Quality Assurance in Pulmonary Function Laboratories

ACCEPTED AS OFFICIAL POSITION PAPER BY THE ATS BOARD OF DIRECTORS, MARCH 1986; REVISED IN RESPONSE TO ATS BOARD, APRIL 7, 1986.

Routine preventive maintenance, calibration, and quality control are important to assure clinically useful results and a well-functioning, efficient pulmonary function testing laboratory (1–13).

Because of the physiologic complexity of pulmonary function testing with interrelation of the subject, the instructions of the laboratory personnel, and the testing equipment, wide-scale proficiency testing is currently not feasible. However, using laboratory personnel as "unknown subjects" and performing intralaboratory and inter-laboratory testing can be helpful. Properly developed quality assurance programs should result in more consistent intra- and inter-laboratory data reporting. A number of regulatory agencies in the United States are concerned about the quality control and validity of laboratory results (2–4).

This document describes the general components of a quality assurance program recommended for pulmonary function laboratories and also includes recommendations regarding quality control procedures for commonly performed tests such as spirometry, measurements of lung volumes by dilution techniques or body plethysmography, and single breath diffusing capacity. In order to develop the highest quality pulmonary function testing laboratory, this document should be used in conjunction with the previously published ATS personnel standards (1). The committee recognizes that because of the variability of existing equipment and study populations, additions to the guidelines recommended here may be required for specific laboratories.

Procedure Manual

A procedure manual is an important base for a quality assurance program and should be available for each test the laboratory performs. The manual should be compiled by the laboratory staff; appropriate sections of a current manufacturer's instrument manual may be extracted and modified for day-to-day laboratory use. The procedure manual should include a quality control plan, guidelines for medical staff to order appropriate pulmonary function tests, action to be taken in case of incomplete or uncertain physician orders, and guidelines for reporting results of tests in a timely manner. Pertinent literature references for testing procedures and for reference value equations should be included. If the testing involves the use of a computer, the manual should have a special section which describes the operation of the computer and the exact role it plays in the test procedure and calculations of results. The manual should be updated at least annually with changes approved by the medical and technical directors of the pulmonary function laboratory.

The laboratory procedure manual should contain the following at a minimum:

1. Name of test, general description of the test, parameters measured (FVC, FEV_1, etc.), and include a summary of the physiological basis for the test.
2. Purpose of the test and guidelines for ordering the test.
3. List of all equipment and supplies needed as well as methods of cleaning and sterilization with corresponding schedule.
4. Calibration check protocols and schedules.
5. Quality control protocols with schedules for control testing and defines limits for results of controls or standards, and corrective action to be taken if results are outside these limits.
6. Step-by-step directions about how to perform, measure, calculate, and interpret tests, including specific instructions to the patient. If a computer is part of the system, these directions should also include the procedure to be used in case of computer failure.
7. All equations used for calculating results and an example of a calculation. Also an indication of the conditions at which the results are reported (e.g., ATPS).
8. Details of methods for all test procedures controlled by computers:
   a. List special procedures, calculations or results, e.g., back extrapolation method for calculation of FEV_1.
   b. Location of software source code listings. Where appropriate, details of signal acquisition and processing algorithms should be described.
   c. Personnel to be contacted if changes in software become necessary. Manufacturer's name and phone number if laboratory personnel are not qualified to make software changes. Numbers for manufacturer's customer service and other contacts should be available.
   d. Availability of software and back-up discs or tapes.
   e. Schedule for developing back-up discs or tapes.
   f. Procedure to be used in case of computer failure.
   g. Guidelines for protection of confidential patient data, and a list of the personnel who have access to information and software security codes. Security codes *SHOULD NOT* be recorded in the procedure manual.
9. Pre-testing patient information:
   a. Loose clothing; recommendations for abstinence from use of cigarettes, alcohol, or therapeutic drugs affecting the lungs prior to testing.
   b. Infection control precautions (TB, hepatitis, AIDS) for personnel and other patients.
   c. Absolute and relative contraindications to testing.
10. Safety procedures for fire, electrical, gas tank, or other hazards for personnel and patients.
11. A current set of reference value equations with the age range and other appropriate population parameters listed along with their journal references. Simply listing the equation reference is not adequate since many articles contain more than one set of reference value equations.
12. Publications and bibliography concerning equipment, limitations of testing, and quality control.
13. Values requiring special physician notification.
14. Effective date of the manual and schedule for review.
15. Signed and approved by the medical and technical directors.

Preventive Maintenance

Equipment maintenance should be performed according to the manufacturer's operation or maintenance manual, and a maintenance log should be established. In general, daily maintenance includes visual inspection of systems prior to use, and monthly maintenance should include evaluating equipment for common problems. For example, water spirometer bells can be evaluated for a leak by placing weights on the bell and recording the change in volume over several minutes. Some spirometers can be tested by attaching a 3-liter syringe to the mouthpiece, expelling the air and waiting for several minutes to determine whether there has been a loss of volume. The procedure manual should also include testing methods for all equipment used in the laboratory. Annual maintenance includes cleaning and oiling the pumps and replacing tubing that is aged, worn, or cracked. The gas analyzers should have their calibrations checked at least every 6 months or more frequently if recommended by the manufacturer. Electrical safety checks should be conducted on each item of equipment according to the ANSI standards (14).

Quality Control and Calibration

For spirometry, the volume should have a calibration check (a test performed to determine the deviation of the observed value from the standard value) at least daily with a calibrated syringe with a volume of at least 3 liters. During industrial surveys or other field studies, the equipment should be calibrated each morning and 2 times during the day. Although

Reprints may be requested from your state or local Lung Association.

there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be determined within one day, thus eliminating needless reporting of false values for several weeks or months. At least quarterly, volume spirometers should be calibration checked over their entire volume range (in 3-liter increments) using a calibrated 3-liter syringe. Testing should be made at least at 3 different injection speeds such as 0.5 to 1.0 second, 1.0 to 1.5 seconds and 5.0 to 5.5 seconds. Spirometer systems should be evaluated for leaks on a daily basis. Devices for testing FEV_1 and $FEV_{25-75\%}$ have been developed, but such calibration equipment is not readily available (10–13). Assessing the recorder speed with a stopwatch should be performed quarterly in all laboratories. If equipment is changed or relocated, e.g., industrial surveys, calibration checking, and quality control procedures should be repeated prior to initiating further testing. Troubleshooting limits should be determined and documented for these calibration checks, e.g., a variation of greater than 3 to 5%.

Lung volumes measured by gas dilution methods should be evaluated at least quarterly by connecting a device of known volume (e.g., 3.0-liter calibrating syringe) to the system and measuring the volume after appropriate correction for apparatus dead space. Apparatus dead space for gas dilution equipment should be redetermined whenever the equipment is repaired or modified. Inspection and testing for leaks in the tubing or the bell should be performed daily. Calibration checking for accuracy and linearity (at least a two point calibration check) of the gas analyzers should be confirmed every 6 months for techniques using a dilution method (6–9) or more frequently if suggested by the manufacturer's operation manual. For the body plethysmograph, a 3-liter container filled with pure copper sponges can be utilized for calibration checks (8, 9); resistance can be assessed by using calibrated flow resistors.

Accuracy of the **single breath diffusing capacity** equipment can be evaluated by checking with a calibrated 3-liter syringe and testing for air leaks in the system daily. Two point calibrations of the gas analyzers (zero and full scale) should be done just prior to each patient. The gas analyzers should be calibrated at multiple points over their entire range at least every 6 months. The recording speed should be checked quarterly. A CO-He dilution test can be performed by withdrawing 1 liter of air into a 3-liter calibrating syringe and placing the syringe into the mouthpiece opening, withdrawing 2 liters of the CO-He gas mixture into the syringe, waiting 10 seconds, and then emptying the syringe into the collection system and measuring the CO and He. These values should be identical to within + or − 3 percent. The test should be repeated using 1 liter of the CO-He gas mixture. It is important that an air leak in the gas sampling system be detected, because the test gas is "pulled" through most gas analyzers rather than blown through. A small amount of contamination from room air "pulled" in with the sample gas can cause a large error.

Performance Assurance Testing

Proficiency testing has been developed for arterial blood gas analyzers (9), but it is difficult for spirometry, lung volumes, and diffusing capacity because pulmonary function testing utilizes the "whole" person as part of the testing process, not quantifiable "products" such as serum or pleural fluid. However, in addition to personnel and quality control standards for pulmonary function laboratories, the following approach to proficiency testing is recommended. First, a log should be established with recorded results of spirometry, lung volumes, and diffusing capacity for at least 3 healthy subjects corresponding to a population studied in the laboratory and for which the reference value equations were derived. This might include laboratory personnel. These measurements should be repeated quarterly and whenever questions arise regarding the accuracy of test results. When sufficient data are available on a given subject, these results can provide the basis to evaluate the instrument, operator, or measurement failures. Any results which are greater than 2 standard deviations from the mean for each subject should result in a complete systems check to remedy potential problems. After the problems are fixed, repeat testing to validate the repair should be conducted. Second, it is highly recommended that interlaboratory testing be performed at least annually by testing these "known" subjects at two or more laboratories in the region. Finally, it is important to assess the reference value equations that have been selected for each laboratory test by testing 10 nonsmoking healthy subjects and comparing their results with the predicted results from the reference value equations.

Glossary

Definition of terms used in quality control will assist in better understanding its concepts.
Accuracy is the quality of freedom from mistake or error, that is, of conformity to truth or a rule.
Calibration is the process of comparing a measure of performance to a reference standard and adjusting instrumentation so that the performance characteristic equals the standard. A *calibration check* is the test performed to determine the deviation of the observed value from the standard value.
Linearity is a property of a component or system describing a constant ratio of incremental cause (input) and effect (output).
Maintenance includes activities intended to assure that mechanical equipment and computerized components are safe and in proper working order.
Performance assurance testing is a process of confirming that the accuracy and precision of test results meet acceptable criteria.
Precision is the quality of being exactly or sharply defined, that is, the quality of repeatability of measurement data.
Preventive maintenance is scheduled or anticipated maintenance designed to reduce the incidence of equipment failure.
Proficiency testing is the process of determining the value of an "unknown" measurement and comparing it to either a predetermined standard or results from reference laboratories.
Repair is unscheduled or unanticipated maintenance needed to correct observed equipment failures.

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TABLE 1

SUMMARY OF TABLE OF QUALITY ASSURANCE TESTING

	Volume	Leaks	Gas Analyzers
Spirometry			
Sensor type			
Volume (Water seal)	*Daily	Daily	
Flow (Pneumotach)	*Daily	NA (Unless tubing is used)	
Volume Determination			
Dilutional method	*Monthly	Daily	At least every 6 months
Plethysmograph	*Daily	NA	NA
Diffusing Capacity			
Single breath method	*Daily	Daily	At least every 6 months

* Use a syringe of known volume (at least 3 liters) for calibration.
NA = Not applicable.

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This position paper was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Laboratories. Members of the committee are:

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