



The Thoracic Society of Australia and New Zealand  
145 Macquarie St, Sydney NSW 2000  
T: +61 2 9256 5457 F: +61 2 9241 4162

## Thoracic Society of Australia & New Zealand

Accreditation of Paediatric Respiratory Function Assessment Services

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## ACCREDITATION OF RESPIRATORY FUNCTION ASSESSMENT SERVICES

### INTRODUCTION

#### 1 PREAMBLE

Accreditation of respiratory function services is, at present, voluntary. The Thoracic Society of Australia and New Zealand (TSANZ) has established an accreditation process to foster excellence in the approach to assessment of respiratory function. The process seeks to define uniform minimum standards for services in Australia and New Zealand. It is intended that, while rigorous, the process be "user friendly". It will be revised periodically and constructive suggestions for improvement are welcomed by the TSANZ Professional Standards Subcommittee. The process assesses the service's organization and administration, staffing and direction, policies and procedures, staff development and education, facilities and equipment, and quality assurance programmes. Its general approach is influenced by programmes established by the Australian Council of Healthcare Standards (ACHS). It is hoped that consistency with ACHS guidelines will decrease the amount of work necessary to prepare the application for those laboratories that have already been involved in ACHS accreditation procedures (eg. hospital accreditation) and help prepare the way for ACHS accreditation where this is anticipated.

Following the establishment of the adult guideline in December 2001, this modified version for laboratories that intend to study children less than 12 years of age and must be separately accredited for paediatric assessment (defined for the purposes of this document as 0 - 18 years age) was developed with support from the Australasian Paediatric Respiratory Group (APRG). The application for adult and paediatric laboratory accreditation is similar, however for paediatric accreditation each individual laboratory can choose any number of modules in which to be accredited. The standards required for each module will be based on standards literature from the American Thoracic Society, European Respiratory Society, TSANZ and Australia and New Zealand Paediatric Societies as available and appropriate. The references to the standards of care will be listed within the modules. Children aged 12-16 years without complex medical conditions or nursing requirements may be studied in adult accredited laboratories provided adequate resuscitation facilities including appropriately trained staff are available.

The first phase of the process involves answering a detailed questionnaire which has been designed to assess the laboratory's readiness for accreditation. Self Assessment is a key feature of this phase of the process. Ability to satisfactorily respond to the questionnaire, guided by the Standards for Accreditation detailed below, should indicate to the applicant service its likely ability to comply with the requirements for accreditation. If satisfied that its responses are adequate the service submits a completed application. If the TSANZ Paediatric Assessment Panel is satisfied that the application meets the required standard a site visit follows. These procedures are detailed under Administration below.

The staff training and physical environmental requirements for lung function testing in children are:

- a child friendly environment
- a child safe environment



- paediatric trained staff to perform the testing
- paediatric trained staff to interpret the testing
- ability to pre-train children to do the procedures
- adequate room within the lung function laboratory for parent/caregivers and siblings
- adequate room within the lung function laboratory to accommodate wheelchairs and pram/pushchairs
- access to playroom
- staff trained in paediatric cardiopulmonary resuscitation procedures with annual updates
- a team trained in paediatric cardiopulmonary resuscitation must be available on site for the duration of the study

The additional staff training and physical environmental requirements for lung function testing in infants and/or preschoolers are

- an appropriate and safe environment
- consent from the parent/caregiver or guardian
- paediatric trained staff to perform testing on infants or preschool children, as appropriate.
- paediatric trained staff to interpret testing on infants or preschool children, as appropriate.
- access to changing room
- access to feeding room
- access to paediatric anaesthetic staff where required

## **2 DEFINITION**

Accreditation is the process whereby the professional standards and competence of a Paediatric Respiratory Function Assessment Service is formally recognised by TSANZ.

## **3 PURPOSE**

- (a) To encourage appropriate standards of medical and technical practice to ensure that a service is effective.
- (b) To grant recognition to services which achieve these standards.
- (c) To foster the standards of service by consultation and advice rather than by regulation, consistent with the voluntary nature of Accreditation.



## ACCREDITATION OF RESPIRATORY FUNCTION ASSESSMENT SERVICES

### ADMINISTRATION

#### 1. Coordinator

2.

- 1.1 The process of Accreditation will be administered on behalf of the Professional Standards Subcommittee (PSS) by an Accreditation Coordinator.
- 1.2 The Accreditation Coordinator will be responsible for administering the process of Accreditation including receipt of applications, appointment of an Assessment Panel, supervision of each Accreditation process including production of a report which is clear and reasonable in its comments and recommendations.
- 1.3 The Accreditation Coordinator will liaise with and accept advice from the Paediatric Representative member of the Professional Standards Subcommittee in relation to the appointment of a Paediatric Assessment Panel.
- 1.4 The Paediatric Representative member of the Professional Standards Subcommittee will be a member of the Accreditation Advisory Panel (Sect.4.1) for each paediatric application.

#### 2. Categories of Respiratory Function Assessment Services

The paediatric respiratory function accreditation process is organised in a series of modules – any laboratory applying for accreditation can nominate any number or combination of modules to apply for accreditation.

Modules	Respiratory Assessment
A	Spirometry
B	Static lung volumes
C	Bronchial challenges
D	Exercise challenge
E	Exercise testing
F	Skin Prick Testing
G	Respiratory muscle strength
H	Gas transfer
I	Breathing response to gas mixes
J	Simulated altitude
K	Infant lung function
L	Preschool lung function
M	Introducing new technologies



### 3. Process

- 3.1 Applications for Accreditation will be received by the Executive Director of the Society. The application should specify the list of the modules for which Accreditation is sought. Accreditation will be granted only in relation to those modules for which application is made.
- 3.2 The Executive Director will respond to all applications by providing applicant laboratories with Accreditation guidelines and the application forms which seek information regarding the laboratory and investigations/measurements that it performs ("the Accreditation Package"). These forms include questions designed to indicate the laboratory's readiness for accreditation. Self assessment is a key feature of this phase of the process. Once satisfied it can respond to the questions adequately the laboratory completes the forms and returns them to the Executive Director, along with an "initial assessment fee" (\$275 incl GST ) ( for NZ \$250 AUD ) which covers the cost of the initial assessment of submitted material. Copies of all correspondence will be sent to the Accreditation Coordinator and the Paediatric Representative on the PSS. A further fee (the "site visit" fee \$2200 incl GST ) ( for NZ \$2000 AUD ) will be charged if the application is found to be acceptable, and a site visit is arranged (see below). These fees, which are set to recover costs, will be determined by the Society and revised from time to time. The current schedule of fees is obtainable from the Society office.
- 3.3 On receipt of the Accreditation fee and application forms the Accreditation Coordinator will appoint an Assessment Panel and its Chairperson. The assessors will be recognized experts in the physiological and/or technical aspects of paediatric respiratory function assessment and its application to the diagnosis and management of respiratory disease. The paediatric assessment panel will normally have three (3) members including a paediatrician trained in respiratory medicine and a paediatric respiratory scientist; at least one (1) member will be from a city other than the service undergoing accreditation.
- 3.4 The Chairperson of the Assessment Panel will cause the documentation supplied by the applicant laboratory to be reviewed by the Panel Members and seek supplementary information where necessary. The result of the initial assessment will be given to the applicant within eight (8) weeks of receipt of the application. If the application is unacceptable the reasons for the decision will be provided. If the application is acceptable a site visit will be arranged at a mutually convenient time (within two (2) to three (3) months of notice of approval). **The site visit is a critical step in the accreditation process.** At the site visit the veracity of answers provided in the application is examined, and all specific questions raised by these responses and by inspection of the facilities addressed. The Chairperson of the Assessment Panel is responsible for the review process including producing a report and recommendations which will be forwarded to the Accreditation Coordinator.
- 3.5 The assessment process has two purposes:
  - (a) Advisory - to advise on ways in which perceived deficiencies of a Service can



be corrected.

(b) Evaluation - to establish whether a Service is competent and effective.

#### **4. Granting Accreditation**

- 4.1 To expedite the process an Accreditation Advisory Panel will recommend accreditation on behalf of the society according to the recommendations of the Assessment Panel. The Advisory Panel will comprise the Chairman of the PSS, the Accreditation Coordinator, the Paediatric Representative on the PSS and the Assessment Panel which assessed the particular laboratory.
- 4.2 The Assessment Panel may recommend that accreditation be awarded to measure adults and/or children unreservedly or subsequent to rectification of identified deficiencies. In the latter case accreditation will be granted on receipt of evidence that all suggested changes have been implemented. Accreditation will be deferred until the suggested changes have been implemented. The application will lapse after 12 months from the date of issue of the recommendations in the absence of such evidence. This provision will only apply where the panel considers that the changes are relatively minor and can be implemented and verified without need for a further site visit. The process seeks "substantial compliance" with the standards. It is recognised that local conditions may preclude absolute compliance with every standard.
- 4.3 Where, in the opinion of a particular Accreditation Advisory Panel, a report is potentially contentious or there is disagreement over its recommendations, the report will be referred to the President and the Executive of the Society for comment and decision.
- 4.4 A recommendation against Accreditation will normally be referred to the President and Executive of the Society for confirmation before the report is issued.
- 4.5 A Certificate of Accreditation will be issued once the recommendation for accreditation is ratified by the Accreditation Advisory Panel or, where applicable, the Executive. The Certificate will be signed by the Chairman of the PSS and the President on behalf of the Society. Accreditation is granted for a period of five (5) years.
- 4.6 Laboratories that fail Accreditation will be advised of the reasons for the decision. If the laboratory wishes to challenge the decision it must do so in writing to the Accreditation Coordinator within 14 days of receiving the decision stating the reasons for appeal. The appeal will then be considered by a meeting of the Professional Standards Subcommittee to be convened within six (6) weeks of receipt of the appeal. A recommendation against Accreditation following appeal will be referred to the President and Executive of the Society for confirmation before the report is issued. The Accreditation Coordinator will advise the laboratory of the decision on the appeal and the reasons for the decision. A



laboratory that fails Accreditation may reapply at any time that it believes its standards have met those required for Accreditation.

- 4.7 Each Accreditation report will be seen in full by the PSS.
- 4.8 The Accreditation Coordinator will provide the Executive of the Society with an Annual Report.

## 5. **Re-Accreditation of an Accredited Service**

- 5.1 No less than 12 months before the end of the five (5) year accreditation period the Executive Officer of the Society will provide to the Medical Director of the Service:
  - a) copy of the previous Assessment Panel report,
  - b) the current accreditation guidelines and application for initial accreditation,
  - c) request for re-accreditation (see Forms C, D & E).
- 5.2 The request for re-accreditation will ask for the category of respiratory function assessment for which accreditation is sought, a list of the individual tests for which accreditation is sought and staffing information. Additionally, the Medical Director will be asked to detail changes to the Service since the previous accreditation. Emphasis will be on the implementation of recommendations suggested by the previous Assessment Panel report.
- 5.3 The Service completes the request for re-accreditation and returns *only these forms* to the Executive Officer, along with the site visit fee current at the time of application. The Service must also complete the application for initial accreditation and update laboratory manuals to reflect current practice. The application for initial accreditation and laboratory manuals are to be retained by the Service for review at any subsequent site visit. Copies of all correspondence will be sent to the Accreditation Coordinator and the Paediatric representative on the PSS.
- 5.4 On receipt of a request for re-accreditation the Accreditation Coordinator will appoint an Assessment Panel and its Chairperson as described in paragraph 3.3. Where practicable at least one member of the Assessment Panel will be from the previous assessment panel.
- 5.5 The Chairperson of the Assessment Panel will arrange for the request for re-accreditation and the previous Assessment Panel report to be reviewed by the Panel Members. The result of this review will be provided to the Service within six weeks of receipt of the request. If the request for re-accreditation is unacceptable then reasons for the decision will be provided and the site visit fee refunded. If the request for re-accreditation demonstrates that the Service has adequately addressed the recommendations contained in the previous Assessment Panel report a site visit will be arranged. Normally, the site visit



will occur at least three (3) months before the end of the current five (5) year accreditation period. At the site visit attention will focus on problems or deficiencies identified during the previous accreditation. Compliance with any new or revised standards introduced since the previous accreditation will also be examined as may any aspect of the Service's operations. The Chairperson of the Assessment Panel is responsible for the review process including producing a report and recommendations that will be forwarded to the Accreditation Coordinator.

5.6 The process of granting re-accreditation will be as described in Section 4 (Granting Accreditation).

## **6. Confidentiality of Assessment Procedures**

All information provided by a testing laboratory in relation to preliminary enquiries or to an application for Accreditation and all information obtained in the course of or in connection with an assessment of the Service is considered by the TSANZ to be completely confidential. Such information is received and studied only by members of the Accreditation Advisory Panel and the Accreditation Assessment Panel and TSANZ Executive and these persons are all made aware of the confidential nature of this information. The TSANZ requires that all documents associated with Accreditation of a Service be maintained in strict confidence. This requirement imposes particular obligations on assessors. An assessor must not disclose any information gained during an assessment to any person other than a member of the AAC. Under normal circumstances there is little need for an assessor to retain a copy of the briefing notes provided for an assessment or a copy of his or her report. It may be prudent for an assessor to keep a copy of the report temporarily to obviate loss in the mail, but this copy should be destroyed once acknowledgment of receipt is received by the AAC. If an assessor retains copies of briefing notes or reports, they must be kept in a secure place. They are not to be incorporated into the general records system of the assessor's employer in a manner which would allow unauthorised access by others.



## ACCREDITATION OF RESPIRATORY FUNCTION ASSESSMENT SERVICES

### STANDARDS FOR ACCREDITATION

*This document outlines the minimum standards required for accreditation of a paediatric respiratory function assessment service. It must be read in conjunction with the questionnaire in the application for accreditation. It should be referred to when completing the application to ensure that the laboratory is likely to meet the requirements before submission.*

#### **THE STANDARDS:**

##### **1. IDENTIFYING INFORMATION**

That information identifying the applicant service be specified at the front of the application (Form A).

##### **2. HISTORICAL OVERVIEW**

That a brief overview of the history of the development of the service be provided with the application.

##### **3. ORGANIZATION AND ADMINISTRATION**

That the service is organized and administered to meet its objectives and the needs of the population it serves.

###### *3.1 Goals and Objectives*

That the service's goals and objectives are specified and that they reflect its role and responsibilities.

###### *3.2 Relationship to Host Institution, Other Laboratories*

That the relationship(s) of service to its host institution and to related laboratories are appropriate to the discharge of its responsibilities. These relationships must be specified and clearly defined. There should be evidence of commitment by the host institution to its support.

###### *3.3 Relationships with Other Specialities*

That the service has established appropriate relationships and communication with other specialities with a common interest in respiratory disease to ensure that clinical problems are directed to clinicians with relevant expertise and to facilitate advancement in clinical standards.

###### *3.4 Referrals*

That the sources and types of referrals to the service are relevant to the services provided. Referrals to the service should be related to respiratory function assessment or other matters for which there is local expertise. For more than simple spirometry, each child should be evaluated by a paediatrician prior to a diagnostic study in modules assessing more simple parameters such as B - F, and a paediatrician with respiratory expertise prior to more complex diagnostic



studies as in modules G-M.

3.5 *Workload*

That the service's resources (staffing, equipment, facilities finances) are sufficient to meet its workload without compromising the minimum standards set elsewhere in this document, and with reference to the standards for the modules (which include the ATS and ERS criteria). A regular updated audit of the laboratory's workload in terms of numbers of tests of each particular type should be kept and these records should be available on a quarterly or yearly basis.

3.6 *Demand*

That the service attempts to adequately cope with the demand for its services. Where demand exceeds capacity, the service should have a system for prioritizing cases perceived to be urgent. The service should be able to assess new patients within two (2) weeks of referral. Urgent cases should be assessed within two (2) days.

3.7 *Budget*

That the service's budget covers its operational costs or that there is a firm commitment by the host institution or company to underwrite budget deficits.

**4. STAFFING AND DIRECTION**

The service is directed and staffed to achieve its objectives.

4.1 *Staff Structure and Direction*

That the service has a medical director responsible for overall standards and development of policies governing the service. These should be ratified by other committees in the host institution as necessary.

That there are clear, documented lines of accountability/ responsibility between medical director and all staff members. These must represent the actual manner in which the service is organised, be regularly reviewed and readily available to all staff.

4.2 *Staff Qualifications and Experience*<sup>1,2,3</sup>

That staff members are appropriately qualified for their tasks by education, training, and/or experience, and that their roles and responsibilities are specified by job description. The medical director should have specific, detailed training in clinical respiratory physiology and meet the criteria set by the relevant TSANZ position paper<sup>1</sup>. The medical director should have detailed training in paediatrics and have FRACP, or equivalent, in Paediatrics. Other consultant medical staff are expected to have completed the equivalent of one (1) years full time training in respiratory physiology, consistent with the TSANZ guidelines for advanced trainees<sup>2</sup> wishing to make respiratory physiology an important area of their practice, and have FRACP, or equivalent, in Paediatrics.

Scientific/technological staff are responsible for accurate performance of tests, equipment maintenance, continuing quality assurance of both equipment and



techniques and patient safety during performance of tests. The basic qualification for classification as either scientific or technical staff depends on local requirements (eg two (2) years tertiary training in biological or physical science for technologists, Bachelor of Science or equivalent for scientists). Until 1995 there was no recognised tertiary training programme in respiratory physiology or function assessment for scientific/technological staff in Australia. Hence most staff received their professional/vocational training through experience in an established service. However formal training in paediatric respiratory science is now offered. These are strongly endorsed, particularly for new staff and those without substantial experience in respiratory function assessment. Paediatric laboratories must have the facility to care for sick children or children with complex conditions. The technical staff must have experience with training children of different ages to do lung function tests, and be able to assess efforts that meet the relevant international guidelines. All staff must be certified competent in paediatric cardiopulmonary resuscitation.

It is recommended that scientific/technical staff acquire the Certified Respiratory Function Scientist (CRFS) credential based on examination by the Australian and New Zealand Society of Respiratory Science (ANZRS).

To function in a supervisory capacity under medical direction a respiratory scientist should have a Bachelor of Science in biological or physical sciences, and between three (3) and five (5) years experience, depending on the nature of that experience and the range of tests performed by the laboratory. In addition acquisition of the CRFS credential and/or relevant postgraduate qualifications is strongly recommended.

#### 4.3 *Staff Numbers*

That sufficient medical, technical and clerical staff are employed to adequately meet service needs. This will depend on the workload, organisation, type of equipment and circumstances of the individual hospital. In the case of paediatric laboratories, a team trained in paediatric cardiopulmonary resuscitation must be available on site for the duration of the studies. Where three (3) or more scientific/technological staff are employed it is advisable that there be a designated Chief Scientist/Technologist to assist the Medical Director to administer the service.

#### 4.4 *Staff Appraisal*

That a staff appraisal system is in operation, that a written report is produced, that the staff member involved is aware of the contents of the report and that a plan to address deficiencies is defined.

#### 4.5 *Training of Staff in Cardiopulmonary Resuscitation*

That all medical, technological and nursing staff are trained in paediatric cardiopulmonary resuscitation, and that a basic level of competence is maintained and evaluated.



## 5. POLICIES AND PROCEDURES

That the service has documented policies and procedures that reflect current knowledge and practice in the conduct of a respiratory function assessment service and, where relevant, comply with statutory requirements.

### 5.1 *Patient Referral, Handling, Documentation, Follow-up*

That procedures exist for prompt, efficient handling of patient referrals, documentation, communication with the referring doctor, and that these are consistent with good professional practice. A patient record should be maintained which is well ordered and contains all laboratory test results and reports (see 5.5 and 5.6), records of consultations and copies of correspondence. Reports and correspondence should be completed promptly (within five (5) working days) following each patient contact. Records should be kept for a period of time that complies with legislative requirements and is consistent with good professional practice.

### 5.2 *Respiratory Function Tests: Equipment and Methods* (see also 5.3 Quality Control, below)

That the methods for conducting respiratory function tests are consistent with recognized standards, including relevant TSANZ guidelines.

#### 5.2.1 *Equipment*

That the equipment used for the conduct of respiratory function and related tests is suitable for the purpose (see also 5.3) and is regularly maintained and safety checked.

The choice of equipment will depend on the type of testing done, the ages of the children tested, the required accuracy of particular measurements, the workload, ease of use, servicing and economic considerations as well as biochemical and electrical safety standards.

Spirometry and Gas Transfer: Equipment used for spirometry and gas transfer and the use of computers for data collection and analysis should meet published standards of the American Thoracic Society<sup>9-11</sup>.

Equipment and systems used for other measurements should have linearity, sensitivity, signal to noise and frequency response characteristics which are appropriate to the particular measurement and should meet currently-accepted, published criteria which help to ensure accurate measurement.

Each service must purchase and maintain the equipment necessary to perform routine calibration of all equipment used in the performance of the above tests.

#### 5.2.2 *Methods*

In the field of respiratory function testing, rigid insistence on the use of particular published methods is inappropriate and would detract from versatility and originality of expertise which reflects the competence of the Service. However,



test procedures should be validated. The TSANZ does not specify which methods a Service may or should use for any particular test. Accreditation will involve examination of the documentation of laboratory methods and their availability to staff working within the Service. To this end each Service should have a procedures manual which contains not only the essential procedural elements of the method but also information on problems that may be encountered and details of any equipment checks and calibrations or other aspects of quality control which may be necessary for that method (see 5.3, below). Personnel performing tests should have ready access to the methods manual and should be encouraged to refer to it frequently.

For a general description of commonly employed methodology for most respiratory function tests, reference to standard texts may be useful<sup>4-8</sup>. Specific information summarising current or standard practices for performing the commonly employed respiratory function tests and investigations is available from the current literature<sup>4,9-14</sup>. In paediatric laboratories the interpretation should conform to the ATS and ERS recommendations for infant and paediatric lung function and should be age appropriate. The references pertaining to each module are listed below.

#### *5.2.3 Computer-aided Respiratory Function Tests*

The basic principles of assessment of computerised testing systems are the same as for any other kind of testing equipment. By their very nature however, computer or microprocessor-aided equipment often requires additional procedures for testing and quality control. Details of any such additional procedures should be documented in the laboratory manual (see 5.2.4 below). Microprocessor controlled systems are by nature prone to subtle errors not normally encountered in purely manual systems. Laboratories using such systems should demonstrate that the methods used and results obtained are valid. A general approach to the use of computers in respiratory laboratories is given by Clausen J.L.<sup>4</sup>, Chapter 27. Specific guidelines for the general use of computers are also given in: Guide to Assessment of Laboratories, National Association of Testing Authorities, Australia, February 1984<sup>15</sup>. These principles will be followed in the assessment of services in so far as they relate to respiratory function testing.

#### *5.2.4 Laboratory Procedures Manual (LPM)*

Laboratory procedures should be described in detail in a laboratory manual. Each test should be separately described with the following detail included or cross referenced from other sources, preferably under appropriate subheadings:

- LPM* 1) The purpose of the test.
- LPM* 2) A description of the equipment used, with special reference to its specifications and their applicability to the measurement.
- LPM* 3) The calibration procedure.
- LPM* 4) The procedure for performance of the test.
- LPM* 5) Troubleshooting: problems which may be encountered in the performance of each test and their appropriate remedies.



- LPM* 6) Specific quality assurance: details of quality control steps required for the method.
- LPM* 7) Cleaning and maintenance
- LPM* 8) Infection control and other safety requirements.
- LPM* 9) Records and Reports (with samples, including interpretation of the results).
- LPM* 10) Normal values and prediction equations used to interpret the results.
- LPM* 11) References. If the test is based on unpublished work, relevant details of this work should be included.
- LPM* 12) The date of issue of and alterations to the method.
- LPM* 13) The signature of the senior laboratory officer - this indicates that the method section has been checked by a senior staff member for procedural and typographical errors before being included in the manual.

Consent for children to do lung function and pretraining procedures. The ability to perform pre-training procedures for a child who has not done, or is not yet proficient, at doing lung function testing.

Appropriate cross-referencing (eg to manufacturer's manual) under each subheading could minimise redundancy while ensuring that all issues relevant to each test have been addressed.

Special requirements for Computer-aided Respiratory Function Tests: Whether written in the laboratory or purchased "off the shelf", computer programs should also be adequately documented in the laboratory manual. Minimum requirements for this documentation include:

- (a) Details of program flow and logic checks performed when implementing the system.
- (b) For programmes written in the laboratory:
  - (i) An outline of the basic structure and logic of the program.
  - (ii) An up-to-date listing of the program.
- (c) Details of comparisons between computer derived results and manually derived results.
- (d) Operating instructions for running the program, including details on restoration of the computer to running condition in the event of computer failure.

Documentation of procedures should be reviewed regularly so that any alterations to methods can be dealt with before the accumulation of such alterations requires the entire manual to be revised. Such reviews should be carried out at least annually.

Personnel performing tests should have ready access to the procedures manual and should be encouraged to refer to it frequently.

Ideally this laboratory manual should be part of a service Policy and Procedures Manual (see 11 below).



### 5.3 *Quality Control of Measurements*<sup>16</sup>

(see also 9. Quality Assurance, below)

That regular monitoring of the accuracy of measurement is undertaken, using appropriate calibrations, internal quality control procedures and, where possible, participation in appropriate inter-laboratory test programs.

Appropriate quality control procedures and equipment for performing them are an essential component of any respiratory function laboratory.

#### *(a) Calibration*

Services should purchase and maintain the equipment necessary to perform routine calibration checks of all testing equipment and set aside non-patient time for equipment calibration. Standard physical calibration should be used routinely. Where electrical calibration is utilized, it must be checked against physical calibration regularly. Calibration results should be labelled, dated and filed for at least the last two (2) years of use of the instrument. Each calibration procedure should be repeated at least twice to ensure reproducibility. Calibration procedures should be performed on a regular basis, or whenever accuracy is in doubt.

Following the calibration of equipment, normal individuals may be utilized to verify the overall performance of the equipment, keeping in mind the reproducibility of the test within a given individual. With more complex tests involving multi-component systems, normal subjects should be employed more frequently.

Guidelines for the calibration and quality control of all individual lung function tests are available from the literature<sup>4,13,16</sup>. Further specific information regarding quality control and calibration guidelines for spirometry, lung volume and diffusing capacity measurements is also available<sup>10,12,16</sup>.

#### *(b) Internal Quality Control*

Internal quality control procedures are the responsibility of the senior laboratory personnel and should be practised in association with each test method at appropriate levels. Details of such procedures must be recorded as part of each test method in the laboratory manual. When routine quality assurance testing indicates that the method is moving out of control and/or the calibration tests show drift, written protocols are helpful in specifying the courses of action to be followed for diagnosis and correction. Graphic records assist the monitoring of internal quality control procedures.

Routine preventive maintenance of equipment used should be documented in the laboratory manual.

#### *(c) External Quality Control*

External quality control, that is participation in inter-hospital proficiency testing programmes, assists in monitoring the effectiveness of internal quality control



procedures.

#### 5.4 *Predicted Values*

That the laboratory utilizes appropriate paediatric predicted values for comparison with the results of each respiratory function test it performs.

The purpose of such a comparison is to help determine whether respiratory function is normal or abnormal. There are a great number of published "predicted" values for many respiratory function tests. Unfortunately, the variability among them is often large, making the choice of predicted values difficult. Frequently there is no objective means of singling out one set of data as being superior to others particularly when different equipment and methodologies have been used.

When a laboratory chooses a set of predicted values, the following recommendations should be taken into account:

- (a) Predictions of expected normal values should be based on studies with large numbers of subjects of both sexes and covering a wide range of ages, heights and weights.
- (b) The equipment and techniques used by a Service and those used to obtain predicted values should, to the extent possible, be similar.
- (c) The population samples should be heterogeneous and incorporate children of all ages and across socio-economic groups. Homogenous groups should be avoided unless a special purpose population is sought.
- (d) Ethnic factors, and respiratory symptoms should be accounted for if possible.
- (e) The equipment and methods used to obtain and analyse the data should be described.

It is highly recommended that the appropriateness of any chosen predicted values should be checked by comparing predicted data with data obtained from a representative sample of "normal" children of all ages.

For general information regarding normal reference values is refer to Clausen J.L. (Chapter 6)<sup>4</sup>, Cotes<sup>6</sup>, and the relevant ATS statement<sup>17</sup>.

#### 5.5 *Laboratory Test Records*

That the laboratory maintains a record of all respiratory function measurements performed.

The TSANZ's basic requirement is that the results are recorded in a clear and unambiguous way, are complete in respect to the performance of the test and can be checked against the original data obtained at the time of measurement. The application of these concepts will vary from one laboratory to another and will depend upon the extent to which the records system is computerized, but the following guidelines will generally be applicable.

If a manual recording system is used, all test data should be recorded clearly and permanently on pro-forma sheets, on test cards or in work books. Sheets of plain paper should not be used because they are easily lost and because they engender a



less disciplined approach to recording the information required. Test records should contain all information needed to show unambiguously what has been done, by whom and when. This will usually mean the following details:

- LPM* 14) Date and time of test
- LPM* 15) Identity of the testing officer
- LPM* 16) Identity of the test method
- LPM* 17) Any variations from the standard method
- LPM* 18) Identification of the subject
- LPM* 19) Reference standard employed (where different from usual)
- LPM* 20) All test data (including units)
- LPM* 21) Any necessary calculations
- LPM* 22) The final results
- LPM* 23) The rounded test result
- LPM* 24) Any other information required by test method
- LPM* 25) Any pertinent observations of the testing officer
- LPM* 26) Signature or initials of the testing officer
- LPM* 27) Signature or initials of the checking officer.

Corrections to the recorded data should be made without obliterating the original data, the reasons for the corrections recorded, and the corrections initialled by the person making them.

The whole records system should be organised in an orderly manner so that any element (sample records, test data, copies of test reports, etc.) may be readily retrieved.

In the case of traditional processes of recording, calculation and typing, printed pro-forma test documents are useful for routine tests. It is the responsibility of the signatory to ensure that all calculations and data transfers have been checked before he or she signs the report.

If test reports are produced by electronic data processing, in some cases remotely from the site of the test, such systems should have built in safeguards as described under computer-aided respiratory function tests (see section 5.2.4).

A copy of all test results and reports should be maintained in a readily accessible state in the records system of the Service. Apart from spirometry, hard copies of original tracings and working sheets should ideally be kept for at least seven (7) years.

## 5.6 *Laboratory Test Reports and Interpretation of Results*

That the test reports provide a clear unambiguous statement of test results.

Each report should contain:

- LPM* 28) Name of Service
- LPM* 29) Unique identification of report for reference
- LPM* 30) Unique identification of patient
- LPM* 31) Test results accompanied by interpretive summary statement(s) relating to clinical significance of test data and addressing any



- specific questions raised in the request for the test.
- LPM* 32) Signature, identification and position of the approved signatory.
  - LPM* 33) Date of report separately from date of test.
  - LPM* 34) The reasons for test request should be on, or attached to, the report.

In examining reporting practice the assessment team will take account of the number of test reports being issued in relation to the number and availability of people authorised to sign them. The number of test reports expected to be signed by any one officer of the laboratory should not exceed that person's capacity to review and check them adequately before issue.

#### 5.7 *Confidentiality of Records and Reports*

That the service protects confidentiality of the patient records and reports.

The service should maintain circumspection regarding the availability of test reports. Generally this should be restricted to the medical and paramedical staff directly involved in requesting the test and in the assessment and management of the particular patient. Information requested by the child or family should normally be dealt with by the medical officer responsible for the Service or by the medical officer/s responsible for the patient's management.

In teaching institutions, access to individual patients' results should be made available to individual students involved in that particular patient's management under the supervision of the medical laboratory staff and the individual patient's attending medical staff. Test reports used for teaching purposes of a general nature (eg. lectures) should have specific patient identifying information removed before use.

Special care should be taken with regard to transmission via facsimile of information which identifiably pertains to individual patient(s). Use of the fax for this purpose should be minimised and any information transmitted by this means should be accompanied by a suitably worded warning regarding the confidential nature of the enclosed information.

#### 5.8 *Safety*

That the laboratory meets standards of laboratory safety<sup>4</sup> consistent with State or Hospital occupational health and safety regulations.

The areas to be covered by documented safety procedures should include infection control, sterilisation, performance of arterial blood gas sampling and handling of samples, handling of hazardous material, handling of gas cylinders, electrical safety and general safety procedures. Electrical supply to the electric monitoring equipment attached directly to patients should be at minimum body protected standard (class B (AS specification)). Laboratory equipment should be supported by a certificate of type testing to AS 3200.1 (1990) or AS 3200 (1986) or equivalent (where available).



## 6. STAFF DEVELOPMENT, TEACHING, RESEARCH

That staff have access to education programmes which maintain and develop their knowledge and skills.

### 6.1 *Staff Development*

That programmes exist to orientate new staff, and for continuing education of existing staff taking into account results of performance appraisal (see 4.4 above), service objectives and quality assurance activities (see 9 below).

That opportunities exist for senior staff to attend relevant professional meetings (state, national, international).

### 6.2 *Teaching*

That where the service operates in a teaching hospital environment it offers education programmes for undergraduates and postgraduates.

### 6.3 *Research*

That where the service operates in a teaching hospital environment it has a commitment to research. This can be demonstrated by reference to current projects, recent presentations (abstracts) and publications.

## 7. FACILITIES

That adequate space and facilities exist for the service to meet its objectives and comply with statutory requirements.

### 7.1 *Space Allocation*

That adequate space exists for the service to function efficiently and effectively. There needs to be adequate space within the lung function laboratory for parent/caregivers and siblings. There needs to be adequate room within the lung function laboratory to accommodate wheelchairs and pram/pushchairs. The requirements of a respiratory function service for space will depend on the type of service provided and in general will consist of:

#### *(a) Primary Service Areas*

These will include the areas set aside for test systems, scientific/technologist staff, and work space for the performance of specific tests or procedures.

#### *(b) Support Areas*

Will include waiting room for patients, patient toilet facilities and adequate storage areas for equipment, consumable stores, gas cylinders and records of investigations.

#### *(c) Administrative Space*

These facilities will depend upon the relationship of the unit to other units, its overall size, and the number of personnel employed in it, as well as occupational health and safety regulations applicable to the location of the unit. This space may include a Medical Director's office, Service supervisor's office (if



applicable), clerical space, record storage facilities, conference room and staff lockers and facilities.

### 7.2 *Facilities*

That the facilities should conform to generally accepted standards for medical suites in size, appearance, privacy, lighting, furniture and provision of other equipment, including office equipment, telephone and other equipment for internal/external communications. Some modern equipment is highly sensitive to ambient temperature making air-conditioning of primary service areas essential.

### 7.3 *Identification*

That the service is identified by signage, telephone and stationery so that it can be easily found and/or accessed.

## 8. **PROVISION FOR EMERGENCIES**

### 8.1 *Medical Emergencies*

That adequate provision is made for paediatric medical emergencies. These should include an on-call roster for medical staff, paediatric CPR training for all staff, availability of resuscitation equipment, oxygen and suction, and easy access to the laboratory and the patient.

### 8.2 *Non-Medical Emergencies*

That provisions complying with relevant site and statutory requirements are made for non-medical emergencies (Fire and Safety).

## 9 **QUALITY ASSURANCE PROGRAMME**

That procedures exist to evaluate the quality of the service provided, correct identified problems, and advance the service's standards.

The process must include the following elements:

Monitoring: regular collection of data relevant to important aspects of service delivery

Assessment: periodic assessment of the data to identify problems or opportunities to improve

Action: action to address such problems or opportunities

Evaluation: evaluation of the effects of such action

Feedback: regular communication to the staff of the results of these activities.

The process must be documented and patient confidentiality must be protected.

## 10. **MEETINGS**

That regular scheduled meetings occur, at no greater than monthly intervals, for the purposes of laboratory function and planning, quality assurance and clinical review, in-service education, and, where applicable, research. There should be records of these meetings. Action statements are encouraged where applicable.

## 11. **POLICIES AND PROCEDURES MANUAL**

That the department maintains a policies and procedures manual which specifies its



organisation and administration, staffing and direction, policies and procedures, staff development and education, facilities and equipment, and quality assurance programme.



## REFERENCES

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## ACCREDITATION OF RESPIRATORY FUNCTION ASSESSMENT SERVICES

### APPLICATION FORM for PAEDIATRICS

*Four copies of the application must be submitted typed, single space on A4 white paper. Each question should be answered specifically but concisely. Answer each question in order and number the response accordingly. If a question is not applicable indicate why.*

*Some questions may be answered by reference to your laboratory manual, provided page and paragraph numbers are specified and four copies of the manual are sent with the application.*

#### **1. IDENTIFYING INFORMATION**

Provide identifying information: complete form A and attach to the front of the application.

#### **2. HISTORICAL OVERVIEW**

Provide a brief historical overview of the service. Include date established, growth of facilities and names of founding staff.

#### **3. ORGANIZATION AND ADMINISTRATION**

##### *3.1 Goals and Objectives*

State general goals and objectives of the service ("mission statement"). Are these compatible with those of the host institution (where applicable)?

##### *3.2 Relationship to Host Institution, Other Laboratories*

Where applicable, describe relationship of service to host institution or to other laboratories if part of a group. Is it a public hospital or private facility? Provide organizational flow chart, showing position within institution and lines of authority.

##### *3.3 Relationships with other specialities*

Describe the service's relationship to related specialities, particularly paediatric respiratory medicine.

##### *3.4 Referrals*

Describe the referral base of the service. What are the service's usual sources of referrals?

##### *3.5 Workload*

Describe the workload of the service. For the most recent calendar or financial year state what type of respiratory function tests were performed and how many of each. Include a breakdown of inpatient and outpatient tests.

##### *3.6 Demand*

- a) Describe how adequately the service copes with the demand for its services.
- b) State the average time in days between referral and assessment.
- c) Describe how the waiting list for investigations is managed and prioritized.
- d) Describe how urgent investigations are managed.



- 3.7 *Budget*  
Describe how the budgetary needs of the service are met.

#### **4. STAFFING AND DIRECTION**

- 4.1 *Staff Structure and Direction*  
Provide organisational chart showing interrelationships/ lines of accountability of all staff members.
- 4.2 *Staff Qualifications and Experience*
- Provide Summary of Staff Information (Form B).
  - Provide Job descriptions for each staff category.
  - What training have medical staff had in respiratory function assessment?  
What training have medical staff had in paediatric respiratory function assessment?
  - Provide CV of all medical staff. For consultant staff: Detail postgraduate qualifications, primary area of specialisation, secondary area of specialisation, hours/week spent solely in respiratory physiology/function assessment, experience in respiratory physiology/function assessment (years). For junior staff: detail proportion of time spent in respiratory physiology and whether a RACP advanced trainee.
  - What training have technologists/scientists had in measuring respiratory function and for what age groups?
  - Provide CV of chief technologist/scientist.
- 4.3 *Staff Numbers*
- Give details of staff establishment (see also 4.2 a).
  - Provide copy of technologist/scientist roster.
  - Detail proportions of time spent by technologists in calibrating equipment, measurement, preparing reports and other duties (specify) including staff meetings, education and research.
  - Specify average time taken for completion of measurements for each type of respiratory function test performed.
- 4.4 *Staff Appraisal*  
Provide details of the service's staff appraisal system.
- 4.5 *Training of Staff in Cardiopulmonary Resuscitation*
- Are all staff trained in paediatric cardio-pulmonary resuscitation?
  - How is knowledge in this area maintained?

#### **5. POLICIES AND PROCEDURES**

- 5.1 *Patient Referral, Handling, Documentation, Follow-up*



How are enquiries from prospective families, individual children and referring doctors handled?

What explanation of investigation(s) is provided to patients?

How are respiratory function tests requested and booked? Are written instructions/information provided to technologists/scientists for the test?

What documentation is kept regarding the patient and for how long?

What information is sent to the referring doctor? Where and how is the record kept? (see also 5.5, 5.6, 5.7)

5.2 *Respiratory Function Tests: Equipment and Methods*

Describe equipment and methods used for the conduct of each test performed by the laboratory, including generation of reports. Include details of relevant equipment specifications, and maintenance and safety check procedures.

Is a manual of laboratory procedures kept? (see 5.2.4 in "Standards") Provide **three** copies with each application (omit where submitted as part of a Policy and Procedures manual (see 11. below).

5.3 *Quality Control of Measurements*

What quality control procedures are in place to ensure that the respiratory function measurements, analysis and interpretation are adequate? Include details relating to calibration (equipment, methods, frequency of), internal quality control, external quality control.

Are methods in place to ensure that problems identified have been adequately addressed?

5.4 *Predicted Values*

Document sources of predicted values for each type of test performed by the laboratory. Document appropriateness of chosen predicted values where possible.

5.5 *Laboratory Test Records*

Describe what records are kept of each type of test performed by the laboratory. Include samples.

5.6 *Reports and Interpretation of Results*

Describe content of reports for each type of test performed and provide sample reports.

How many copies of each patient report are generated and where are they sent?

What is the average time taken from completion of test to issuing the final report?

5.7 *Confidentiality of Records and Reports*

Describe methods by which confidentiality of patient reports and records is maintained.

5.8 *Safety*



Describe procedures to ensure adequate infection control, sterilization, performance of arterial blood gas sampling, handling of samples, handling of hazardous material, handling of gas cylinders, fire and electrical safety, general safety. Describe electrical supply system.

## **6. STAFF DEVELOPMENT, TEACHING, RESEARCH**

### *6.1 Staff Development*

- a) What programmes does the service offer? i) to train new staff; and ii) for continuing education of existing staff. How do these programmes relate to the service's quality assurance programme?
- b) What opportunities exist for senior staff to attend state, national and international meetings? Provide record of recent attendances.

### *6.2 Teaching*

What educational programmes does the service offer to non-staff members (undergraduates, postgraduates)?

### *6.3 Research*

What research activities is the service involved in? What is its research record?

## **7. FACILITIES**

### *7.1/7.2 Space Allocation, Facilities*

- a) Describe location of the service.
- b) Provide floor plan of primary service areas, support areas, and administrative space including dimensions of each room.
- c) Describe lighting, floor coverings, sound-proofing, air conditioning.
- d) How is security maintained for equipment, staff and patients?
- e) Describe office equipment used to generate reports and for internal and external communication.
- f) Describe frequency of cleaning of the facilities.

### *7.3 Identification*

How is the service identified?

- a) Is there a dedicated phone line?
- b) What signage is provided?
- c) Is there separate stationery? Provide samples where applicable.

## **8. PROVISION FOR EMERGENCIES**

### *8.1 Medical Emergencies*

- a) Are all staff trained in paediatric cardiopulmonary resuscitation? How often are they retrained?
- b) Is oxygen available in the laboratory?
- c) Is suction available in the laboratory?



- d) Is a "crash trolley" available?
- e) Is there on-site medical back-up available?
- g) Is there free access to the laboratory and patients in case of emergency?

#### 8.2 *Non-medical Emergencies*

- a) What provisions are made to deal with fire? Describe fire and general safety facilities. Are these compatible with site and statutory requirements?

### 9. **QUALITY ASSURANCE (see also 5.3, above)**

- a) Summarise the quality assurance procedures followed in the service.
- b) What quality control procedures are in place to ensure that the conduct and interpretation of respiratory function tests are adequate? What methods ensure that identified problems are adequately addressed?
- c) Are patient and referring doctor opinions of the service assessed?

### 10. **MEETINGS**

What meetings exist, who attends and how often are they held to meet the following purposes?

service function/planning  
quality assurance  
clinical review  
in-service education  
research.

Are records kept of these meetings? Are action statements used?

### 11. **POLICIES AND PROCEDURES MANUAL**

Does the service maintain a Policy and Procedures manual? Provide **three** copies with this application.



**APPLICATION FOR ACCREDITATION OF PAEDIATRIC RESPIRATORY  
FUNCTION ASSESSMENT SERVICES**

Please return this form to the TSANZ office.  
145 Macquarie St, Sydney, NSW 2000

**FORM A**

IDENTIFYING INFORMATION Date:

*Attach this form to the front of the application (page 1)*

Laboratory Name:

Address:

Tel No:

Fax No:

Email:

Medical Director (Name):

Chief Technologist/Scientist (Name):

Is the laboratory a private or public hospital facility? (circle)

Parent Hospital (if applicable):

Academic Affiliation (if applicable):

Module/s for Paediatric Respiratory Function Assessment for which accreditation is sought:

**This statement must be signed by the medical director of the service:**

*I certify that the statements herein are true and complete to the best of my knowledge.*

signed.....

(name)

(title)

(date)



**APPLICATION FOR ACCREDITATION OF PAEDIATRIC RESPIRATORY  
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**FORM B**

SUMMARY OF STAFF INFORMATION Date:

*Attach this form to the front of the application (page 2)*

Name:

Qualifications:

%FTE:

Title / Role:

Experience\*(years):

Clinical / Research:

1. Medical staff  
(attach rosters)

2. Clerical Staff

3. Scientific/Technical  
(attach rosters)

4. Nursing  
(attach rosters)

5. Other

\* in respiratory function assessment



**THORACIC SOCIETY OF AUSTRALIA & NEW ZEALAND**

**REQUEST FOR RE-ACCREDITATION OF PAEDIATRIC RESPIRATORY  
FUNCTION ASSESSMENT SERVICES**

Please return this form to the TSANZ office.  
145 Macquarie St, Sydney, NSW 2000

**FORM C - IDENTIFYING INFORMATION**

Laboratory Name:

Address:

Tel. No.:

Fax. No:

Email:

Medical Director:

Head Scientist / Technologist:

Date of Previous Accreditation:

Application for Accreditation updated to reflect current practice: Yes / No

Laboratory manuals updated to reflect current practice: Yes / No

Category of Respiratory Function Assessment Service for which accreditation is sought:

List of individual tests for which accreditation is sought:

**This statement must be signed by the medical director of the service:**

*I certify that the information herein is true and complete to the best of my knowledge.*

*signed*.....

(Name)

(Title)

(Date)



**THORACIC SOCIETY OF AUSTRALIA & NEW ZEALAND**

**REQUEST FOR RE-ACCREDITATION OF PAEDIATRIC RESPIRATORY  
FUNCTION ASSESSMENT SERVICES**

Please return this form to the TSANZ office.  
145 Macquarie St, Sydney, NSW 2000

**FORM D - SUMMARY OF STAFF INFORMATION**

Name	Qualifications	%FTE	Title/role	Experience* (yrs) clinical / research
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**1 Medical**

**2 Clerical**

**3 Scientific/Technical**

**4 Nursing**

**5 Other**

**6 Attach Curriculum Vitae of Medical Director and Head Scientist/Technologist**

assessment

\*in respiratory function



**THORACIC SOCIETY OF AUSTRALIA & NEW ZEALAND**

**REQUEST FOR RE-ACCREDITATION OF PAEDIATRIC RESPIRATORY  
FUNCTION ASSESSMENT SERVICES**

Please return this form to the TSANZ office.  
145 Macquarie St, Sydney, NSW 2000

**FORM E - CHANGES TO THE SERVICE**

(use additional pages where necessary)

1. Detail changes to the Service resulting from the recommendations contained within the previous Assessment Panel report. Please use the same numbering system as the previous report.
2. List any other changes to the Service since the previous Accreditation. Include details of any staffing changes (medical or scientific).