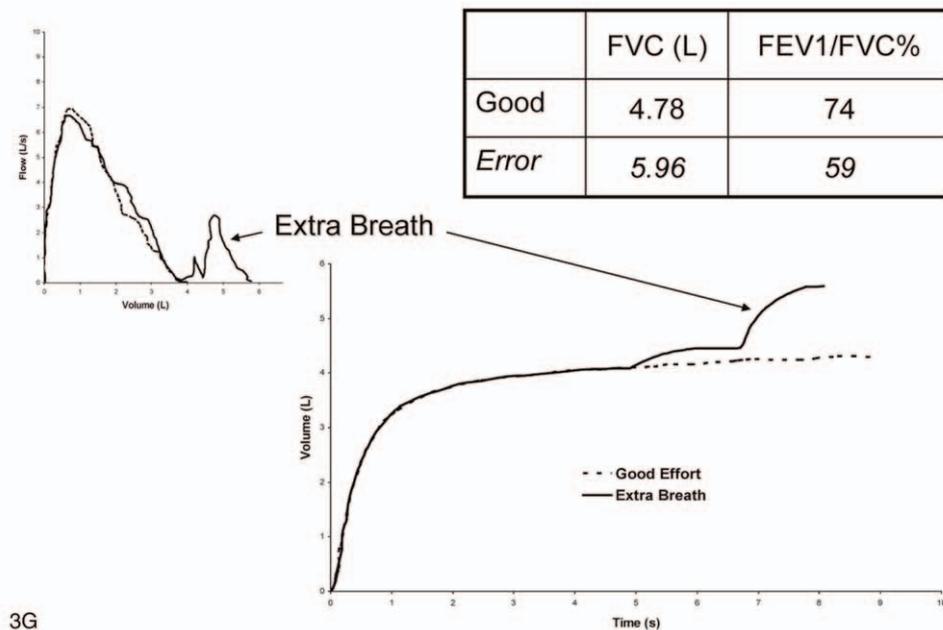
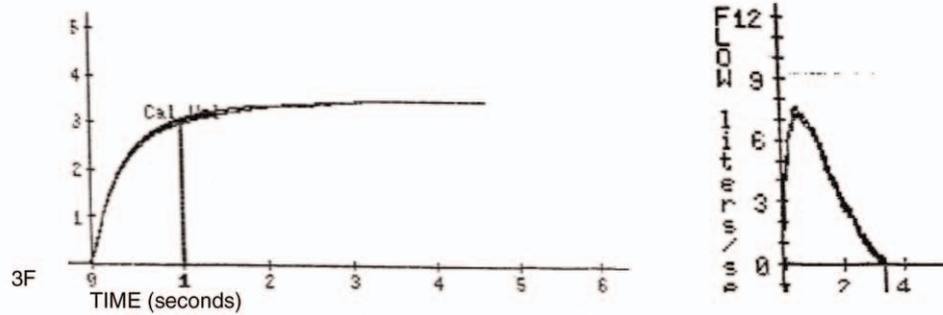


FIGURE 3. (F) Acceptable Test for Young Worker with FVC Plateau. Because the subject recorded 1-second FVC plateaus and the curves are repeatable, the maneuvers are acceptable.^{5,6,9} Spirometer error messages about “early termination” or “unacceptable test” should be ignored. Based on “*Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.*” OSHA 3637-2013.⁸ **FIGURE 3.** (G) Error: Extra Breath through the Nose at End of Test (solid curves). DISCARD THIS CURVE. At the end of the forced expiration, this worker inhaled additional air through the nose and quickly exhaled it into the spirometer mouthpiece. The flow-volume curve (top figure) shows multiple maneuvers and the volume-time curve (bottom figure) shows additional expirations in increasing steps at the end of the test. This error erroneously elevates the FVC, greatly reduces the FEV₁/FVC, and causes a false spirometer interpretation of “airways obstruction.” Solution: have the worker wear nose clips.²⁷ Based on “*Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.*” OSHA 3637-2013.⁸ OSHA; Occupational Safety and Health Administration.

TABLE 3. Daily Calibration Checks^{4,5,8}

Flow Spirometers:

1. Inject 3 L of air at three different speeds (taking approximately 0.5 s, 3 s, and 6 s).
2. Verify that the recorded value is between 2.91 and 3.09 L at all three speeds (ie, $\pm 3\%$ of 3.00 L).⁵

Volume Spirometers*:

1. Check that there are no leaks causing an air loss > 0.030 L/min (30 mL/min.).
2. Inject 3 L of air and verify that the recorded value is between 2.91 and 3.09 L (ie, $\pm 3.0\%$ of 3.00 L).⁵

*Quarterly checks of linearity are also needed for volume spirometers—see reference⁸ for details. Do not conduct spirometry tests if the spirometer fails any calibration checks, until the cause of failure is identified and corrected.

Adapted from “Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.” OSHA 3637-2013.⁸

OSHA; Occupational Safety and Health Administration.

7. For use in a NIOSH-approved CWHSP clinic, spirometers must provide electronic transfer of spirometry data files using a NIOSH-approved procedure for the format, content, and data structure specified by the 2005 ATS/ERS recommendations.⁷

Items 1 to 5 have also been recommended or required by ACOEM⁴ and by OSHA^{8,15} and an image made to scale of the minimum recommended display size is available in Appendix A.^{4,8} An online NIOSH table of spirometers approved for use in the CWHSP is available.¹⁷ Though this list is not an exhaustive compilation of spirometers that meet ATS recommendations, it may provide a useful starting point for clinics that need to purchase spirometers.

ACOEM recommends that spirometers used for all occupational spirometry tests meet NIOSH criteria 1 to 5 above. Meeting these criteria will ensure that occupational spirometers comply with the ATS/ERS recommendations.^{5,7,8} For NIOSH-approved clinics that test coal miners, criteria 1 to 5 are currently in place and criteria 6 to 7 will soon be fully in place.¹⁷

Spirometer Accuracy Checks

ATS/ERS,^{2,5,7} ACOEM,⁴ OSHA,^{8,15} and NIOSH¹³ all recommend or require daily checking of spirometer accuracy when the spirometer is in use, more frequently when the ambient conditions change, and at least every 4 hours when many tests are performed throughout the day.⁸ Such frequent “calibration checks” ensure that spirometers are accurate when in use, preventing interpretation of erroneous test results caused by inaccurate equipment. Details of the checks given by ATS/ERS,⁵ ACOEM,⁴ and OSHA^{8,15} are summarized in Table 3. Further details were given by ATS/ERS in Tables 3 and 4 of the 2019 Spirometry Standardization document.⁵

For many models of spirometers, the calibration is *checked* but cannot be adjusted by the user. If these spirometers

become inaccurate and repeatedly fail their calibration checks, and there are no obvious mechanical causes for the inaccuracy, they must be recalibrated by the manufacturer. But some spirometers require *recalibration* on a regular basis. In this case, the technician must carefully follow the manufacturer’s instructions since the spirometer’s calibration factor will be reset by this procedure. Once the spirometer is recalibrated, technicians should then perform the calibration checks listed in Table 3. Technicians should use spirometer software programs designed for calibration checks whenever possible.⁸

ACOEM, ATS, ATS/ERS, and OSHA recommend saving these calibration check records indefinitely.^{2,4,5,8} “Availability of such records permits later troubleshooting of problematic spirometry test results, which is particularly important when conducting periodic spirometry testing.”² ATS also recommends performing calibration checks when spirometer software is updated and “supplement[ing] calibration checks by using standard subjects as biological controls.”^{2,5}

ACOEM, ATS, and OSHA recommend or require checking spirometer

accuracy, ie, performing “calibration checks,” daily when spirometers are in use. They also recommend saving calibration records indefinitely and keeping a log of technical problems found and solved, as well as all changes in protocol, computer software, or equipment. As noted earlier, the purchase of spirometers with dedicated calibration check routines for use in the occupational setting is recommended. And supplementing calibration checks by using standard subjects as biological controls is valuable.^{2,5}

Avoid Sensor Errors during Subject Tests

Even though a spirometer passes its check of calibration accuracy, subject test results can be invalidated by equipment errors occurring during subject tests.^{5,24} Two errors that can occur during subject testing using some flow-type spirometers are contamination or blockage of a spirometer sensor, and incorrect setting of the zero-flow reference point.

First, if a subject’s fingers, secretions, or water vapor block or contaminate a flow-type spirometer’s sensor, increasing its resistance, the test results will be falsely *increased* and become invalid. The impact of this problem is seen by comparing a valid test (Fig. 1) with a test having sensor contamination (Fig. 2A). Even though such contaminated sensor problems are not identified as errors by the spirometer, the technician needs to identify the error when it occurs and discard the erroneous curve immediately so that the results are not reported as the largest results from the test session.

Second, most flow-type spirometers set a zero-flow reference point before each maneuver, or before each set of maneuvers. All flows during a subject’s subsequent expiration(s) are measured relative to this reference point. The “zero” flow reference baseline can be incorrect if: (1) a gravity-

TABLE 4. Spirometry Test Acceptability Requirements for Adults*

1. Maximal inhalation
2. A good start of exhalation with extrapolated volume $< 5\%$ of FVC or 0.10 L, whichever is greater, that is, no excessive hesitation⁵
3. Free from artifacts
4. No cough during first second of exhalation (for FEV₁)
5. No glottis closure or abrupt termination (for FVC)
6. No early termination or cutoff (for FVC). Timed expiratory volumes can be reported in maneuvers with early termination, but FVC should be reported only with qualification.
7. Maximal effort provided throughout the maneuver: inhalation, blast, complete exhalation
8. No obstructed mouthpiece
9. No extra breaths taken through the nose
10. No zero-flow errors

*FVC and FEV₁ are each considered separately for acceptability. FEV₁ acceptability does not consider anything after the first second, whereas FVC does.

Adapted from Ref. [9].

sensitive pressure-transducer moves during the subject test; (2) pressure tubing is disconnected or loose; (3) a sensor is degrading; (4) electronics are unstable; or (5) very slow airflow passes through the sensor in either direction while “zeroing” is in progress. Such airflow might be caused by slight sensor motion, background fans, or forced air ventilation. Blocking the sensor and holding it still next to the subject’s face often prevents these errors.^{5,24}

Unless a zero-flow error is large, most spirometers do not alert the user to this problem. Zero-flow errors can be recognized by the apparently constant flow rate that appears near the end of the maneuver in both the flow-volume and volume-time curves, as can be seen in Fig. 2B to D. Even though such zero-flow problems may not be identified as errors by available spirometers, the erroneous curves should be discarded immediately (not saved), so that their results are not reported as the results from the test session.

Since neither of these types of errors are typically detected by spirometer software, health professionals need to recognize the effects of contaminated sensors and zero-flow errors on test results and curve shapes. Both errors can produce very inconsistent results (failing to meet repeatability criteria, as discussed below), sometimes along with large percent of predicted values, exceeding 130% to 140%. Tests with zero-flow errors often are falsely interpreted by the spirometer as indicating obstructive impairment.

ACOEM and OSHA recommend that users of flow-type spirometers become familiar with the flawed patterns shown in Fig. 2, and institute protocols of preventive actions as well as corrective actions if those patterns are observed. Such protocols might include occluding sensors⁵ during premaneuver sensor “zeroing,” frequent checks for sensor moisture and mucus deposits, maintaining sensors in an upright position to minimize accumulation of condensation, and keeping subjects’ fingers far from the sensor outlet.

CONDUCTING TESTS

Technician Training

In 1978 and again in 2019, the OSHA Cotton Dust Standard stated that the goal of spirometry training courses is to provide technicians with “the basic knowledge required to produce meaningful test results.”¹⁵ In the regulation’s preamble, OSHA noted that:

The most important quality of a pulmonary function technician is the motivation to do the very best test on every

employee. The technician must also be able to judge the degree of effort and cooperation of the subject. The test results obtained by a technician who lacks these skills are not only useless, but also convey false information which could be harmful to the employee.

NIOSH was designated as the agency responsible for reviewing and approving occupational spirometry training courses, based on topics addressed by Appendix D of OSHA’s Cotton Dust Standard (29 CFR 1910.1043). NIOSH approves both initial Spirometry courses and Spirometry Refresher courses, which must be taken every 5 years (in addition to allowing for a 7 month additional grace period) to maintain the certificate of completion from a NIOSH-approved course. NIOSH conducts on-site course audits and periodic reviews of course approval status to monitor the quality of its approved courses. The NIOSH web page lists a schedule of NIOSH-approved courses,²⁶ and NIOSH spirometry training videos are available.¹⁸ ATS/ERS has endorsed NIOSH-approved courses as prototypes for technician training,^{2,25} and more recently stated that “Technicians should undergo initial practical training and refresher courses to maintain their skills.”² Most recently, ATS/ERS stated that “Operator training and attainment and maintenance of competency must be integrated in any spirometry testing service.”⁵

Since 2016, both OSHA’s Respirable Crystalline Silica Standards for Construction, General Industry, and Maritime and NIOSH’s CWHSP have required that spirometry tests conducted under these regulations must be conducted by individuals who have a current certificate from a NIOSH-approved course.^{10,11,13} Such training is also required by OSHA’s Cotton Dust Standard.¹⁵ The Cotton Dust Standard requires persons other than licensed physicians to complete the NIOSH approved course, while the Silica Standard requires all technicians to complete the NIOSH approved course. An OSHA Letter of Interpretation has recently stated that under the silica standard, OSHA views all medical personnel (eg, physicians, physicians’ assistants, nurses) who administer spirometry testing as technicians.¹¹

In 2013, OSHA’s Guidance also recommended that:

All technicians and other persons conducting occupational spirometry tests obtain certification by completing a NIOSH-approved course; and that “Supervisors and/or interpreters of test results also complete a NIOSH-approved spirometry course or equivalent training that emphasizes recognition

and troubleshooting of technical errors and the interpretation of spirometry results.”⁸

OSHA requires that individuals conducting spirometry tests required by the Respirable Crystalline Silica or Cotton Dust Standards maintain a current certificate from a NIOSH-approved course.^{10,11,15}

NIOSH requires completion of such a course when technicians test coal miners in NIOSH’s CWHSP.¹³ ACOEM⁴ and OSHA⁸ recommend that all technicians conducting occupational spirometry tests should complete NIOSH-approved courses. And ATS/ERS^{2,25} recommend that courses similar to Initial and Refresher NIOSH-approved courses should be taken to develop and maintain technician skills.

Conducting the Test

“Perhaps the most important component in successful pulmonary function testing is a well-motivated, enthusiastic technician.”²⁵ ATS/ERS,^{5,7} ACOEM,⁴ and OSHA⁸ emphasize that technicians explain, demonstrate, and coach subjects throughout their maneuvers, even when workers have performed the test previously. Consistent with decades-long occupational spirometry testing protocol, technicians need to encourage maximal inhalations, hard initial blasts, and complete exhalations. In 2019, the ATS/ERS presented separate protocols for testing that measures the forced expiration only, as has been done in occupational testing since 1978, and for testing that measures forced expiration followed by a maximal inspiration.⁵ ATS/ERS has confirmed that the former protocol, used in occupational testing and required by OSHA¹⁵ and NIOSH,¹³ meets the requirements of the 2019 Update of the ATS/ERS Spirometry Statement.^{19–21}

Occupational spirometry tests traditionally have been conducted with workers in the standing posture, permitting maximal inspirations and blasts on expiration, and yielding maximal FEV₁s and FVCs.^{1,4,8} ATS/ERS has noted that subjects with “excessive weight at the mid-section” achieve larger inspirations when standing,²⁵ and ATS also “recognize[ed] that standing may yield slightly increased values.”² A chair without wheels is to be placed behind the subject, and the technician must be ready to assist the subject into the chair if the subject begins to feel faint. If there is a history of fainting or if the subject is deemed to be at risk from fainting or falling, the test should be conducted in the sitting position. In all cases, the test posture should be documented and kept consistent over time whenever possible. Changes in test posture need to be taken into account when interpreting results over time.²

The subject's head is to be slightly elevated and he/she needs to stand or sit upright. The tongue cannot block the mouthpiece, and lips are to be tightly sealed around it. ATS/ERS recommends that nose clips be used for all spirometry tests,^{5,7} which prevents extra breaths through the nose, a technical error that invalidates results,²⁷ but is not detected by most spirometry software—see Fig. 3G.

ACOEM, ATS/ERS, and OSHA recommend that technicians explain, demonstrate, and actively coach workers to perform maximal inspirations, hard and fast expiratory blasts, and complete expirations. Occupational testing should be conducted standing, unless workers have experienced problems with fainting in the past, or are deemed to be at risk from fainting or falling. Testing posture should be recorded on the spirometry record and the same posture should be used for serial tests over time. Disposable nose clips are recommended.

Testing Goal for a Valid Test

ATS/ERS^{5,7,9} continues to define a valid spirometry test as having two components: (1) at least three “acceptable” curves that are free of technical flaws; and (2) “repeatable” results for the FVC and FEV₁ among the acceptable curves, as defined below. Most healthy workers can achieve this testing goal, and up to eight maneuvers “is generally a practical upper limit for most adults.”^{5,7}

Acceptable Curves

The components of “acceptable” occupational spirometry maneuvers—maximal inhalations, hard initial blasts, and complete exhalations—have not been changed.^{4,7,9,19–21} However, since some subjects experience difficulty in fully recording their FVCs, ATS/ERS^{5,7} recognized that curves that do not completely record the exhalation may be “usable” for FEV₁ measurement if they are free of hesitation and cough in the first second (Fig. 3A and B).

ATS/ERS has recently stated that “there is no [longer a] requirement for a minimum Forced Expiratory Time (FET),”⁵ though other End of Forced Expiration (EOFE) criteria are still applied to “ensure the best estimate of FVC.”⁶ The goal for an acceptable EOFE is still: (1) to reach a one-second FVC plateau,^{4,5,6,8,9} or (2) to exhale for 15 seconds, or (3) “if the patient cannot expire long enough to reach a plateau (eg, children with high elastic recoil or patients with restrictive lung disease)...to repeatedly achieve the same FVC.”⁵ Length of exhalation should be limited to 15 seconds since longer exhalations will not affect clinical decisions made about the subject.^{5,7,8} Though many

spirometers will continue to flag curves as incomplete and unacceptable if they are recorded for <6 seconds (until testing software is updated), users should now ignore those messages and determine whether one of the 3 EOFE criteria above has been met. Fig. 3E shows the impact of early termination for a worker with airways obstruction: the FVC is under-recorded, the FEV₁/FVC ratio is falsely elevated, and true airways obstruction may be missed.

Since working populations are often younger and healthier than clinic patients, the decision by the ATS/ERS to no longer require a minimum FET for an acceptable curve permits many workers to be labeled correctly as having achieved valid tests. The time taken to achieve a plateau generally increases with age, decreases with body size, and decreases in the presence of restrictive lung disease, so that young workers, adults with small body frames (eg, Asian females), and patients with restrictive lung disease may reach plateaus quickly, before 6 seconds has elapsed. Their results [can] be considered acceptable in such cases and an appropriate comment by the reviewer should be made.”^{6,9} Until spirometer software is updated, if a curve that plateaued in less than 6 seconds is labeled as unacceptable, technicians should mark such curves as “acceptable” so that the results will be included in the final test results. Similar to the worker shown in Fig. 3F, 54% of 4568 healthy nonsmoking subjects aged 19 or older in the NHANES III study group reached their FVC plateau before 6 seconds elapsed.^{9,28} Examples of a valid test with an exhalation less than 6 seconds in length, and of unacceptable curves caused by flawed testing technique are shown in Fig. 3A to G. Acceptability criteria are summarized in Table 4.

Repeatable FVC and FEV₁

Since 2005, ATS/ERS^{5,7,9} has defined the level of consistency to be achieved among test results as a difference of up to 0.15 L (150 mL) between the largest and second largest values of the FVC and the FEV₁. In general, up to eight total maneuvers can be attempted, emphasizing maximal inhalation, if repeatability among acceptable curves exceeds 0.15 L.

As ATS recently stated:

“The most common reason for low FVC, FEV₁, and PEF values is an incomplete inhalation. Achievement of maximal inhalation is best assessed by measures of repeatability and also by the consistency of the shape of the flow-volume or volume-time curve.” (See Fig. 3D).

To emphasize the importance of a complete inhalation in a valid spirometry test, technicians should *exaggerate* the

maximal inhalation as they demonstrate performance of the test. Failure to achieve repeatability does not rule out interpretation of results, since it may also occasionally be caused by underlying respiratory disease.⁹ Lack of repeatability needs to be documented and taken into account during the interpretation process.

ACOEM recommends that occupational spirometry tests strive to meet ATS/ERS criteria for a valid test, that is, recording three or more acceptable curves, with FVC and FEV₁ repeatability of less than or equal to 0.15 L (150 mL.) The recent decision by the ATS/ERS to no longer require a minimum FET⁵ means that healthy workers who reach their FVC plateau in a short time will now be labeled as having valid tests when the FVCs are consistent among curves. Failure to achieve FVC repeatability is often caused by inhalations that are not maximal.

Reporting Results

Values to be Reported

The largest FVC and the largest FEV₁ from all acceptable curves are reported as the test results even if they are taken from different curves. The FEV₁/FVC is calculated using these two values.^{4,5,7,8,15} To permit thorough review of a spirometry test, results from all acceptable curves, or at least the three best curves, should be shown on the spirometry report. As discussed below, ATS continues to strongly discourage evaluating the forced expiratory flow (FEF) rates, recently saying that “forced expiratory flow at 75% of FVC (FEF_{75%}) and FEF_{25% to 75%} have not demonstrated added value for identifying obstruction ... and therefore are not recommended for routine use.”^{6,9} But if reported, all FEF, except for the Peak Expiratory Flow (PEF), are to be drawn from one acceptable curve with the highest sum of (FEV₁ + FVC). The highest PEF recorded from among all acceptable curves is to be reported.^{4,6,8}

Test Report Format

ATS recently issued an Official Technical Standard on “Recommendations for a Standardized Pulmonary Function Report.”⁹ Key points from that standard relevant to occupational spirometry reports include:

1. Keep the reports simple: Include subject identification number, sex, date of birth, height, weight, ethnicity, date of test, normal reference source, Lower Limit of Normal (LLN), flow-volume and volume-time graphs showing technical quality, percentage of Predicted values,⁹ and test posture.² Scales of the graphs

have been previously defined,^{4,7,8} and can be adjusted as needed “to maximize the image within the available space for the report.”⁹ Z-scores of the results (the number of standardized residuals below the predicted value) are optional.⁹

Exclude parameters with no clinical value, limiting parameters to FVC, FEV₁, FEV₁/FVC, [PEF] and FET for technical quality assessment. “Limiting the number of parameters reported and showing the LLN next to the measured value should improve interpretive accuracy, particularly for those less experienced.”⁹

There should be a “place for technician comments on the test session, any quality issues, date of last calibration or calibration check,⁸ and other relevant information that may aid in interpretation.”⁹

2. Specify whether the reference values are adjusted for race (and what adjustment factor is used).^{2,9}
3. “Standardized electronic formats for the saving of all PFT data, including each individual maneuver, are ... recommended. This will allow reviewers the flexibility to see additional detail or to reanalyze previous PFTs or apply new reference values as they become available.”⁹

Many of these recommendations have also been made by ACOEM⁴ and by OSHA.⁸

ACOEM, ATS, and OSHA recommend or require that occupational spirometry test reports include values and curves from all acceptable curves (or at least the three best curves) and that the largest FVC and largest FEV₁ be interpreted, even if they come from different curves. Default spirometer configurations often need to be adjusted to meet these recommendations. Technicians should also check to be sure that ambient conditions are correctly recorded.

Quality Assurance (QA) Reviews

In addition to technician training, ATS recently emphasized the importance of periodic technical review of spirometry to provide on-going feedback on the quality of each technician’s testing.^{2,9,25} Samples of randomly selected tests, all invalid tests, and tests with abnormally low or improbably high results (FEV₁ or FVC >130% of predicted) can be reviewed. Around 80% or more of an occupational health program’s spirometry tests should be technically acceptable.^{8,29} Figures illustrating some of the technical errors that can affect spirometry test results are presented in Figs. 2 and 3 in this statement, in the 1994 ATS Spirometry Update,³⁰ the 2019 ATS/ERS Spirometry Statement Online Supplement,⁵

TABLE 5. Importance of a Valid Test: Summary

- Some spirometry errors falsely *elevate* FVC and/or FEV₁: excessive hesitations (Fig. 3A), extra inhalations through the nose (Fig. 3G), contaminated sensors (Fig. 2A), and over-recorded flows caused by zero-flow errors (Fig. 2B and C). *It is especially important to reject these curves because spirometers use the largest test results to interpret the test.*
- Other errors, such as submaximal inhalations (Fig. 3D) and weak expiratory pushes (Fig. 3C) often falsely *reduce* FVC and/or FEV₁. Spirometers usually discard such falsely low values when good coaching leads to higher, more accurate results on subsequent maneuvers.
- However, even if it leads to reduced FEV₁, coughs in the first second of exhalation (Fig. 3B) make the maneuver unusable.⁶
- Interpretation of falsely elevated or reduced results may indicate incorrectly that impairment exists when a worker is normal, or that a worker is normal when impairment in fact exists.

Based on “Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.” OSHA 3637-2013.⁸
OSHA; Occupational Safety and Health Administration.

and the OSHA Best Practices Guidance document.⁸

In 2017, ATS stated that “quality review of PFTs needs to move beyond ‘did, or did not, meet ATS standards,’ but a grading system is most helpful if the grades have a common meaning; therefore adoption of a uniform system is desirable.” A standard scheme for grading spirometry tests on a scale of A-F was recommended,^{5,9} with the grades incorporating both acceptability and repeatability. “A grading system allows the user to evaluate the likelihood that spirometry results are representative of true values in the face of test performance that is not ideal.”⁹ But as noted above, “technicians should be trained not to rely exclusively on spirometer quality-control prompts, since technical errors may occur that are not among those recognized by the software,”²⁵ and incorporated into the letter grade (Table 5).

“While strict application of the grading criteria can be done by computer software, the reviewer’s role is to apply judgment by reviewing the individual curves, which may change the scoring and allow interpretation.”⁹ The grades are summarized in Table 6.⁹ “In general, tests with grades of A, B, or C are usable; tests with grade D are suspect; tests with grade E might be used by the interpreter only to show values ‘within the normal range’ or at ‘at least as high as,’ without demonstrated

repeatability; and tests with grade F should not be used.”⁹

ACOEM, ATS, and OSHA recommend that technicians “receive on-going feedback about the quality of the tests they perform, and how to correct problems in test performance.”² The frequency of such reviews should be at least quarterly, and more often if technicians are inexperienced or if poor technical quality is observed. It is recommended that reviews be conducted by those experienced in recognizing and correcting flawed spirometry tests results.²⁹ When used with caution, test quality grades may be helpful in evaluating spirometry test results.

COMPARING RESULTS WITH REFERENCE VALUES

After establishing the technical validity of a test, spirometry results are evaluated at the time of the test, comparing the worker’s results with the normal range expected for his/her current demographic characteristics. The likely presence or absence of impairment is based on this evaluation and details are presented below. In addition, a worker’s results are often evaluated longitudinally, comparing their current results with their previous test results. This assessment serves as a helpful adjunct to traditional cross-sectional evaluation since increased change over time may indicate that further medical assessment is

TABLE 6. Test Quality Categories for FVC or FEV₁ in Adults

Grade	No. of Acceptable Curves	Repeatability
A	≥3	≤0.150 L
B	≥2	≤0.150 L
C	≥2	≤0.200 L
D	≥2	≤0.250 L
E	1	N/A
F	0	N/A

Adapted from Official American Thoracic Society Technical Statement: Recommendations for a Standardized Pulmonary Function Report. AJRCCM. 2017;196:1463–1472.⁹

appropriate for a worker even though he/she is not impaired based on traditional evaluation. Updated recommendations for longitudinal interpretation are summarized in the Longitudinal Interpretation section.

Three critical aspects of traditional pulmonary function evaluation influence cross-sectional interpretation: (a) the source of the reference values used; (b) how the reference values are adjusted when a worker's race/ethnicity differs from the reference study subjects; and (c) selection of the interpretation algorithm used to categorize pulmonary function as normal or abnormal, that is, the choice of lung function parameters to be evaluated and the sequence in which they are examined.

Reference Values

As stated by the ATS 1991, "A reference population should, ideally, be representative of the general population from which the clientele of the laboratory comes."³¹ Reference values define the average and the lower boundary of the normal range for individuals similar to the tested worker for factors related to the size and shape of the thoracic cavity, that is, age, height, race, and sex. Obtaining accurate information on these characteristics for the worker is critical to accurately interpreting spirometry results, and inaccurate information can lead to incorrect assessment of a worker's pulmonary function. Reference values are obtained from research studies of asymptomatic never smokers of varying ages, heights, and sex, and optimally, varying ethnic/racial backgrounds. Subject ethnic/racial group should be based on self-report and standing height in stocking feet should be measured periodically and not simply reported by the subject.⁵ The worker's sex should be sex assigned at birth,^{5,32,33} though this might misclassify some transgender workers who began gender-affirming hormone therapy before the onset of puberty. (Defining best practices to elicit an accurate sex designation from transgender workers warrants further research.) The relationships of pulmonary function parameters with these four demographic variables are summarized in regression equations, which produce average "predicted" values and 5th percentile LLN. (Note that LLN is equivalent to a Z-score of -1.645). Since predicted values and LLNs describe the average and the bottom of the normal range based on a single research study, both indices need to be drawn from a single source of reference values.^{31,34}

Many reference values studies have been conducted in a single geographical location,^{35,36} but ATS/ERS,^{2,9,19–21,34} ACOEM,⁴ OSHA,^{8,15} and the AMA Guides 6th edition,³⁷ support using reference values from the National Health and Nutrition Examination Study, Round III (NHANES

III)²² for occupational testing in the US. NHANES III tested large random samples of nonsmoking asymptomatic US Caucasians, African Americans, and Mexican Americans. Equipment and testing protocols were held constant and quality control was strictly maintained, so that observed differences between groups reflect biological differences and not simply varying equipment or testing techniques. Race-specific NHANES III reference equations are available for Caucasians, African-Americans, and Mexican-Americans (Hispanics).

However, uncertainty about whether the NHANES III values were a good fit for countries outside of the United States prevented the ATS/ERS from recommending NHANES III for use in Europe and other countries. To meet the need for reference values for Europe and other parts of the world, and for subjects younger and older than the NHANES population, the Global Lung Function Initiative (GLI) combined data from 70 research studies in 26 countries (mostly outside of North America) and published the GLI-12 equations.³⁸ Though ATS/ERS recently recommended use of the GLI equations in Europe, Australia, New Zealand, and North America,^{5,9} particularly in clinical research studies to permit comparisons with international studies, they stated that the NHANES III values "remain appropriate where maintaining continuity is important,"⁹ as it is the occupational setting.² Also in November, 2019, the ATS/ERS stated that "for occupational spirometry testing in the United States, the use of the NHANES III spirometry reference values is in full compliance with the 2019 Update of the ATS/ERS Spirometry Standards."^{19–21} Effective July 15, 2019, OSHA mandated use of the NHANES III reference values when workers are tested under the updated cotton dust standard.¹⁵ And since "a reference population should, ideally, be representative of the general population from which the [subjects come],"³¹ workers who are tested in the United States are best compared with values obtained from the highly standardized NHANES III research study conducted in the United States.

OSHA mandates use of the NHANES III (Hankinson 1999) reference values for occupational spirometry testing required by the updated Cotton Dust Standard¹⁵ and recommends NHANES III normal values for use⁸ in occupational testing under other regulations, unless a regulation mandates another specific set of reference values. ACOEM, ATS/ERS, and the AMA Guides 6th edition endorse use of the NHANES III reference values in occupational testing in the United States.²² Most spirometers calculate NHANES III reference values, and tables of NHANES III predicted values and LLNs are in Appendix A of the OSHA

Guidance document.⁸ If not calculated by older spirometers, NHANES reference values can be calculated using a Reference Value Calculator.³⁹ Since reference values can vary significantly and affect the percent of predicted values, the selected reference values should always be identified on the spirometry printout, as noted earlier.

Race-Adjustment of Predicted Values and LLNs

If a worker's self-reported race/ethnicity is the same as the reference value group, no adjustment of the reference values is required. Since NHANES III reference values were generated specifically for Caucasians, African-Americans, and Mexican Americans (used for Hispanics), the predicted values and LLNs are not adjusted when workers of these race/ethnicity groups are tested. However, when Asian-American workers (ie, Chinese, Japanese, Indian, or Pakistani) are tested, race-specific NHANES reference values are not available. To determine appropriate Asian-American reference values, Caucasian values for FVC and FEV₁ should be multiplied by a scaling factor to account for the larger average thoracic cavities observed in Caucasians compared with Asian-Americans of the same age, height, and sex. The scaling factor required by OSHA in 2019 and recommended by ATS/ERS in 2014, 0.88, was based on recent evidence indicating that it minimizes false positives when used to calculate Asian-American reference values.^{2,8,15,40}

*ACOEM and ATS/ERS recommend that race-specific NHANES III reference values be used whenever possible, basing the worker's race/ethnicity on self-report. To evaluate Asian-American workers, ACOEM recommends applying a scaling factor of 0.88 to Caucasian predicted values and LLNs for FVC and FEV₁. For cotton-exposed workers, OSHA requires that the 0.88 scaling factor be used for Asian-American workers. Note that FEV₁/FVC predicted values and LLNs are **not** adjusted.*

Interpretation Algorithm

For almost three decades, ATS has recommended applying a stepwise algorithm to three pulmonary function parameters to interpret spirometry results.^{2,9,31,34} ACOEM endorsed this approach in its previous statements^{1,4} and OSHA adopted it in their Guidance document.⁸ Since consensus exists on how to distinguish normal from abnormal results, and which measurements identify obstructive or possible restrictive impairment, these determinations are presented in Fig. 4. Since recommendations for grading severity of impairment are quite disparate,^{34,41} this statement's interpretation algorithm (Fig. 4) does not grade severity of impairment.

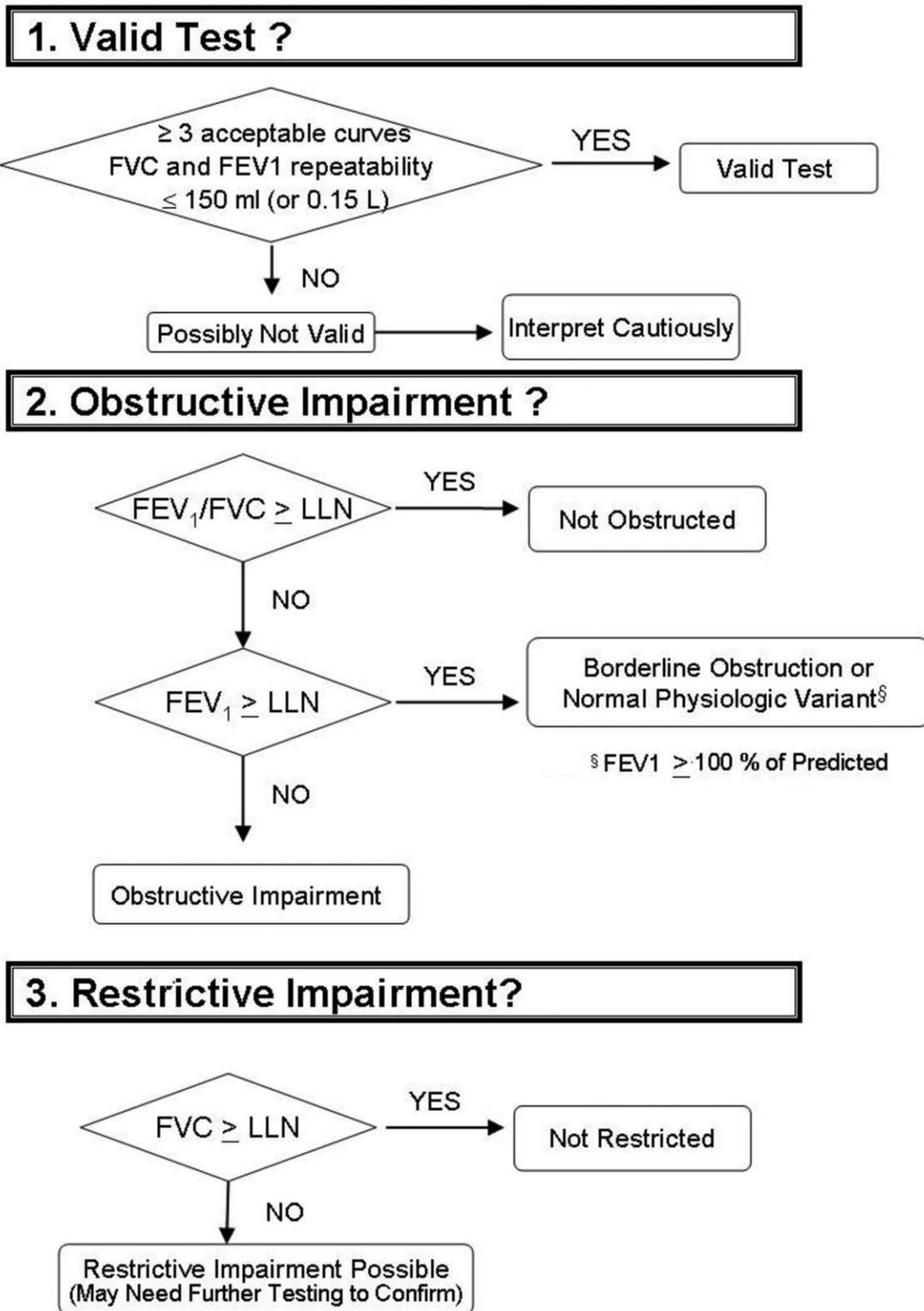


FIGURE 4. Spirometry interpretation algorithm. Based on “Spirometry Testing in Occupational Health Programs: Best Practices for Healthcare Professionals.” OSHA 3637-013.⁸ LLN, lower limit of normal; OSHA; Occupational Safety and Health Administration.

LLN Defines Abnormality

Since 1991, ATS has officially endorsed using the 5th percentile, the point below which only 5% of nonexposed asymptomatic subjects are expected to fall, as the LLN range.^{2,9,31,34} (As previously noted, the LLN corresponds to a Z-score of -1.645 .)

Determining what constitutes an abnormal versus a normal spirometry result is particularly important when spirometry is performed related to the workplace. In addition to prompting further evaluation of a worker and workplace exposures, an 'abnormal' spirometry result can also impact a worker's job (eg, determining job placement). The ATS/ERS and ACOEM recommend using the fifth percentile lower limit of normal (LLN) to differentiate normality from abnormality, rather than a fixed value, such as 80% of predicted for the FEV₁ and FVC, or 0.70 for the observed ratio of FEV₁/FVC.²

Because the Global Initiative for Chronic Obstructive Lung Disease criteria have been used in the primary care setting to screen smokers and symptomatic patients for chronic obstructive pulmonary disease,⁴² clinics may erroneously adopt the fixed cut-point of a measured ratio of less than 0.70 to indicate the presence of airways obstruction for all individuals. Since the measured ratio declines by about 10% across the decades from 20 to 70, a fixed cut-point is only accurate in the middle of that age range and not in younger or older individuals. As an example, for Caucasian males, the NHANES III LLN for the FEV₁/FVC ratio equals 0.70 at about age 40. But at age 20, the ratio LLN is 0.74 and at age 70, it is 0.64. This means that young people who should be exhaling 74% or more of their volume in the first second will not be labeled with "airways obstruction" until their ratio is less than 0.70 if the GOLD criterion for obstruction is used. In occupational settings, where the goal is to identify impairment at an early stage, these are unacceptable false negatives. The older subject has the opposite problem: many older people who are not obstructed will exhale less than 0.70 of their volume in the first second. These false positives may result in unnecessary job restrictions or treatment.

As ATS has stated: "The fixed values commonly used. . . are estimates based on middle-aged adults, and therefore erroneous clinical decisions based on these fixed cutoffs are more likely to occur"^{2,9} in young workers and in those with small lung volumes, ie, older, shorter, and/or female adults. And "because the FEV₁/FVC ratio declines with age, using a fixed value, such as 0.70, to determine an

obstructive defect will result in false negative results for younger workers, and false-positive results in older workers."² Using the 5th percentile LLN to define abnormality for the major spirometry measurements avoids such problems.^{43,44}

"Spirometry values that are below the fifth percentile LLN are considered abnormal, and may reflect a pulmonary problem. However, by definition, 5% of a healthy population will also fall below the fifth percentile LLN"² and so false positives are possible. According to ATS, "interpreters should be aware of uncertainty when interpreting values near any dichotomous boundary . . . and so caution is indicated when interpreting values close to the LLN."⁹ ATS gives a practical example of how clinical circumstances affect a diagnosis of impairment:

For example, consider the meaning of a spirometric study that shows FEV₁ values and other expiratory flow rates to be just above the lower limit of normal. If the patient were a healthy male who sought medical assistance because he was disqualified for life insurance on the basis of his spirometry, it would be appropriate to interpret his spirometry as within normal limits. If, in contrast, the same data were obtained from a smoker with complaints of intermittent coughing and occasional wheezing, it would be appropriate to suggest that the study is consistent with mild obstructive dysfunction, although it could also represent a variant of normal. *In both of these instances, computer printouts, or robotic physician interpretation that simplistically declare the results to be 'normal' or 'abnormal' on the basis of whether the observed values fall to one side or the other of a single number, could give information that does not perform a useful service to the patient[emphasis added].*³¹

Applying the Interpretation Algorithm

Spirometry interpretations should specify whether the worker's lung function is in the normal range, or shows an obstructive, restrictive, or mixed impairment pattern. Merely stating which values are normal or low, without concluding if there is an impairment pattern, is not helpful.³⁴

"OSHA recommends following the algorithm pictured in Fig. 4 to interpret lung function. This general approach has previously been recommended by ACOEM,⁴ ATS/ERS,³⁴ and NIOSH.⁴⁵ Figure 4 lists three steps to be followed in interpreting spirometry test results: first, evaluate the validity of the test results, second, assess

whether expiratory airflow is slowed (obstructive impairment), and finally, consider whether expired lung volumes might be reduced (restrictive impairment). It is important to follow the steps in the order specified to minimize false positive findings when interpreting spirometry test results. All three steps should be evaluated for every set of test results.

The algorithm shown in Fig. 4 is used to classify the worker as having:

- Obstructive impairment (airways obstruction);
- Possible restrictive impairment;
- Possible mixed impairment (both obstructive and possible restrictive impairments); or
- Normal spirometry results (no obstructive or restrictive impairment).

Each of these classifications is described below, following the sequence in Fig. 4.⁸

Is Test Valid?

As shown in Fig. 4, the first step in interpreting spirometry test results is to determine whether a valid test has been performed or if more maneuvers may be needed. ATS/ERS has cautioned that "omitting the quality review and relying only on numerical results for clinical decision making is a common mistake, which is more easily made by those who are dependent upon computer interpretations."³⁴

Obstructive Impairment

Once test validity is established, FEV₁/FVC is the first measurement to be evaluated, to "distinguish obstructive from nonobstructive patterns."³¹ When the FEV₁/FVC and FEV₁ are both less than LLN, airways obstruction is present. However, when FEV₁/FVC is less than LLN, but FEV₁ is greater than LLN, borderline obstruction or "possible physiologic variant" may exist.^{31,34}

ATS/ERS cautions that FEV₁/FVC less than LLN combined with FEV₁ greater than equal to 100% of predicted is "sometimes seen in healthy subjects, including athletes" and "is probably due to 'dysanaptic' or unequal growth of the airways and lung parenchyma."³⁴ This pattern is labeled as a "possible physiologic variant,"^{31,34} and is not unusual among physically fit non-smoking emergency responders, firefighters, and police. However, if these healthy workers are exposed to known hazardous substances, the possibility of obstructive impairment needs to be considered when a reduced FEV₁/FVC is observed.

Restrictive Impairment

FVC, the forced expiratory measurement of vital capacity, is next evaluated to

determine whether restrictive impairment may exist. If FVC less than LLN, restrictive impairment is possible, and true restriction will need to be confirmed using additional pulmonary function tests, such as lung volume measurements.

However, in the presence of airways obstruction ($FEV_1/FVC < LLN$), FVC less than LLN indicates a possible mixed impairment pattern (not labeled in the flow-chart), whose restrictive component may need to be confirmed by additional pulmonary function tests.

Static lung volume measurements are necessary to distinguish restrictive from mixed-restrictive and obstructive abnormalities. When only spirometry is available, it is not possible to determine whether restriction is present, because the FVC may be reduced by restriction due to a reduced Total Lung Capacity (TLC) or by elevation of the residual volume due to air trapping.^{6,34}

Normal Spirometry Results

If $FEV_1/FVC \geq LLN$, there is no obstructive impairment and if FVC greater than equal to LLN, there is no restrictive impairment: the worker has normal spirometry results. Since the LLN is defined so that 5% of healthy individuals will fall below it, spirometry results from a worker without any apparent health problems are occasionally found to be slightly below the LLN. As noted above, such values, just above or just below the LLN should be interpreted with caution. The worker should be retested at a later date to confirm the results and, if still abnormal, the complete clinical presentation should be evaluated. Additional tests of pulmonary function should be done if clinically indicated.

Forced Expiratory Flow Rates (FEF)

As presented above, because of the wide variability of the $FEF_{25\% \text{ to } 75\%}$ and the instantaneous flow rates, both within and between healthy subjects, ATS/ERS continues to discourage their use for diagnosing small airway disease in individual patients,^{6,9,31,34} or for assessing respiratory impairment. Interpretation of $FEF_{25\% \text{ to } 75\%}$ and other flow rates is not generally recommended if the FEV_1 and the FEV_1/FVC are within the normal range.^{46,47} If flow rates are interpreted at all, “the wide variability of these tests in healthy subjects must be taken into account in their interpretation.”³⁴ “The practice of using 80% of predicted as the lower limit of normal for $FEF_{25\% \text{ to } 75\%}$ or the instantaneous flows will cause important errors since, for these flows, the lower limits of normal are closer to 50% of predicted.”^{31,34}

ACOEM and OSHA recommend that occupational medicine practitioners follow the algorithm pictured in Fig. 4 to separate normal from abnormal test results. This general approach has also been recommended by ATS/ERS³⁴ and NIOSH.⁴⁵ Presence of airways obstruction is indicated by FEV_1/FVC below the worker’s LLN, and possible restrictive impairment is indicated by FVC less than LLN. Practitioners need to remember that an FEV_1/FVC that is barely abnormal, in the presence of $FEV_1 \geq 100\%$ of predicted, may indicate “possible physiologic variant” pattern in healthy nonsmoking workers, such as emergency responders. However, if such healthy workers are exposed to known respiratory hazards, the possibility of airways obstruction should also be considered when an abnormal FEV_1/FVC is observed. Interpretation of results that are near the LLN should be performed with caution.

LONGITUDINAL INTERPRETATION

Since “workers can undergo periodic, often annual, spirometry tests in mandated or recommended medical surveillance programs, it is important to evaluate such measurements not only relative to normal ranges [based on predicted values and LLNs], but also relative to the workers’ baselines, particularly when lung function values are within the normal range. Many workers have FVC and FEV_1 that exceed their predicted values. Such individuals must lose a significant portion of their lung function before their spirometry results fall below the LLN, and they are identified as abnormal. Longitudinal evaluations of periodic spirometry testing may detect excessive lung function loss due to an exposure or underlying condition earlier than using a single spirometry test”² for these individuals. However, while an FEV_1/FVC or FVC less than LLN is widely recognized as indicating obstructive or possible restrictive lung impairment, interpreting a greater than expected loss in FEV_1 is less well standardized and should not be used to label workers as impaired, but rather as a guide to designate workers who may need more medical follow-up.

“How to evaluate loss of lung function over years [had] not been directly addressed by the ATS or ERS,”^{2,34} so an ATS committee “performed an evidence-based systematic literature review to identify evidence relevant to the question of how to evaluate excessive decline in lung function.”² Results from that review are summarized here. “Assessment of decline in lung function is affected by several factors [which are considered below], including: spirometry technical quality and test variability; testing frequency and duration

of follow up; and definition of excessive decline. The primary measurement used to assess longitudinal change should be the FEV_1 , as it is less affected by technical factors than the FVC.”^{2,4,34}

Spirometry Testing Quality and Test Variability

Some diseases cause increased variability in spirometric measurements over time.^{2,31,48–52} However, increased variability of measurements can also be due to technical flaws in testing technique or equipment. “Comprehensive spirometry programs should be established so that valid measurements are recorded over time. Even with good programs [emphasis added], spirometer inaccuracy and imprecision and survey biases (unexplained technical changes) may limit the size of the detectable change or contribute extraneous variability to longitudinal measurements.² Changes in weight over time should be recorded, since weight gain can contribute to decline in lung function.^{2,3,9} Maintaining calibration check records and tracking spirometry results for groups of workers over time (eg, mean FEV_1 , within-person variation, proportions of high or low values) can help identify ongoing health hazards and also anomalous results possibly resulting from technical issues.”^{2,3,8}

Frequency and Duration of Testing

“As length of follow up increases, real decline in pulmonary function becomes easier to distinguish from background measurement variability. The precision of the estimated rate of FEV_1 decline improves with increasing frequency of measurement and duration of follow-up.^{2,53} Because chronic occupational respiratory diseases (such as chronic obstructive pulmonary disease and pneumoconiosis) typically develop over many years, spirometry performed less frequently than annually (eg, every 2 to 3 y) should be sufficient to monitor for the development of such diseases.² However, for diseases that can develop more rapidly (such as flavoring-related lung disease or occupational asthma), more frequent follow up at intervals of 6 months to 1 year may be appropriate.”²

Determination of Abnormally Reduced or Highly Variable FEV_1

“Great care is required in determining what constitutes an ‘excessive’ FEV_1 decline [or unusually variable measurements] when evaluating periodic testing in worker populations. It is important to avoid the consequences of either false-positive or negative findings. The purpose of such periodic testing is to detect

progressive lung disease at an earlier stage, which might otherwise be missed, especially when lung function values are above LLN.”²

Due to “the relatively large technical variability often encountered in spirometry testing,” longitudinal evaluation “methods are most effective for evaluating declines in FEV₁ over relatively long time periods (≥ 5 y).”² “Excessive shorter-term (< 5 y) longitudinal FEV₁ declines have been shown to presage long-term losses, but can be difficult to interpret in any individual worker. . . . Despite this variability, to protect lung health among workers with diseases that develop rapidly, clinicians may need to identify individuals who may have experienced declines in FEV₁ over shorter time periods (months to a few years).”²

But ATS cautions that “the greatest errors occur when one attempts to interpret serial changes in subjects without disease because test variability will usually far exceed the true annual decline, and reliable rates of change for an individual subject cannot be calculated without prolonged follow-up. Thus, “yearly changes [in FVC or FEV₁] of 15% or more were generally thought by the [ATS] Workshop to be clinically important.”^{31,54}

In 2014, ATS concluded that “The most practical thresholds for clinicians to use in comparing longitudinal FEV₁ measurements are based on a 15% loss from baseline, taking into account expected age-related loss. . . . A threshold of 15% decline in FEV₁ from baseline to follow up for longer periods of time, beyond the expected loss due to aging during the follow-up period, has been recommended by NIOSH to monitor coal miners⁵⁵ and by ACOEM.”^{3,4} As also noted by the California Department of Health,²⁹ and OSHA,⁸ this cut-off is chosen to avoid the false positives that may occur when pulmonary function is measured in many nonstandardized, real-world clinic situations. This approach will identify FEV₁s that are lower than expected due to aging, whether due to steeper declines in function or unusually variable measurements over time. And as noted above, this method was designed to monitor FEV₁ from baseline on, regardless of the length of follow-up.^{2,55}

The easiest way to calculate the allowed FEV₁ decline of 15% beyond that expected due to aging is to apply the “Percent Predicted Method”² (previously known as “Method 1 for Baselines greater than 100% Predicted”³):

Baseline (initial) FEV₁% of predicted minus current FEV₁% of predicted; Interpretation: If $\geq 15\%$, then observed decline in FEV₁ may be excessive, or variability of measurements may be increased.²

For example, if a worker’s initial FEV₁ was 120% predicted, his decline might be considered excessive or his results extremely variable if he falls to 105% predicted (a decrease of 15% of predicted), even though he is still above average and remains well above the LLN. First his tests would be reviewed for technical quality and the follow-up test possibly repeated. If the conclusion remained the same, a medical evaluation would be considered as described in section 5 below.

Though a “volume method”² was originally described as “Method 2 for Baselines less than equal to 100% Predicted,”³ it is more cumbersome than the percent predicted method and the two approaches “provide very similar thresholds for excessive decline in FEV₁.”² Similarly, regression of FEV₁ on time^{1,3} requires greater than or equal to 5 years of follow-up, is not appropriate if FEV₁ decline is not linear, and a fixed mL/y threshold will flag workers with low baseline FEV₁s sooner than workers with higher FEV₁s.² Therefore, in clinical settings, ACOEM recommends adopting the simpler “Percent of Predicted” method instead of the “volume” or regression methods.

The “Percent Predicted” approach and more complicated computerized approaches “are quantitatively similar” when within-person testing variability is about 6%, as is probably common in real-world testing scenarios.^{31,54} And “spirometry programs with more variability should evaluate if it is due to technical issues or increased prevalence of disease, and should use the 15% approach above to evaluate individual results.”² So for most occupational testing, use of the “Percent Predicted Method” is recommended² and it is appropriate for any length of follow-up.⁵⁵

However, “for diseases that develop rapidly, declines in FEV₁ of less than 15% over shorter time periods may be clinically important,”² if they identify workers who should have further evaluation for possible disease. If spirometry programs maintain tighter QA programs and their measurements have less within-person technical variability, declines of 10% to 15% may indicate a problem. One computerized approach, Spirola, accounts for variability among measurements as it determines a threshold for abnormal decline or measurement variability.⁵⁶ For follow-ups less than or equal to 5 to 8 years, the computerized lower limit of longitudinal decline (LLD) method,⁵⁶ may flag smaller declines as “abnormal” when within-person variability is minimal. This may be particularly important when “diseases that can develop more rapidly (such as flavoring-related lung disease or occupational asthma),” are of concern, and “more frequent follow

up at intervals of 6 months to 1 year may be appropriate.”²

But as ATS cautions, “these small short-term longitudinal changes (≤ 5 years) may be difficult to interpret because of the relatively large inherent FEV₁ technical variability in spirometry testing.”² It is essential that the assumptions that underlie application of a computerized program are understood. For example, Spirola requires specification of a within-subject variability of measurements and a reference rate of loss of function. Spirola’s recently used default setting of 4% variability and 40 mL/y are not universally appropriate, and the assumed within-person variability, in particular, dramatically impacts the number of subjects flagged as having an abnormal FEV₁ decline or abnormally variable measurements.⁵⁷

It is important to note that NIOSH now recommends setting Spirola’s defaults to match “the ACOEM-recommended longitudinal limit based on a decline of 15% from baseline in excess of that expected due to aging. [This] can be specified by selecting a 6% pairwise-within person variation and 30 mL/y referential rate of decline in the Options tab. Those defaults will be used in the next release of SPIROLA.”⁵⁸

Though the Percent Predicted method can be used to monitor “decline in FEV₁ from baseline to follow up for longer periods of time”² the computerized LLD method is not recommended for follow-up greater than 5 to 8 years. For these longer follow-ups, the computerized LLD method should be replaced by the Percent of Predicted method.

And finally, it must be borne in mind that an “abnormal” decline must be “considered together with other information (eg, spirometry quality, respiratory symptoms, exposure to respiratory hazards such as tobacco smoking or occupational exposures, radiological findings). Before making a final decision, the quality of the baseline and final spirometry tests should be evaluated, and if needed, spirometry should be repeated.”⁵⁹ The ATS caveat about avoiding errors “when one attempts to interpret serial changes in subjects without disease”³¹ must always be considered.

ACOEM recommends that the interpretation of pulmonary function change over time start with an evaluation of technical quality of the tests and an adequate length of follow-up. When high quality spirometry testing is in place, ACOEM recommends further medical evaluation for workers whose FEV₁ falls more than 15% below that which is expected due to aging. The Percent Predicted method is the easiest way to assess FEV₁ longitudinally for usual occupational health clinic measurements and can be used for all lengths of follow-up.

Smaller declines of 10% to 15%, after allowing for the expected loss due

TABLE 7. Workers Referred for Further Evaluation*

1. Assess technical quality of spirometry and repeat testing if indicated based on spirometry quality, and other relevant information below
2. Obtain comprehensive medical and occupational history and physical exam including:
 - (a) Work and exposure history
 - (b) Smoking history
 - (c) Respiratory symptoms, timing in relationship to work
 - (d) Physical exam, including lung exam and chest wall deformities
 - (e) SDSs, results of workplace measurements, if available
3. Review preemployment, follow-up questionnaires and spirometry, if available
4. Possible additional diagnostic testing:
 - (a) If airflow obstruction, spirometry with bronchodilator response
 - (b) If restrictive pattern, full pulmonary function tests (lung volumes, diffusing capacity)
 - (c) Chest imaging (chest x-ray, CT scan)
 - (d) If asthma, consider peak flow recordings at and away from work
 - (e) If interstitial lung disease, consider high resolution chest CT scan
 - (f) If nonreversible airflow obstruction, consider occupational etiologies, even in smokers (eg, occupational COPD, bronchiolitis obliterans)
5. If a possible work-related problem is identified, consider other at-risk workers

SDS, Safety Data Sheet.

*Reprinted with permission of the American Thoracic Society. Copyright © 2019 American Thoracic Society. Redlich C, Tarlo S, Hankinson J, Townsend MC, et al. Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting. *AJRCCM*; 189(8):984–994, 2014. *The American Journal of Respiratory and Critical Care Medicine* is an official journal of the American Thoracic Society.²

to aging, may be important in diseases that progress rapidly and have tests performed more frequently than annually.⁶⁰ These smaller declines must first be confirmed, and then, if the technical quality of the pulmonary function measurement is adequate, acted upon. In such cases, a computerized approach may detect small but important early changes in function if the spirometry testing is of very high technical quality.

FURTHER EVALUATION OF SPIROMETRIC ABNORMALITIES

Although ACOEM has stated that “excessive declines” in FEV₁ should trigger further medical surveillance once the declines were confirmed, the details of medical follow-up were not specified.⁴ But in 2014, ATS described an “Action Plan for Spirometry in the Work Setting.”² Steps in evaluating workplace spirometry results and further medical evaluation plans were given in detail. Those details are presented in this section.

“Workers with values below the LLN and/or an excessive decline in FEV₁ should be further evaluated for potential causes and preventable risk factors. Factors such as work exposures, respiratory symptoms, and medical information (eg, diagnoses, medications) should always also be considered, as spirometry values or rates of decline can remain “normal” when other factors may indicate that further evaluation is needed.”²

“The specific steps to be taken will depend on several considerations, including the exposures of concern, the magnitude of

the lung function abnormality and/or decline over time, and the clinical context.”² Detailed suggestions from ATS are shown in Table 7.² Moreover “in addition to management of the individual worker, the analysis of aggregate worker data (from the same workplace, company, job, or industry), both cross-sectional and longitudinal, can offer significant benefit.”²

RECORDKEEPING

“Adequate recordkeeping is a critical component of a good spirometry program. To improve the quality of spirometry testing programs, OSHA makes recommendations below on three recordkeeping components: (1) spirometry test reports; (2) equipment maintenance records; and (3) personnel training and evaluation records.”⁸ ATS and ACOEM recommend that “to protect worker confidentiality, providers must not disclose individual workers’ personal health information to employers without employee consent.”^{2,61}

1. Spirometry Test Reports: Most OSHA standards require employers to ensure that medical records for each worker, including the spirometry test results, are maintained for at least 30 years following the end of employment (see 29 CFR 1910.1020).⁸ Details of the recommended spirometry report format are given elsewhere.⁸ Record storage methods should be updated as technology changes to assure future record access.

Under the OSHA silica rule, employers must: (1) retain medical records which are in their possession (eg, the Physician or Licensed Health Care Practitioner’s (PLHCP) written medical opinion about any limitations on respirator use); and (2)

ensure that medical records in the PLHCP’s possession (eg, written medical report) are retained. To meet the second obligation, employers can include the retention requirement in a written agreement with the PLHCP, or the employer can otherwise specifically communicate OSHA’s record-retention requirements to the PLHCP.¹⁰ A recent Letter of Interpretation on this topic describes the limited amount of information that may be given to the employer under both the Silica and Respiratory Protection Standards, stating that these standards “do not authorize the transfer of spirometry test or other medical records to employers.”¹⁶ These issues and others are addressed in OSHA’s Occupational Exposure to Respirable Crystalline Silica 29 CFR §1910.1053 and §1926.1153: Frequently Asked Questions for General Industry and for Construction.^{62,63}

2. Equipment Maintenance Records: “Since equipment maintenance records support the accuracy of the spirometry test results in the medical record, OSHA recommends saving the equipment calibration check log and information about the spirometer. Availability of such records permits later troubleshooting of problematic spirometry test results, which is particularly important when conducting periodic spirometry testing.” Details of the recommended equipment maintenance records to be retained are given elsewhere.⁸ Record storage methods should be updated as technology changes to assure future record access.

3. Personnel Training and Evaluation Records: OSHA recommends that personnel qualifications be documented and available for review. Records should include: technician continuing medical education, certificates from completed NIOSH-approved spirometry training courses, and results of evaluation and feedback to technicians.

ACOEM Recommendations—2020

1. Equipment Performance
 - ACOEM recommends that facilities performing occupational spirometry tests maintain a procedure manual documenting equipment type, spirometer configuration, manufacturer’s guidelines, calibration check log, service and repair records, personnel training, and standard operating procedures. Such a manual will permit troubleshooting if problems arise with test results.

a. Spirometer Specifications

1. ACOEM recommends that spirometers of all types meet or exceed recommendations made by ATS/ERS 2005 and by ISO 26782:

- Performance-based criteria for spirometer operation, including, for example, accuracy, precision, linearity, frequency response, expiratory flow impedance, and other factors;
- Minimum sizes and aspect ratios for real-time displays of flow-volume and volume-time curves (Appendix A); and
- Standard electronic spirometer output of results and curves.

2. It is also recommended that spirometers which will be used in the occupational setting:

- Store all information from up to eight maneuvers in a subject test session;
- Permit later editing and deletion of earlier flawed test results;
- Be capable of including flow-volume and volume-time curves and test results from at least the 3 best maneuvers, and preferably from all saved efforts, in the spirometry test report;
- Provide computer-derived technical quality indicators;
- Provide a dedicated routine for verifying spirometer calibration; and
- Save indefinitely a comprehensive electronic record of all calibration and calibration verification results.

b. Validation Testing of Spirometers

If spirometers are purchased for use in the occupational health setting, ACOEM recommends that:

- The manufacturer provides written verification that the spirometer successfully passed its validation testing, preferably conducted by an independent testing laboratory, and that the tested spirometer and software version correspond with the model and software version being purchased; and
- The spirometer meets the ATS/ERS recommended minimum real-time display for flow-volume and volume-time curves and ISO minimum aspect ratios for these displays, as well as providing a standard spirometer electronic output (Appendix A).

c. Spirometer Accuracy Checks

ACOEM recommends that:

- Spirometer accuracy be checked daily when in use, following the steps summarized in Table 3;
- Tracings and records from these checks be saved indefinitely;
- A log is kept of technical problems found and solved, as well as all changes in protocol, computer software, or equipment; and
- Spirometers purchased for use in the occupational setting have dedicated calibration check routines (as noted above.)

d. Avoiding Sensor Errors during Subject Tests

- Users of flow-type spirometers need to recognize the flawed curves and test results that may be caused by sensor contamination or zero-flow errors (Fig. 2), and
- Protocols need to be established and used to prevent these errors from occurring and to correct the errors if they do occur. See text for specific suggestions.

2. Conducting Tests

a. Technician Training

- All technicians conducting occupational spirometry tests should successfully complete a NIOSH-approved spirometry course initially, and a NIOSH-approved refresher course every 5 years. Such training is mandatory if cotton dust- or respirable crystalline silica-exposed workers are tested. NIOSH-approved courses are also mandatory for those testing coal miners in the NIOSH CWHSP program.

b. Conducting the Test

- Consistent with decades-long occupational spirometry testing protocol, technicians need to explain, demonstrate, and actively coach workers to perform maximal inspirations, hard and fast expiratory blasts, and complete expirations. ATS/ERS has confirmed that this protocol meets the requirements of the 2019 Spirometry Update.^{19–21}
- Testing should be conducted standing, positioning a sturdy chair without wheels behind the subject, unless the subject has previously sat for the test or experienced a problem with fainting or is deemed to be at risk of fainting or falling.
- Record test posture on the spirometry record and use the same posture for all serial tests over time.
- Disposable nose clips are recommended.

c. Testing Goal for a Valid Test

- To achieve a valid test, occupational spirometry should attempt to record or more three acceptable curves, with FVC and FEV₁ repeatability of 0.15 L (150 mL) or less. See text for definitions of terms.
- Failure to achieve repeatability is often caused by submaximal inhalations, though very poor repeatability (eg, >0.50 L) may indicate sensor contamination or zero-flow errors.
- Workers who are young, have small body frames, or restrictive lung disease often reach their FVC plateaus very quickly. Such tests, if repeatable,

are valid, even if the spirometer flags the effort as unacceptable or invalid. *There is no longer a minimum length of exhalation required for an acceptable test,*⁵ though it is unlikely that spirometer software will be updated immediately to reflect this change.

- ATS test acceptability requirements are presented in Table 4. Importance of a valid test is summarized in Table 5.

d. Reporting Results

- Spirometry test reports need to present values and curves from all (or at least the best three) acceptable maneuvers to permit technical quality to be fully evaluated, and
- The largest FVC and largest FEV₁ are interpreted, even if they come from different “acceptable” curves.
- Default spirometer configurations often need to be adjusted to meet these recommendations.

e. QA Reviews

- ACOEM recommends that facilities performing occupational spirometry tests need to establish on-going programs providing QA reviews of spirometry.
- Reviews need to be conducted at least quarterly, and more often if technicians are inexperienced or if poor technical quality is observed.
- The goal of such reviews is to assure that 80% or more of an occupational health program’s spirometry tests are technically acceptable.
- It is recommended that QA reviewers be experienced in recognizing and correcting flawed spirometry test results.
- Table 6 presents ATS test quality categories for FVC and FEV₁.

3. Comparing Results With Reference Values

a. Reference Values

- ACOEM recommends that the NHANES III (Hankinson) reference values²² be used for occupational spirometry in the United States unless a regulation mandates another specific set of reference values. OSHA mandates use of NHANES III in the recently updated Cotton Dust Standard.¹⁵ NHANES III values are recommended for the United States when continuity over time is important, as it is in occupational health, and ATS/ERS has confirmed that use of NHANES III reference values is in full compliance with the 2019 ATS/ERS Spirometry Standardization Statement.^{19–21}
- It is essential to obtain accurate worker information on factors that

are related to the size and shape of their thoracic cavity, that is, age, height, sex, and race. Details of gathering this information are presented in the section Comparing Results With Reference Values; Reference Values, and new recommendations are made for testing transgender workers.⁵

b. Race-Adjustment of Predicted Values and LLNs

- Use NHANES III race-specific reference values, basing a worker's race/ethnicity on self-report.
- As recommended by ACOEM and required by OSHA's Cotton Dust Standard,¹⁵ a scaling factor of 0.88 should be applied to Caucasian predicted values and LLNs for FVC and FEV₁ to obtain appropriate reference values for Asian-American workers.
- The predicted FEV₁/FVC and its LLN are *not* race-adjusted.

c. Interpretation Algorithm

- Spirometry results should always be interpreted in light of the full clinical picture of the worker.
 - Figure 4 presents a three-step interpretation algorithm to use when distinguishing normal from impaired workers.
 - To separate normal from abnormal test results, first examine the FEV₁/FVC to determine whether obstructive impairment is present, and then evaluate the FVC to determine if restrictive impairment may exist. The FEV₁ is examined if the FEV₁/FVC indicates possible obstructive impairment, as shown in Fig. 4.
 - All three indices of pulmonary function are considered abnormal if they fall below their 5th percentile LLN. Fixed cutoff points for abnormality such as 80% of the predicted value or an observed FEV₁/FVC ratio less than 0.70 should not be used in the occupational health setting since they are known to cause known false positives and false negatives.
 - An FEV₁/FVC that is barely abnormal, in the presence of FEV₁ greater than 100% of predicted, may indicate a “possible physiologic variant” in healthy individuals. However, if such healthy workers are exposed to known respiratory hazards, clinical judgment is needed to evaluate the possibility of early airways obstruction.
 - Values that are either just above or just below the LLN should be interpreted with caution.
4. Evaluating Results Over Time
- Spirometry results should always be interpreted in light of the full clinical picture of the worker.
 - Evaluate technical quality of the spirometry tests and the adequacy of the follow-up period before interpreting change in pulmonary function over time.
 - ACOEM recommends that FEV₁ losses of greater than equal to 15% since baseline, after allowing for the expected loss due to aging, trigger further medical evaluation when spirometry is of high technical quality. The simplest method to use is the Percent of Predicted method, comparing the baseline FEV₁% Predicted with the follow-up FEV₁% predicted, as described in Section 4c.
 - The Percent of Predicted method and computerized methods give virtually identical results when the length of follow-up is less than or equal to 5 to 8 years. For longer follow-ups with many measurements, ACOEM recommends use of the Percent of Predicted Method.
 - ACOEM recommends that a confirmed FEV₁ decline of 10% to 15% since baseline, after allowing for the expected loss due to aging, would trigger further medical evaluation in rapidly developing diseases with very frequent measurements. For short-term follow-ups when high technical quality of testing is maintained, a computerized algorithm may be recommended.
 - Assumptions that underlie application of a computerized program must be understood and evaluated for appropriateness. NIOSH now recommends setting Spirola defaults to be consistent with ATS recommendations: 6% within-person measurement variability and 30 mL/y expected loss of FEV₁ over time.⁵⁸
5. Further Evaluation of Spirometric Abnormalities²
- Assess technical quality of spirometry and repeat testing if indicated based on spirometry quality, and other relevant information below.
 - Obtain comprehensive medical and occupational history and physical exam including: (a) work, exposure, and smoking histories; (b) respiratory symptoms, timing in relationship to work; (c) physical exam, including lung exam and chest wall deformities; and (d) SDSs, results of workplace measurements, if available.
 - Review preemployment, follow-up questionnaires and spirometry, if available.
 - Possible additional diagnostic testing:
 - If airflow obstruction, spirometry with bronchodilator response
 - If restrictive pattern, full pulmonary function tests (lung volumes, diffusing capacity)
 - Chest imaging (chest x-ray, CT scan)
 - If asthma, consider peak flow recordings at and away from work
 - If interstitial lung disease, consider high resolution chest CT scan
 - If nonreversible airflow obstruction, consider occupational etiologies, even in smokers (eg, occupational chronic obstructive pulmonary disease, bronchiolitis obliterans).
 - If a possible work-related problem is identified, consider other at-risk workers.

6. Recordkeeping

- *Spirometry Test Reports:* Under most OSHA regulations, medical records, including spirometry test results, must be maintained for at least 30 years following the end of employment (see 29 CFR 1910.1020).⁸ A recent Letter of Interpretation on this topic describes the limited amount of information that may be given to the employer under both the Silica and Respiratory Protection Standards, stating that these standards “do not authorize the transfer of spirometry test or other medical records to employers.”¹⁶
- *Equipment Maintenance Records:* Since spirometer maintenance records support the accuracy of the spirometry test results, OSHA recommends saving the equipment calibration check log and information about the spirometer to support the accuracy of the medical record.
- *Personnel Training and Evaluation Records:* Records of technician continuing medical education, certificates from completed NIOSH-approved spirometry training courses, and results of evaluation and feedback to technicians should be documented and available for review.

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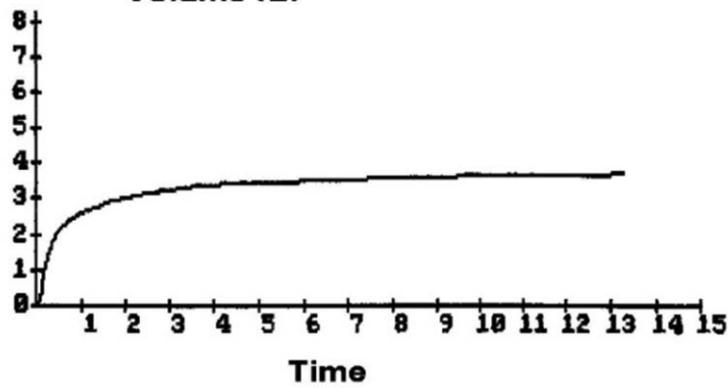
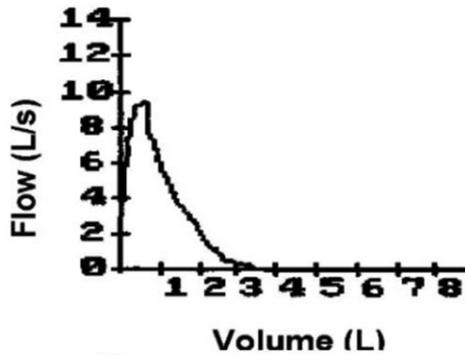
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Appendix A

ATS Minimum Size Instrument Display *



- Volume Scale ≥ 5 mm/ L
 - Flow Scale ≥ 2.5 mm/ L/s
 - Time Scale ≥ 5 mm/ s
- * Complies with ANSI ISO 25672 aspect ratio requirements.