UNIT THREE: THE QUALITY ASSURANCE PROGRAM

Why worry about it? Spirometry is among the most useful and accurate measures of lung health. However, when not performed correctly, the values obtained can be misleading, and result in misclassification of the worker's health status (14,15). Some workers may be told they have normal lung function when they actually have airway obstruction (a falsely negative report), and other workers may be told that they have a disease when their lungs are actually normal (a falsely positive report). Physicians who are asked to follow-up workers who have had inaccurate tests may conclude the spirometry results cannot be trusted, and the entire worker monitoring program may be placed in jeopardy. Thus, a good quality assurance (QA) program is essential to assure that spirometry results are beneficial in monitoring the health of workers (16,17).

A. Components of a good spirometry QA program:

- Management support and sufficient resources
- Knowledgeable QA program director
- Procedure manual
- Accurate spirometry equipment
- Daily spirometer checks
- Monthly spirometry quality reports
- Equipment maintenance records
- Technician training and review
- Maneuver quality checks

Management support. Spirometry testing requires time, space, and administrative support. Technicians need proper training, equipment, supplies, and a realistic testing schedule, as well as a quiet and private testing area. Management support is essential to assure resources are sufficient for a reliable program.

QA program director. The QA program director assumes direct responsibility for the entire quality assurance program. The director ensures that technicians are trained properly and maintain their levels of competency, resources are available to technicians to do their job properly, all methods used follow sound scientific evidence, and that all technicians follow guidelines established in the quality assurance program (18). The program director should have enough confidence in the QA process that he or she can personally verify that all test results reported from that laboratory are valid and accurate. The program director should participate in continuing education to maintain proficiency in current techniques, protocols, and equipment.

Procedure manual. Each monitoring program should develop and use a spirometry procedure manual. An operator's manual from the spirometer manufacturer is not enough. The procedure manual assures that spirometry testing procedures and equipment calibration information are available for quick reference. It helps the program to maintain consistency by ensuring that the same standardized procedures are available to all staff and substitute staff, and should be used to help train new staff. A spirometry procedures manual titled "Pulmonary Function Laboratory Management and Procedures Manual" may be obtained from the American Thoracic Society (ATS). To order the Pulmonary Function Laboratory Management and Procedure Manual, go to

the ATS web site (http://www.thoracic.org/statements/) and follow the instructions located under the "Pulmonary Function and Exercise Testing" section. The program director can modify the manual to reflect the program's choice of equipment and procedures. The program's manual should be updated as needed, and copies made available to staff members.

The following topics should be included in the spirometry procedure manual:

- Spirometry standards or regulations pertaining to your industry
- A description of employees eligible and a testing schedule
- Equipment calibration and leak test procedures, and how often they are performed
- A specific description of the spirometry testing procedures
- A copy of the article from which the reference values are derived
- A sample of the pretest questionnaire and examples of reports
- Spirometer operator's manual and contact information for manufacturer and local distributor
- A list of the necessary supplies
- Instructions for infection control procedures, including cleaning or sterilizing the spirometer
- The date and filename for the current version of the procedure manual

Accurate spirometry equipment. Some electronic flow-sensing spirometer models manufactured before 1995 were not accurate. Almost all newer models are accurate when they leave the factory, but some are more likely than others to lose accuracy over months to years of use. The American Thoracic Society has published guidelines for testing spirometer accuracy using a spirometry waveform generator (1). Before buying a spirometer, review the results of accuracy testing for that model, and ask the dealer how long the spirometer is warranted to maintain its accuracy. Purchase a rugged 3.00 liter calibration syringe to perform daily checks. Ask the dealer whether the spirometer can be configured for NHANES III reference equations, maneuver quality checks, storage of the results from the 3 best maneuvers, and printing of both flow-volume and volume-time graphs.

Daily spirometer accuracy checks. Daily checks for leaks and volume accuracy of the spirometer are needed. False positive or false negative tests can result from inaccurate spirometers. Volume-sensing mechanical spirometers are prone to leaks. A leak can cause a falsely low measurement of the vital capacity of tested workers (19). On the other hand, flow-sensing spirometers are prone to clogging, which can falsely increase the results. Some spirometers may experience other problems such as high internal temperatures causing inaccurate BTPS corrections, and chart drives slipping due to old rubber belts. It is important that laboratories keep accurate records of all equipment testing done for leak detection, calibration, and maintenance. These records will assist in identifying problems with the equipment to minimize accuracy errors. (See section on **Equipment maintenance records** below).

Monthly spirometry quality reports. A supervisor, medical director, or a knowledgeable third party should review and grade the quality of all spirometry tests (and calibration check records). Monthly or quarterly reports on test session quality (by technician) are an essential part of a spirometry QA program. At least 95% all tests should have acceptable quality (meet the criteria listed below for reproducibility and maneuver acceptability). Supervision or retraining of a technician is indicated when the overall spirometry test quality falls below a 90% success rate.

Equipment maintenance records. For each spirometer, maintain a quality log which records calibration checks, maintenance, upgrades, and repairs, including the date and time, name of the technician, procedures performed and the results, and remedial steps taken. Some computerized spirometry systems store this information in a database. Record the model, serial number, and identification number for every spirometer used. Also keep the manufacturer's manuals, warranties, etc. with the procedure manual. Manufacturers often update or revise their software. The program director will want to check these updates to review their relevance to his or her laboratory's needs.

Technician training and review. A well-trained and competent technician is the most important factor in assuring good quality spirometry results (20). Each technician should have successfully completed a 16 hour NIOSH-approved spirometry training course prior to performing spirometry tests in the occupational setting. Their certificate of completion should be framed and mounted on a wall in the spirometry testing room. Ongoing professional development and seminars for technician reviews of the latest techniques, equipment, and procedures will assure that the program keeps up-to-date.

Maneuver quality checks. Technicians must vigorously coach each subject in performing acceptable maneuvers, and recognize the various patterns of poorly performed maneuvers. A slow start (poor blast effort) can cause falsely low FEV_1 values. Failure to fully inhale before the maneuver or exhale during the test can cause falsely low FVC values. Spirometers which automatically check the acceptability of each FVC maneuver can serve to remind the technician (21).

Some automated software will review each spirometry maneuver for ATS acceptability criteria. (1) An error code may or may not be displayed on the computer screen for the technician. The presence of any error code would deem that maneuver unacceptable. Remember that the technician's goal is to obtain at least three acceptable maneuvers. A maneuver is considered acceptable if it does not contain any the following seven errors:

1) extrapolated volume ≥ 5% of FVC or 150 ml
2) presence of cough during the first sec
3) variable effort
4) glottis closure
5) exhalation time < 6 seconds
6) leaks
7) baseline error

Test sessions in which the highest minus second highest FEV_1s (or FVCs) don't match within 0.20 liters indicate poor reproducibility (repeatability or degree of match) and should be interpreted with caution. Poor reproducibility of the FEV_1 or FVC within a test session is an indication that effort was submaximal. This also reduces confidence in the interpretation of subsequently measured changes in lung function (changes across the work shift or year-to-year). The repeatability of the FEV_1 and FVC, and the quality of all test sessions should be checked either manually or by an automated spirometer.

B. Calibration checks and other equipment quality control measures

Daily accuracy checks. Daily checks for leaks and volume accuracy of the spirometer are needed. Volume spirometers should be checked for a leak every day before use, and their accuracy verified using a 3.00 liter syringe. Flow spirometers should be checked for volume accuracy at 3 different flows, every day before use. During industrial surveys or other field studies where large numbers of people are tested, calibration checks should be done at least every four hours.

When using a volume spirometer, perform the following checks every three months:

1. Check the accuracy of the chart drive
2. Check the accuracy of the internal thermometer
3. Check the calibration syringe for a leak
4. Check for accurate volume measurements across the entire volume range

How to check for a leak in a volume spirometer. Leaks are common following disassembly of volume spirometers for cleaning. A leak check should be done every day before testing subjects and before the volume calibration check. Various spirometers use gravity, a metal weight, or a spring ("negator") to return the bell to zero volume at the end of each FVC maneuver. For some spirometers, this return pressure may provide sufficient pressure (about 2 cm water) for leak checks, while for others, a weight or a large rubber band may be needed. Consult the operator's manual or the dealer's customer service to determine the recommended method to increase the pressure inside the spirometer for leak checks. Start the leak check by inserting about 3 liters of room air into the spirometer (perhaps using the calibration syringe), occlude the end of the breathing hose, and use the recommended method to provide internal pressure. Then note the starting volume, wait one minute, and note the ending volume. There should be no measurable change in the volume (less than 0.02 liters). A decrease in volume by more than 0.02 liters indicates a leak, and testing should not be done until it is corrected. Look for the usual sources of leaks (such as a crack in the breathing hose, a loose hose connection, a loose plate, a missing rubber O ring, etc). To track down the problem, try repeating the leak check without a breathing hose connected, by plugging the spirometer opening with a rubber stopper. Silicone sealant may be used to fix some leaks.

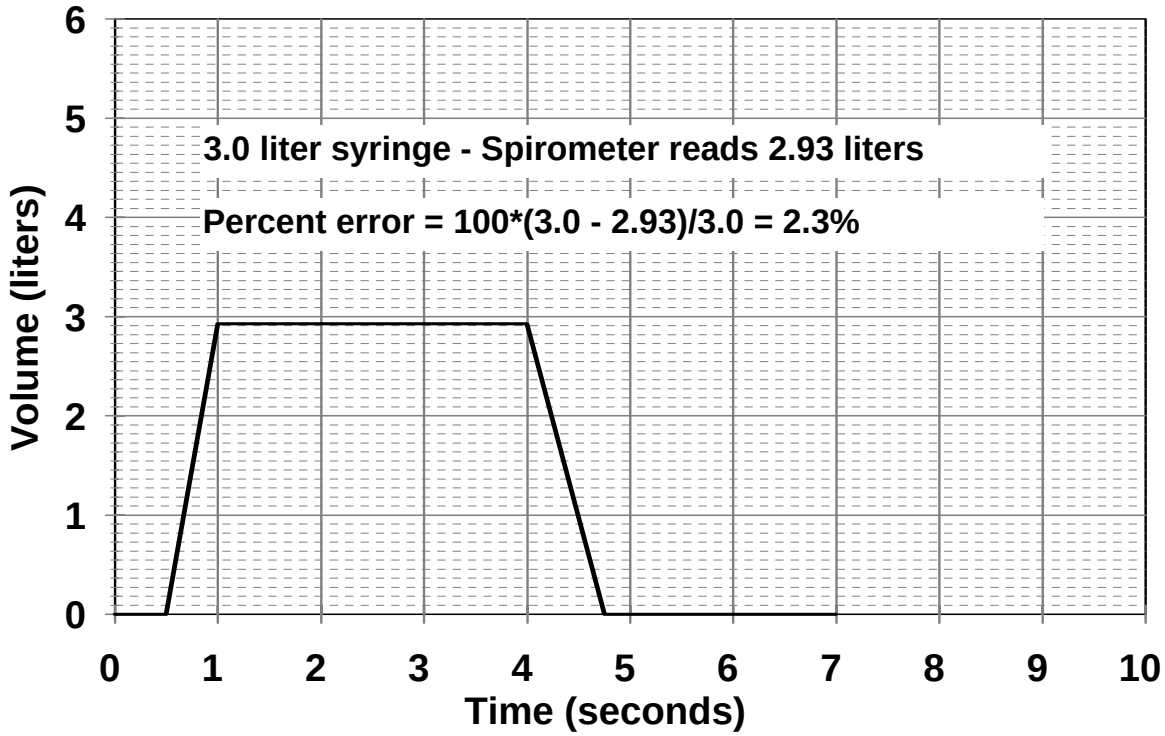
How to check the accuracy of a volume spirometer. Use an accurate 3.00 liter calibration syringe. If the calibration syringe has been dropped accidentally, or has loose components, or a leak, it should be returned to the manufacturer for repair and re-calibration. Make sure that the BTPS correction is turned off, to avoid a calculation error when calibrating a computerized spirometry system. [1] Keep the syringe near the spirometer so it is at the same temperature. The volume recorded when air is injected from the syringe into the spirometer must be within $\pm$3 % of 3.00 liters (between 2.91 and 3.09 liters). (See **Figure 3-1. Volume Time Syringe Calibration**.)

[1] This usually is done by selecting "calibration check" from the display or printout. If regular FVC testing has been inadvertently selected, and air is injected from the calibration syringe (simulating an FVC maneuver from a subject), the computer will report the FVC as if the air were exhaled at body temperature. This will falsely increase the 3.00 liter calibration result to about 3.30 liters (the BTPS correction factor).

Record the calibration and leak check results on the daily worksheet or quality log. If the volume is low (less than 2.91 liters), first repeat the leak check. If using a water-sealed spirometer, check the water level. If the volume is high (above 3.09 liters), check to see if the zero volume is correct, and ensure that the temperature of the calibration syringe is identical to the spirometer.

EXAMPLE: Air from a 3 liter syringe was injected into the spirometer, producing the tracing below (**Figure 3-1. Volume Time Syringe Calibration Check**). To meet the criterion of ±3% of 3 liters, a volume must fall between 2.91-3.09L. The volume reads 2.93 liters so it is within the acceptable range. (If the baseline does not start at zero, remember to adjust accordingly.)

FIGURE 3-1. VOLUME TIME SYRINGE CALIBRATION CHECK



It is important to understand the difference between ***calibration checks*** and re-calibration of the spirometer. You should *check* the calibration of the spirometer every day; however, the calibration of the spirometer should not be adjusted unless repeated checks determine that it has become inaccurate, and no mechanical cause for the loss of accuracy can be determined. Review the volume-time tracing exercise (**Figure 3-2. Volume Time Syringe Calibration Check**) from a calibration check of a dry rolling seal spirometer at the end of this chapter.

How to check the accuracy of a flow spirometer. Check the volume accuracy using a 3.00 liter calibration syringe every day before using the spirometer. Select "calibration check" from the menu of the spirometer (so that the software does not apply a BTPS correction factor to the results). If the flow sensor is permanent and heated (as in some older models), check the manual to see if the heater should be turned off for at least 30 minutes before calibration checks. If an

unheated permanent flow sensor is used and it was recently cleaned, be sure that it is completely dry and at room temperature before the calibration check. If the spirometer uses disposable flow sensors, use a new flow sensor from each box of flow sensors for the calibration checks. For calibration checks, some flow spirometers require a special adaptor that fits between the syringe and the flow sensor.

First fill the syringe with air completely, then attach it firmly to the flow sensor, and empty it smoothly and completely. End the maneuver carefully until a soft click is heard, meaning that the syringe was emptied completely. Do not bang the syringe while emptying it, to avoid damage. Disconnect, refill with air, and then empty the syringe three times, each time at a different speed: First, empty it in less than one second (fast), next in 2 or 3 seconds (medium), and the third time take about six seconds (slow). Count "one-one-thousand, two-one-thousand" etc, while emptying the syringe, to gauge the speed of emptying. The resulting FVC for all 3 of these maneuvers should be between 2.91 and 3.09 liters. Record all three results on the daily worksheet or quality log.

Quarterly equipment checks for volume spirometers. To check a mechanical chart recorder, use a stopwatch to ensure that one second recorded on the tracing equals one second to within $\pm$1% (or one half of the smallest time division on the graph). Since one second is difficult to measure accurately, measure how long it takes for the pen to traverse a 10 second segment of chart paper and divide the result by ten. Observe that the chart drive is functioning smoothly, since the clutch or rubber rollers may slip (indicating the need for replacement). Record your results in the quality log.

Use a reference thermometer to check the accuracy of the thermometer used to measure the internal temperature of the spirometer. If the two temperatures do not match within one degree Centigrade, the BTPS correction factor will be inaccurate. If the volume spirometer does not measure the temperature inside the bell or volume chamber, ask the manufacturer how to install a thermometer, or ask an engineer to install one. Electronic indoor/outdoor thermometers (available for about $20) should work fine.

Check that the spirometer starts the test at the right time. Some spirometers falsely start the test if the subject shakes the mouthpiece when inhaling. This causes the FEV_1 to be artificially low (22). Some require excessive exhalation volume before the mechanical chart or pen starts moving. Calculate the FEV_1 by hand from the tracing and compare to the electronically-derived FEV_1 to ensure that the equipment is using the equivalent to the back extrapolation method to determine the start of the test. (Directions for calculating FEV_1 and back extrapolation are given in **Unit Five: Basic Spirometric Calculations.**)

C. Infection control. Although the transmission of infection through spirometry has not been documented, the theoretical risk should not be overlooked. The Centers for Disease Control and Prevention (CDC; http://www.cdc.gov) has published several guidelines for preventing cross-contamination.

Always wash your hands before and after spirometry testing.
Instruct workers to attach, remove, and discard the disposable mouthpiece for each session.

Use disposable or sterilized nose clips.
Don’t test workers who have an active respiratory infection (a cold or the flu).
When using a volume spirometer, use a clean breathing tube for each subject.
When using a volume spirometer, consider using disposable spirometry “filters.”
Don't re-use flow sensors designed for single patient use.
Follow the spirometer manufacturer's recommendations for cleaning and disinfecting.
Most hard surfaces may be disinfected by wiping with isopropyl alcohol.
Check with your state health department for state mandates on infection control in health care settings.

Figure 3-2. Volume Time Syringe Calibration Check has been included below for students to practice their calculation skills.
EXERCISE: Air from a 3 liter syringe was injected into the spirometer, producing the tracing below. Is the spirometer in need of repair?

FIGURE 3-2. VOLUME TIME SYRINGE CALIBRATION CHECK - EXERCISE

FEEDBACK: The volume from the calibration check reads 3.1 liters, which is not within the acceptable range. Check that the syringe is working properly. If it is, repair the spirometer before using.