# General Accreditation Guidance

## TSANZ Standard for Respiratory Function Laboratories (2024) - Gap Analysis

**December 2024**

# Background information and purpose

The TSANZ *Standard for Respiratory Function Laboratories* (December 2024) has been developed through the adoption of the technical requirements (Section 7) from the former TSANZ *Respiratory Function Laboratory Accreditation Program Manual* (June 2021), which have then been formatted to follow the framework of ISO 15189:2022 *Medical laboratories - Requirements for quality and competence*.

This document serves as an informative guide mapping the clauses in the TSANZ Standard for Respiratory Function Laboratories (2024) to the TSANZ Respiratory Function Laboratory Accreditation Program Manual (June 2021).

The main changes between the two standards are highlighted in this document, as follows:

**Table A** Compares the TSANZ *Standard for Respiratory Function Laboratories* (December 2024) to the former TSANZ *Respiratory Function Laboratory Accreditation Program Manual*, Section 7 (June 2021).

Please note that whilst the wording of the clauses (requirements) may have changed, the intent of the old clauses has been largely retained. Only major differences have been specifically highlighted.

**Table B** Compares the TSANZ *Respiratory Function Laboratory Accreditation Program Manual*, Section 7 (June 2021) to the TSANZ *Standard for Respiratory Function Laboratories* (December 2024).

This table maps the clauses so that the corresponding requirement in the 2024 version of the Standard can be identified. It also allows users to identify requirements that have not been included in the new version.

The scope of the TSANZ/NATA Respiratory Function Laboratory Accreditation Program does not include pathology testing. All requirements related to pathology testing (such as blood gas analysis) have been removed from the Standard. Accreditation for pathology testing falls under the Human Pathology Accreditation Program and must comply with both ISO 15189 and the NPAAC requirements.

Further, some content from the TSANZ *Respiratory Function Laboratory Accreditation Program Manual* has been relocated to other supporting documents.

The content of this document is informational in nature and does not constitute a requirement for accreditation.

# Table A - Comparison of TSANZ *Standard for Respiratory Function Laboratories* (2024) to the TSANZ *Respiratory Function Laboratory Accreditation Program Manual* (June 2021).

The following table maps the clauses from the TSANZ *Standard for Respiratory Function Laboratories* (December 2024) (TSANZ 2024)) to the clauses of TSANZ *Respiratory Function Laboratory Accreditation Program Manual*, Section 7 (June 2021) (TSANZ 2021.

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 1 | **Scope** | |
| 2 | **Terminology and Presentation** | |
| 3 | **Definitions** | |
| 4 | **General Requirements** | |
| 4.1 | Impartiality | New requirement |
| 4.2 | Confidentiality | 7.2.5 |
| 4.3 | Requirements regarding patients | New requirement |
| 5 | **Structural Requirements** | |
| 5.1 | Legal entity | 7.1<br>Expanded requirement |

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 5.2 | Laboratory Director | 7.2.1.3, 7.2.2, 7.2.2.1, 7.2.2.2 |
| 5.3 | Laboratory activities | 7.2 |
| 5.4 | Structure and authority | 7.2.1.1, 7.2.1.2, 7.2.1.3, 7.2.1.4, 7.2.4.4, 7.2.7.2 |
| 5.5 | Objectives and policies | 7.2.1.1, 7.2.1.3, 7.2.3, 7.2.6 |
| 5.6 | Risk Management | New requirement |
| 6 | **Resource Requirements** | |
| 6.1 | General | 7.2.2 |
| 6.2 | Personnel | 7.2.2.1, 7.2.2.2, 7.2.2.3, 7.2.4.4, 7.2.7.1, 7.2.10, 7.3.2.4 |
| 6.3 | Facilities and environmental conditions | 7.2.8, 7.2.8.1, 7.2.8.2 |
| 6.3.1 | General | 7.2.8, 7.2.8.2, 7.2.8.3, 7.2.10 |
| 6.3.2 | Primary service areas | 7.2.8.1 |
| 6.3.3 | Administrative space | 7.2.8.1 |
| 6.3.4 | Storage facilities | 7.2.8.1 |
| 6.3.5 | Personnel facilities | 7.2.8.1 |
| 6.3.6 | Reception facilities | 7.2.8.1 |

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 6.3.7 | Mobile laboratories | 7.2.8.4 |
| 6.3.8 | Infection prevention and control | 7.2.9 |
| 6.3.9 | Safety procedures | 7.2.10 |
| 6.4 | Equipment | 7.2.10, 7.3.1 |
| 6.5 | Equipment calibration and metrological traceability | 7.3.1.1, 7.3.2.1, 7.3.2.2 |
| 6.6 | Reagents and consumables | New requirement |
| 6.7 | Service agreements | 7.3.2.4 |
| 6.8 | Externally provided products and services | 7.3.2.3 (QC only)<br>Expanded requirement |
| 7 | **Process Requirements** | |
| 7.1 | General | 7.2.3 |
| 7.2 | Pre-test processes | 7.2.3 |
| 7.3 | Requests for laboratory tests | 7.2.3 |
| 7.4 | Patient reception procedures | 7.2.3 |
| 7.5 | Test methodology | 7.3.1 |

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 7.5.1 | Documentation of test procedures | 7.2.4.1, 7.3.2, 7.3.4 |
| 7.5.2 | Test method selection | 7.3.1, 7.3.1.2, 7.3.2, 7.3.3 |
| 7.5.3 | Verification of test methods | New requirement |
| 7.5.4 | Validation of test methods | 7.3.2 |
| 7.5.5 | Reference ranges and clinical decision limits | 7.3.2 |
| 7.5.6 | Validity of results | New requirement |
| 7.5.7 | Internal quality control (IQC) | 7.3.2 |
| 7.6 | Post-test processes | |
| 7.6.1 | Reporting | 7.2.3, 7.2.4.2, 7.2.4.4 |
| 7.6.2 | Critical result reports | New requirement |
| 7.6.3 | Special consideration for results | New requirement |
| 7.6.4 | Requirements for reports | 7.2.4.2, 7.2.4.4 |
| 7.6.5 | Amendments to reported results | New requirement |
| 7.7 | Non-conforming work | New requirement |

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 7.8 | Control of data and information management | New requirement |
| 7.8.1 | Control of data | 7.2.4.1, 7.2.6 |
| 7.8.2 | Information systems management | 7.2.4 |
| 7.8.3 | Downtime plans | New requirement |
| 7.8.4 | Off-site management | New requirement |
| 7.9 | Complaints | 7.2.6 |
| 7.10 | Continuity and emergency preparedness planning | 7.2.10<br>Expanded requirements |
| 8 | **Management System Requirements** | |
| 8.1 | General requirements | Expanded requirements |
| 8.2 | Management system documentation | Expanded requirements |
| 8.3 | Control of management system documents | 7.2.4<br>Expanded requirements |
| 8.4 | Control of records | 7.2.3, 7.2.4, 7.2.4.2, 7.2.8.4, 7.3.2.1<br>Expanded requirements |

| TSANZ Standard (2024) Clause No. | Clause/Sub-clause Heading | Corresponding TSANZ Laboratory Manual (2021) Clause No. |
|---|---|---|
| 8.5 | Actions to address risks and opportunities for improvement | 7.2.6<br>Expanded requirements |
| 8.6 | Improvement | 7.2.6<br>Expanded requirements |
| 8.7 | Nonconformities and corrective action | 7.2.6<br>Expanded requirements |
| 8.8 | Evaluations | 7.2.6<br>Expanded requirements |
| 8.9 | Management reviews | 7.2.6<br>Expanded requirements |
| 9 | **Appendix A** | Appendix A |
| 10 | **Appendix B** | Appendix B |

# Table B - Comparison of TSANZ *Respiratory Function Laboratory Accreditation Program Manual* (June 2021) to the TSANZ *Standard for Respiratory Function Laboratories* (December 2024).

The following table maps the clauses from the TSANZ *Respiratory Function Laboratory Accreditation Program Manual* (June 2021) (TSANZ lab manual 2021) to the TSANZ *Standard for Respiratory Function Laboratories* (December 2024) (TSANZ 2024.

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.1 | This information is collected in the application form/s and includes the laboratory name, physical location, and the details of all physical site where the laboratory staff are authorised to conduct tests and deliver services that are to be assessed as part of the accreditation application and assessment. This information is also required for any branch sites. | Removed from the Standard.<br>Will be placed in supporting documentation. |
| 7.2 | The laboratory must have documented policies and procedures that reflect current knowledge and practice in the conduct of a respiratory function laboratory assessment service and, where relevant, comply with statutory requirements. | 5.3.1 |
| 7.2 | Details regarding all aspects of the respiratory function laboratory assessment service must be succinctly and accurately described in this manual. It is recommended that this manual must include (at a minimum) descriptions of the following items described in the remainder of this section. | 5.3.2 |
| 7.2.1.1 | The laboratory's goals and objectives must be specified and reflect its role and responsibilities. | 5.4.1 |
| 7.2.1.2 | The relationship(s) of the laboratory to the host institution (where relevant) and to related laboratories (e.g. branch sites) must be described. | 5.4.1 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.1.2 | There must be an institutional organisation chart showing the lines of accountability of the laboratory to the host institution. | 5.4.1 |
| 7.2.1.2 | There must be evidence of commitment by the host institution to its support. | Requirement removed |
| 7.2.1.2 | The laboratory should have documented that there are 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. | Requirement removed |
| 7.2.1.3 | A regular updated audit of the laboratory's workload in terms of number of tests of each particular type must be kept and these records must be available on a quarterly or yearly basis. | 5.5.4 |
| 7.2.1.3 | A copy of workload audits for the past five years must be provided with the application. | Requirement removed |
| 7.2.1.3 | The laboratory's resources (staffing equipment, facilities and finances) must be sufficient to meet its workload without compromising the minimum standards (e.g. for patient testing, staff development, quality assurance program and quality control, infection control and laboratory safety) set elsewhere in this document. | 5.2.1<br>6.2.1 |
| 7.2.1.4 | Regular scheduled meetings must 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. Meetings must involve the medical and scientific directors, scientific, nursing, technical and administrative staff as appropriate. There must be records of these meetings including attendance. Action statements should be utilised where applicable. Branch site staff can participate in meetings at the primary site or locally at the branch site. | 5.4.2 |
| 7.2.2 | The laboratory must be directed and staffed to achieve its objectives. | 5.2 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.2 | The laboratory must have a director responsible for overall standards and development of policies governing the laboratory. These should be ratified by other committees in the host institution, as necessary. | 5.2 |
| 7.2.2 | There must be clear, documented lines of accountability/responsibility between the medical and scientific directors 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. | 5.4.1 |
| 7.2.2 | There must be an organisation chart showing the lines of accountability of laboratory staff to relevant management. | 5.4.1 |
| 7.2.2.1 | The Medical Director must have specific, detailed training in clinical respiratory physiology as per the TSANZ Medical Director statement. | 5.2.2 |
| 7.2.2.1 | Staff members must be appropriately qualified for their tasks by education, training, and experience, confirmed as competent in their duties, and their roles and responsibilities must be specified by their institutional job description. | 6.2.1 |
| 7.2.2.1 | Only scientific staff may be responsible for accurate performance of tests, equipment maintenance, continuing quality assurance of both equipment and techniques and patient safety during performance of tests. | Requirement removed. |
| 7.2.2.1 | The scientific staff must meet the Australian and New Zealand Society of Respiratory Science (ANZSRS) guidelines for qualifications and experience. | 6.2.4 |
| 7.2.2.1 | A record of training and competency must be available for any staff conducting testing, equipment maintenance, and quality activities. | 6.2.2 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.2.1 | It is strongly recommended that scientific staff should be registered as a respiratory clinical physiologist with the Australian Council for Clinical Physiologists (ACCP) or the Clinical Physiologists Registration Board (CPRB) in New Zealand. | 6.2.5 |
| 7.2.2.2 | That sufficient medical, scientific, and administrative staff must be employed to adequately meet service needs. This will depend on the workload, organisation, type of equipment and circumstances of the individual institution. | 6.2.1 |
| 7.2.2.2 | Current staffing levels with details of qualifications and experience must be included with the application. | Removed from the Standard.<br>Will be placed in supporting documentation. |
| 7.2.2.2 | Where three (3) or more laboratory staff are employed (irrespective of the total full-time equivalent), there must be both a designated Scientific Director and Medical Director to manage the laboratory. | 5.2.3 |
| 7.2.2.2 | Appropriate supervisory roles and responsibilities must be included in both position descriptions. | 5.2.5 |
| 7.2.2.3 | Programs must exist to orientate new staff, and must exist for continuing education of staff, taking into account results of performance appraisal, service objectives and quality assurance activities. | 6.2.1 |
| 7.2.2.3 | Opportunities must exist for staff to attend relevant professional meetings where appropriate (local, state, national, international). | 6.2.7 |
| 7.2.2.3 | A staff appraisal system must be in operation, with a written report produced, where the staff member involved is aware of the contents of the report and where a plan to address any deficiencies is defined. | 6.2.13 |
| 7.2.3 | the sources and types of referrals to the laboratory are relevant to the services provided. | 7.3 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.3 | Referrals to the laboratory must be related to respiratory function laboratory assessment or other matters for which there is local expertise. | 7.3.4 |
| 7.2.3 | The procedures for allocation of appointments must be appropriate and clearly defined. | 7.3.5 |
| 7.2.3 | Triaging of priority for more urgent tests must be described. | 7.3.4 |
| 7.2.3 | The laboratory must demonstrate systems to cope with the demands for its services. | 5.5.1 |
| 7.2.3 | Where demand exceeds capacity, the laboratory must have a system for prioritising cases perceived to be urgent. | 7.3.4 |
| 7.2.3 | The laboratory should be able to assess new patients within two (2) weeks of referral (where appropriate). Urgent cases must be assessed within two (2) working days. | Requirement removed |
| 7.2.3 | Procedures must exist for prompt, efficient handling of patient referrals, documentation, communication with the referring doctor, and that these are consistent with good professional practice. | 7.3.4 |
| 7.2.3 | Reports and correspondence must be completed promptly (within five (5) working days) following each patient contact. | 7.6.1.2 |
| 7.2.3 | A patient record must be maintained which is well ordered and contains all laboratory test results and reports, records of consultations and copies of correspondence. | 8.4 |
| 7.2.3 | There must be a record storage protocol such that records are kept for a period of time that complies with legislative requirements and is consistent with good professional practice. | 8.4 |
| 7.2.4 | It is the responsibility of the signatory to ensure that all calculations and data transfers have been checked before the report is authorised. | 7.8.2.1 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.4 | Test data and records, including data and records maintained remotely from the site of the test, must have built in safeguards including, but not limited to, data and document backup, and control procedures. | 7.8.4.1 |
| 7.2.4 | In the event the laboratory uses hard copy processes, there must be a documented system that details calculation and data transfer processes to ensure accuracy, which is subject to the audit process. | 7.8.2.1 |
| 7.2.4 | In the case of traditional processes of recording, calculation and typing, printed pro-forma test documents should be used to ensure consistent recording of critical information. | Requirement removed. |
| 7.2.4 | The whole records system must be organised in an orderly manner so that any element (sample records, test data, copies of test reports, etc.) may be readily retrieved. | 8.4 |
| 7.2.4 | The laboratory must maintain a record of all respiratory function measurements performed in accordance with their host institution’s record policy. | 8.4 |
| 7.2.4 | Results must be 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. | 8.4 |
| 7.2.4 | The application of these concepts will vary from one laboratory to another and will depend upon the extent to which the records system is computerised, but the following guidelines will generally be applicable. | Requirement removed. |
| 7.2.4 | It is strongly encouraged that electronic systems are used. | Requirement removed. |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.4 | Test records must contain all information needed to show unambiguously what has been done, by whom and when. This will mean the following details must be included:<br>• date and time of test;<br>• identity of the testing officer;<br>• identity of the test method;<br>• any variations from the standard method;<br>• identification of the subject;<br>• all test data (including units) and any necessary calculations;<br>• final results;<br>• any other information required by test method; and<br>• any pertinent observations of the testing officer. | 8.4.1 |
| 7.2.4 | Corrections to the recorded data must be made without obliterating the original data, the reasons for the corrections recorded, and the person making the corrections must be documented. | 8.4.3 |
| 7.2.4.2 | The test reports must provide a clear unambiguous statement of test results.<br>It is recommended that the report format should follow ATS/ERS standards. | 7.6.1.1<br>7.6.1.1 (note) |
| 7.2.4.2 | Hardcopy final laboratory reports for inclusion in patient medical records (whether paper-based or electronic) must be printed on an approved medical record form in compliance with local institutional requirements and national hospital accreditation standards. | Requirement removed. |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.4.2 | At a minimum, each report must contain:<br>• name and contact information of the laboratory;<br>• a descriptor of test(s) performed;<br>• unambiguous identification of the patient, including full name and unique identification number;<br>• date and time of test;<br>• test results accompanied by interpretive summary report relating to clinical significance of test data and addressing any specific questions raised in the request for the test;<br>• limits of normality and, where possible, z scores;<br>• signature and position of the approved signatory. Signatures can be hard copy or electronic, provided the electronic signature can be authenticated;<br>• date of report separately from date of test; and<br>• the reasons for test request. | 7.6.4.1 |
| 7.2.4.2 | A copy of all test results and reports must be maintained in a readily accessible state in the records system of the laboratory for the minimum period designated by hospital policy or legislative requirements. | 8.4 |
| 7.2.4.3 | Use of the TSANZ logo must be in accordance with conditions of use for the TSANZ accredited respiratory function laboratory logo | Removed from the Standard.<br>Will be placed in supporting documentation. |
| 7.2.4.4 | All laboratory test results must be interpreted and signed off by a qualified clinician and/or scientist. | 7.6.1.6 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.4.4 | Policies detailing responsibilities for interpretation must be described, and to minimise potential for inter-reporter variability in interpretation, recommendations for standardisation in approach to interpreting test results must be included. | 7.6.1.5<br>7.6.1.7 |
| 7.2.4.4 | It is highly recommended that ATS/ERS guidelines for interpretation should form the basis of such recommendations, and other reputable references, such as Interpreting Lung Function Tests: a step-by-step guide, could also be utilised. | 7.6.1.7 note |
| 7.2.4.4 | Definitions of normality/abnormality must be clearly stated and based upon statistically valid techniques. | 7.6.1.7 |
| 7.2.4.4 | Comparisons to 95% confidence intervals, rather than with fixed percentage of predicted values, are required, and the laboratory report form must facilitate these comparisons by including appropriate normal ranges (upper and lower limits of normal). | 7.6.4.1 note |
| 7.2.4.4 | There should be adequate recognition of problems with certainty/uncertainty associated with test results close to normal/abnormal cut-off values. | 7.6.1.8 |
| 7.2.4.4 | The interpretation guidelines should also highlight the importance of addressing the reason the testing was requested. | 7.6.4.1 l). Now a requirement. |
| 7.2.4.4 | Clear processes must be described for responsibilities for overseeing training of clinicians in respiratory function interpretation, including feedback, correction and signing off processes, where applicable. | 6.2.3 |
| 7.2.4.4 | 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 interpreted by any one officer of the laboratory must not exceed that person's capacity to review and check them adequately before issue. | 5.4.4 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.5 | The laboratory must protect confidentiality of patient records and reports and there must be a documentation of policies. | 4.2 |
| 7.2.5 | Test reports used for teaching purposes of a general nature (e.g. lectures) must have specific patient identifying information removed before use. | 4.2 |
| 7.2.5 | The laboratory 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. | 4.2 Confidentiality now a requirement |
| 7.2.5 | In teaching institutions, access to individual patient's results should be made available to individual students involved in that particular patient's management under the supervision of the laboratory staff and the individual patient's attending medical staff. | 4.2 Confidentiality now a requirement |
| 7.2.5 | Policies regarding requests for laboratory results from the patient or other individuals must be developed. | 4.2 |
| 7.2.5 | Hardcopy storage of results must be in a secure location with keyed or password-lock access only. | 4.2 |
| 7.2.5 | All computer systems accessible to patient information must be password protected. | 6.2.6 |
| 7.2.5 | Policies must exist to ensure that special care is taken with regard to electronic transmission (via fax, email, or other means) of information which identifiably pertains to individual patient(s). Information transmitted by such means must be accompanied by a suitably worded warning regarding the confidential nature of the enclosed information. | 4.2.7 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.6 | A quality assurance program must be in place to facilitate continual quality improvement by evaluating the quality of the service provided, correcting identified problems, and overall advancing the laboratory's standards. At a minimum, the types of activities that must be incorporated into the quality program include, but are not limited to:<br>• consumer/client satisfaction;<br>• reporting turnaround times;<br>• appointment bookings and waiting periods for routine and urgent studies;<br>• workload audits; and<br>• complaints management. | 8<br>5.5.4 |
| 7.2.6 | The review process must occur regularly, be documented and patient confidentiality must be protected. | 8 |
| 7.2.6 | Additionally, laboratories should also incorporate the following activities into their quality assurance program:<br>• identification and control of non-conformities;<br>• corrective actions;<br>• preventive actions;<br>• internal audits, with resulting actions and changes; and<br>• management review | 8 Management system elements now a requirement |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.6 | The (QI) process must include the following elements:<br>• monitoring: regular collection of data relevant to important aspects of service delivery;<br>• assessment: periodic assessment of the data to identify problems or opportunities to improve;<br>• action: action to address such problems or opportunities;<br>• evaluation: evaluation of the effects of such action; and<br>• feedback: regular communication to the staff of the results of these activities. | 8 |
| 7.2.7.1 | There must be educational programs for advanced trainees in respiratory medicine which ensure trainees receive practical and theoretical respiratory physiology teaching, and involvement and training in quality assurance activities within the laboratory. | 6.2.8 |
| 7.2.7.1 | Where the laboratory operates in a teaching hospital environment, it should offer education programs for undergraduates and postgraduates in medical, nursing, scientific and allied health areas. | 6.2.9 |
| 7.2.7.2 | Where the laboratory operates in a teaching hospital environment, it should have a commitment to research. This can be demonstrated by reference to current projects, recent presentations (abstracts) and publications. | 5.4.3 |
| 7.2.8 | Adequate space and facilities must exist for the laboratory to meet its objectives and comply with statutory requirements. | 6.3.1 |
| 7.2.8 | All laboratory testing and scientific work areas must comply with institutional and/or national Work Health and Safety guidelines and be confirmed as fit for purpose and safe for resuscitation of patients. | WHS - 5.3.2<br>Resuscitation - 6.3.1.1 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.8 | Where available, the local Work Health Safety department should formally assess laboratory facilities and provide written documentation that the facilities comply with statutory requirements, are fit for purpose and are safe for patients and staff. | 6.3.1 (note) |
| 7.2.8.1 | Adequate space must exist for the laboratory to function safely, efficiently and effectively. | 6.3.1 |
| 7.2.8.1 | The space requirements of a respiratory function laboratory will depend on the type of service and tests provided and, in general, will consist of:<br>(a) Primary service areas<br>These must include the areas set aside for test systems, separate workspaces for scientific staff, and workspace for the performance of specific tests or procedures. The laboratory must provide patient privacy during testing (both visual and acoustic) in a built environment which must not impact on the quality or accuracy of test performance and results. Testing must occur in separate fully enclosed rooms with effective ventilation and patients must not be tested concurrently in the same room. Laboratory staff must have the ability to test patients effectively and safely. Hence, testing rooms must be of an adequate size and design to allow staff to perform their duties safely and not impeded in their movements event of a medical or other emergency.<br>(b) Support areas<br>Must include a waiting space for patients (including inpatients if the laboratory is based within a hospital), appropriate reception facilities, accessible patient toilet facilities and adequate storage areas for equipment, consumable stores, gas cylinders and records of investigations.<br>(c) Administrative space<br>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 should include a Medical Director's office, Scientific Director's office (if applicable), clerical space, record storage facilities, access to conference room and staff lockers. | 6.3.1 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.8.2 | The facilities must conform to generally accepted standards for medical procedure and treatment rooms in size, appearance, privacy, lighting, furniture, flooring and provision of other equipment, including office, equipment, telephone and any other equipment required for internal/external communications. Some<br>modern equipment is highly sensitive to ambient temperature making stable air-conditioning of primary<br>service areas essential. Carpet must not be used in any procedural areas. Facilities must also meet any local requirements for infection control and prevention, including negative pressure testing rooms and ability to terminally clean testing rooms where required. | 6.3.1 |
| 7.2.8.3 | The laboratory must be clearly identified by signage or appropriate wayfinding, telephone, and stationery so that it can be easily found and/or accessed. | 6.3.1.3 |
| 7.2.8.4 | The requirements for mobile spirometry providers must be consistent with those outlined in the Respiratory Function Laboratory Accreditation Program Manual and adhere to specific conditions unique to mobile delivery. | Removed from the Standard.<br>Will be placed in supporting documentation. |
| 7.2.8.4 | Mobile providers must ensure that they have access to a dedicated space suitable for testing at any given site. If they are travelling to more than one testing site per day, steps must be taken to ensure an appropriate space is allocated at each site specifically for lung function testing. | 6.3.7 |
| 7.2.8.4 | Mobile providers will also need to take measures to ensure strict cleaning and infection control procedures are in place as the equipment travels from site to site, and this will have to be recorded as evidence in their equipment maintenance logs. | 6.3.8 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.8.4 | Extra mobile equipment is required in order to maintain temperature and humidity for accurate spirometer measurement. The spirometer must also be calibrated, or calibration verified, prior to each testing and this verification recorded as evidence of proper test function. | Requirement removed. (General calibration requirements apply - see 6.5). |
| 7.2.8.4 | Additional details will be required in equipment maintenance logs to ensure that calibration and/or verification records are kept at different sites. | 8.4 |
| 7.2.9 | Respiratory function laboratories raise very specific infection control issues and adequate understanding and commitment to minimising risk of cross-infection is essential. | Requirement removed. |
| 7.2.9 | Clearly defined infection control procedures must be developed in accordance with current state and/or national standards | 6.3.8 |
| 7.2.9 | Where there is a hospital infection control department they must be engaged in the development and endorsement of these procedures.<br>All laboratory testing and scientific work areas must be formally assessed by the local infection control department (where available) in accordance with institutional and national guidelines and confirmed as fit for purpose. | 6.3.8 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.9 | Infection control procedures must include, but not necessarily be limited to, addressing the following issues:<br>• cleaning and/or sterilisation of patient testing equipment;<br>• use of in-line bacterial filters;<br>• procedures for storage of re-usable equipment such as cleaned mouthpieces;<br>• details regarding 'standard precautions and the differences between critical, semi-critical and non-critical equipment;<br>• policies with regard to single-patient use equipment;<br>• special procedures for patients with known infectious diseases including Multi-resistant Organisms (MROs); and<br>• laboratories should resource recyclable items when possible. | 6.3.8 |
| 7.2.10 | The laboratory must meet standards of laboratory safety consistent with national workplace health and safety legislation. | 5.3.2<br>6.3.9 |
| 7.2.10 | The areas to be covered by documented safety procedures must include:<br>• handling of hazardous materials including blood and other body fluids;<br>• safe handling, storage, and transportation of gas cylinders. Gas cylinders must all be secured; and<br>• electrical safety and general safety procedures. | 6.3.4.2 |
| 7.2.10 | Electrical supply to the electric monitoring equipment attached directly to patients must be at minimum body protected standard (class B (AS specification)). | 6.3.1.2 note |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.2.10 | Laboratory equipment must be listed on the Australian Register of Therapeutic Goods (ARTG) as a medical device and the public summary must indicate that the equipment is suitable for the proposed use. | 6.4.2 |
| 7.2.10 | Emergency procedures meeting local requirements must have been developed and documented. | 6.3.9.2 |
| 7.2.10 | Adequate provision must be made for medical emergencies including an on-call roster for medical staff, Cardiopulmonary resuscitation (CPR) training for all staff, availability of resuscitation equipment, oxygen and suction, and easy access to the laboratory and the patient. | 6.3.9.3 |
| 7.2.10 | Testing rooms must be large enough to allow an effective and safe response to patients and/or staff during a medical emergency. This includes entry of a crash trolley and emergency response team. | 6.3.1.1 |
| 7.2.10 | Rooms must allow unimpeded access for ambulant and non-ambulant patients, including wheelchair access. | 6.3.1.1 |
| 7.2.10 | All medical, laboratory and nursing staff who conduct procedures in the laboratory must be trained in cardiopulmonary resuscitation, and a basic level of competence must be maintained, and records of this training must be maintained by the laboratory or its host institution. | 6.2.11 |
| 7.2.10 | CPR competency must be achieved at an interval set down by the host institution, or where no host institution exists, no less than annually. | 6.2.12 |
| 7.2.10 | Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies such as fire, aggression, bomb threats etc. | 5.3.2<br>6.3.1.1 |
| 7.3.1 | The methods for conducting respiratory function tests must be consistent with established techniques and in accordance with published national and international standards. | 7.5.2.1 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.1.1 | The equipment used for the conduct of respiratory function and related tests must be suitable for the purpose and must be calibrated in line with current best practice guidelines (ATS/ERS). | 6.4.3 |
| 7.3.1.1 | The choice of equipment will depend on the required accuracy of particular measurements, the workload, ease of use, servicing, and economic considerations as well as relevant safety standards. | 6.4.1 |
| 7.3.1.1 | Equipment used for spirometry, lung volumes and gas transfer, and the use of computers for data collection and analysis, must meet published standards of the ATS/ERS6. | 6.4.3 |
| 7.3.1.1 | Quality control procedures for blood gas analysers must be appropriate to ensure validity of test results and participation in external quality assurance programs is essential. Compliance with relevant testing authority requirements for arterial blood gas analysis is essential. | Requirement removed. |
| 7.3.1.1 | Equipment and systems used for other measurements must have linearity, sensitivity, signal to noise and frequency response characteristics which are appropriate to the particular measurement and must meet accepted, published criteria which help to ensure accurate measurement. | 6.5.1 |
| 7.3.1.1 | Each laboratory must purchase and maintain the equipment necessary to perform routine calibration of all equipment used in the performance of the above tests. | 6.5.2 |
| 7.3.1.3 | Where a laboratory wishes to include any test in their scope of accreditation, the onus is on the laboratory to demonstrate ongoing competence for each test. | 6.2.1 |
| 7.3.1.3 | For infrequently performed tests, a documented procedure must be available describing how the facility assures the results and maintains the skills necessary to perform the test (see Note 1). | 5.6.3 |
| 7.3.1.3 | A test that is performed two or less times a year (averaged over the previous three years) is considered ineligible for accreditation. | Requirement removed. |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.1.3 | Note 1: An infrequent test is defined as having been performed less than 10 times per year but more than twice per year, averaged over the previous three years. Evidence of testing frequency must be provided for infrequent tests. | Requirement removed. |
| 7.3.2 | For routine clinical assessment of spirometry, carbon monoxide transfer factor, lung volume measurement, bronchial provocation testing and performance of the Six Minute Walk Test, test protocols used within the laboratory must comply with the most recent ATS/ERS standardisation guidelines. | 7.5.2.2 |
| 7.3.2 | If a laboratory does not use these guidelines for routine testing, adequate explanatory notes and rationale must be included in the laboratory manual. | 7.5.2.2 (note) |
| 7.3.2 | Where appropriate, validation of differing techniques must be provided. | 7.5.4 |
| 7.3.2 | Recent data from the ERS Global Lung Initiative has demonstrated that age (in years) and height (in cm) must be recorded to one (1) decimal place to minimise prediction errors. | 7.5.5.4 |
| 7.3.2 | Staff performing tests must have ready access to the methods manual and should be encouraged to refer to it as needed | 7.5.2.4 |
| 7.3.2 | One of the key aspects of the quality system is ensuring the quality and accuracy of laboratory measurements.<br>Regular monitoring of the accuracy of measurements must be undertaken, using appropriate calibrations, internal quality control procedures and, where possible, participation in appropriate inter-laboratory quality assurance programs. | 7.5.7 |
| 7.3.2 | Appropriate quality control procedures and equipment for performing them are an essential component of any respiratory function laboratory. | Requirement removed. |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.2.1 | Laboratories must purchase and maintain the equipment necessary to perform routine calibration checks of all testing equipment and must set aside non-patient time for equipment calibration. | Requirement removed. |
| 7.3.2.1 | Standard physical calibration must be performed routinely. | 6.5 |
| 7.3.2.1 | Where electrical calibration is utilised, it must be checked against physical calibration regularly. | Requirement removed. |
| 7.3.2.1 | Calibration results must be labelled, dated, and filed (either electronically or manually) for at least the last two (2) years of use of the instrument. | 8.4 |
| 7.3.2.1 | Each calibration procedure must be repeated at least once to ensure reproducibility. | Requirement removed. |
| 7.3.2.1 | Calibration check procedures must be done on at least a daily basis when that instrumentation is in use, or whenever accuracy is in doubt | 6.5.3 |
| 7.3.2.2 | Routine preventive maintenance of equipment used must be documented in the laboratory manual. | 6.4.1 |
| 7.3.2.2 | In addition to daily calibration checks of equipment, biological and non-biological control measures must be utilised to verify the overall performance of the equipment. | 6.5.4<br>6.5.5 |
| 7.3.2.2 | Guidelines for the calibration and quality control of all individual lung function tests are available from the ATS/ERS Guidelines. Further general knowledge can be found in a range of medical texts | 6.5.2 (note) |
| 7.3.2.2 | The table (in appendix A) outlines the type of non-biological controls that must be performed for each of the common respiratory function tests (on each separate piece of equipment), and the interval for testing. | 6.5.4 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.2.2 | The table (in Appendix B) outlines the recommendations and testing intervals for biological control measurements for each of the common respiratory function tests. | 6.5.5 |
| 7.3.2.2 | When performing biological controls, subjects must be healthy and free of cardiopulmonary disease.<br>It is desirable that in large laboratories (more than 2.0 FTE scientists), more than one biological control participates in testing.<br>However, for laboratories where more than one biological control is employed, each biological control must be incorporated regularly in the biological control program. | 6.5.5 |
| 7.3.2.2 | All quality control data must be recorded, dated, and filed (either electronically or manually). | 6.5.2 |
| 7.3.2.2 | When routine quality control testing indicates that the method is moving out of control, detailed protocols specifying the courses of action are to be followed for diagnosis and correction. | 6.5.2 |
| 7.3.2.2 | Graphical records of all quality control data are required and must be kept for at least the last two years of use of the instrument. | 6.5.2 |
| 7.3.2.3 | External quality control, that is participation in inter-hospital proficiency testing programs, assists in monitoring the effectiveness of internal quality control procedures. | Requirement removed. |
| 7.3.2.4 | Where resourcing allows, laboratories operating in a hospital (or other host institution) environment should work with administration to ensure the equipment used to undertake spirometry throughout the institution is appropriately calibrated and maintained. | 6.7.4 |
| 7.3.2.4 | The laboratory should also play an active role in the training of all staff to correctly perform spirometry using this equipment. | 6.2.9 |
| 7.3.2.4 | For some laboratories, this may mean a commitment to undertaking all routine inpatient testing. | Requirement removed. |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.3 | The laboratory must utilise appropriate predicted values for comparison with the results of each respiratory function test it performs to help determine whether the test result is normal or abnormal. There are a great number of published predicted values for many respiratory function tests and rationale for selecting one set of data should be provided. | 7.5.5 |
| 7.3.3 | The ERS Global Lung Function Initiative (GLI)15 has released multi-ethnic all-age spirometry reference values, and these have been endorsed by the TSANZ and ANZSRS as the preferred spirometry reference data set. The validity of these equations for contemporary healthy Caucasian subjects has recently been demonstrated | 7.5.5.1 (note) |
| 7.3.3 | Use of the GLI TLCO and Static Lung volume reference values is expected and if they are not being used, a justification must be provided as to why they are not being used | 7.5.5.1 (note) |
| 7.3.3 | Z scores should also be added where possible. | 7.5.5.1 (note) |
| 7.3.3 | When a laboratory chooses a set of predicted values, the following recommendations must be taken into account:<br>a) Predictions of expected normal values must be based on studies with large numbers of subjects of both sexes and covering a wide range of ages, heights, and weights (where relevant).<br>b) The equipment and techniques used by a laboratory and those used to obtain predicted values should, to the extent possible, be similar.<br>c) The population samples should be heterogeneous, crossing socio-economic groups. Surveys should be of communities or towns, not of professional groups. Homogenous groups – religious groups, miners, subjects in sanatoria, etc., should be avoided unless a special purpose population is sought.<br>d) Ethnic factors, smoking habits and respiratory symptoms should be accounted for, if possible.<br>e) The equipment and methods used to obtain and analyse the data must be appropriate and clearly described. | 7.5.5.3 |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.4 | Personnel performing tests must have ready access to the methods manuals and should be encouraged to refer to them frequently | 7.5.2.4 |
| 7.3.4 | Laboratory procedures must be described in detail in the laboratory procedures manual. Each test must be separately described and include the following information:<br>1. The purpose and clinical indications for performance of the test.<br>2. Contraindications to testing.<br>3. A description of the equipment used and, where appropriate, reference to equipment specifications and their applicability to the measurement.<br>4. The procedure for performance of the test must be fully described in the manual, with adequate reference to published guidelines and/or manufacturer's manuals.<br>5. Where the same test is performed on multiple pieces of equipment, a separate methodology must be documented.<br>6. Troubleshooting for remedy of problems that might be encountered with test performance.<br>7. Specific calibration and quality assurance requirements for the test, including details of steps to be taken in the event of out-of-control or inaccurate calibration findings.<br>8. Cleaning and maintenance requirements.<br>9. Infection control issues relevant to the test, and any other safety requirements.<br>10. Methods for production of interim and finalised test reports.<br>11. Appropriate references, including predicted values and, if test techniques are based upon unpublished work, copies of relevant documents should be included as appendices.<br>12. The signature/digital signature of the scientific director and/or medical director indicating responsibility for the contents of the section of the manual.<br>13. Date of issue with indication of version and/or update number (i.e. appropriate document control). | 7.5.1.1<br>7.5.1.3 |
| 7.3.4 | Documentation of procedures must 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.<br>Such reviews should be carried out annually. | 8.3.2 c)<br>Timeframe removed |

| TSANZ lab manual (2021) Clause No. | Extract of text from TSANZ 2021 | TSANZ Standard (2024) Clause No. |
|---|---|---|
| 7.3.4 | Processes must be in place to ensure that only the most recent versions of the laboratory manuals are readily available and that out-dated versions are removed from circulation. | 8.3.2 d) |

# References

### Standards

ISO 15189 *Medical laboratories - Requirements for quality and competence.*

TSANZ *Respiratory Function Laboratory Accreditation Program Manual* (June 2021)

TSANZ *Standard for Respiratory Function Laboratories* (December 2024)

# Amendment table

The table below provides a summary of changes made to the document with this issue.

| Section or Clause | Amendment |
|---|---|
| All | New document |