RESPIRATORY FUNCTION LABORATORY ASSESSMENT WORKSHEET

This worksheet is designed for laboratories who wish to undertake a **self assessment** against the TSANZ Standard for Respiratory function laboratories. This document does not need to be returned to NATA.

Clause	Requirement	Comments
General Requirements		
Impartiality		
4.1.1	Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard impartiality.	
4.1.2	The laboratory management shall be committed to impartiality.	
4.1.3	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.	
4.1.4	The laboratory shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel.	
4.1.5	If a threat to impartiality is identified, the effect shall be eliminated or minimised so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threats.	
Confidentiality		
4.2.1	The laboratory shall be responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information shall include privacy and confidentiality.	
4.2.2	The laboratory shall inform the laboratory user and/or the patient in advance, of the information it intends to place in the public domain.	
4.2.3	Except for information that the laboratory user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.	
4.2.4	Patient-related content used outside of the regular clinical management (e.g. teaching) must be de-identified before use.	

Clause	Requirement	Comments
4.2.5	Where students are involved in patient management, 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.	
4.2.6	Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.	
4.2.7	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.	
Requirements regarding patients		
4.3.1	Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement the following processes: a) opportunities for patients and users to provide helpful information to aid the laboratory in the selection of the test methods, and the interpretation of the test results; b) provision of patients and laboratory users with publicly available information about the test process, including costs when applicable, and when to expect results; c) periodic review of the tests offered to ensure that they are clinically appropriate and necessary; d) disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms; e) treatment of patients with due care and respect; f) obtaining informed consent when required; g) ensuring the ongoing availability and integrity of records in the event of the closure, acquisition or merger of the laboratory; h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf; i) upholding the rights of patients to care that is free from discrimination. NOTE: For procedures where there is a higher risk of an adverse event it is recommended to obtain written consent	

Clause	Requirement	Comments
Legal entity		
5.1.1	The laboratory or the organisation of which the laboratory is a part, shall be an entity that can be held legally responsible for its activities.	
Laboratory Director		
5.2.1	The laboratory must be directed by a person or persons, however named, with the specified qualifications, competence, delegated authority, responsibility and resources to fulfil the requirements of this document.	
5.2.2	Where appointed, director/s must have specific, detailed training in clinical respiratory physiology as per the TSANZ/ANZSRS Position Statement - Directors of a Respiratory Function Laboratory.	
5.2.3	Where 3 or more scientific 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.	
5.2.4	The laboratory director/s is/are responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.	
5.2.5	The laboratory director/s may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented. However, the laboratory director/s shall maintain the ultimate responsibility for the overall operation of the laboratory.	
Laboratory activities		
5.3.1	The laboratory shall specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location.	
5.3.2	Details regarding all aspects of the respiratory function laboratory must be accurately described and must cover the requirements of this document, the laboratory users, statutory requirements, and regulatory authorities.	
5.3.3	Laboratory management shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and laboratory users.	

Clause	Requirement	Comments
5.3.4	The laboratory shall establish arrangements for communicating with laboratory users on the following when applicable: a) advising on choice and use of tests, including any preparation, clinical indications and limitations of test methods. b) providing professional judgments on the interpretation of the test results. c) promoting the effective utilisation of laboratory tests. d) advising of failure where pre-test criteria is not met.	
Structure and authority		
5.4.1	The laboratory shall: a) define its organisation, and management structure including branch and mobile sites, its place in any parent organisation, and the relationships between management, technical operations and support services; b) specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of results across all sites.	
5.4.2	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 all director/s and laboratory staff from all sites. There must be records of these meetings including attendance and action items.	
5.4.3	The laboratory should have a commitment to research. This can be demonstrated by reference to current projects, recent presentations (abstracts) and publications.	
5.4.4	The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance and improvement of the management system; b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimise such deviations; d) reporting to laboratory management on the performance of the management system and any need for improvement; e) ensuring the effectiveness of laboratory activities.	

Clause	Requirement	Comments
Objectives and policies		
5.5.1	Laboratory management shall establish and maintain objectives and policies to: a) meet the needs and requirements of its patients and laboratory users; b) commit to good professional practice; c) provide tests that fulfil their intended use; and d) conform to this document.	
5.5.2	Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organisation.	
5.5.3	Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.	
5.5.4	The laboratory shall establish quality indicators (QI) to evaluate performance throughout key aspects of pre-test, test and post-test processes and monitor performance in relation to objectives. NOTE: QI's must include, as a minimum, the following: - number of tests of each particular type; - waiting periods for routine and urgent studies in line with clinical risk stratification; - reporting turnaround times; - workload audits.	
Risk Management		
5.6.1	Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its tests and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).	
5.6.2	The laboratory director/s shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective.	
5.6.3	Infrequently performed tests are identified as high risk. The laboratory must have documented procedures describing how the facility assures the results and maintains the skills and competency necessary to perform the test.	

Clause	Requirement	Comments
Resource Requirements		
General		
6.1.1	The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.	
Personnel		
6.2.1	The laboratory shall: a) have access to a sufficient number of competent persons to perform its activities. b) ensure all personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, ethically, be competent and work in accordance with the laboratory's management system. c) communicate to laboratory personnel the importance of meeting the needs and requirements of laboratory users as well as the requirements of this document. d) have a programme to introduce personnel to the organisation, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.	
6.2.2	The laboratory shall: a) specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience. b) ensure all personnel have the competence to perform laboratory activities for which they are responsible. c) have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment. d) have documented information demonstrating competence of its personnel.	
6.2.3	Medical staff must be appropriately credentialled and hold current registration. Medical staff are responsible for training and supervision of medical trainees.	
6.2.4	Scientific staff must have relevant qualifications and experience. NOTE: Staff qualifications should meet the Australian and New Zealand Society of Respiratory Science (ANZSRS) guidelines for qualifications and experience.	

Clause	Requirement	Comments
6.2.5	It is recommended that scientific staff 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.	
6.2.6	The laboratory shall authorise personnel to perform specific laboratory activities, including but not limited to, the following: a) selection, development, modification, validation and verification of methods; b) review, release, and reporting of results; c) use of laboratory information systems, in particular: accessing, entering and/or changing patient data, information and/or test results.	
6.2.7	A continuing education programme shall be available to personnel who participate in managerial and technical processes. All personnel shall participate in continuing education and regular professional development, or other professional liaison activities. The suitability of the programmes and activities shall be periodically reviewed. NOTE: Laboratory scientific and medical staff are expected to attend professionally relevant scientific meetings and conferences.	
6.2.8	Where a service employs advanced trainees, there must be respiratory medicine educational programs in place that ensure trainees receive practical and theoretical respiratory physiology teaching, and involvement and training in quality assurance activities within the laboratory.	
6.2.9	The laboratory should offer education for undergraduates and postgraduates in medical, nursing, scientific and allied health areas.	
6.2.10	The laboratory shall have procedures and retain personnel records for: a) determining and monitoring the competence requirements specified in 6.2.2 a); b) position descriptions; c) training and re-training; d) authorisation of personnel (see 6.2.6).	
6.2.11	All staff that conduct tests and/or manage patient care in the laboratory shall be trained in cardiopulmonary resuscitation.	
6.2.12	A basic level of competence in cardiopulmonary resuscitation (Basic Life Support: BLS) shall be maintained as per the Australian and New Zealand Committee on Resuscitation (ANZCOR) Guidelines and records of this training shall be maintained by the laboratory or its host institution.	

Clause	Requirement	Comments
6.2.13	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.	
Facilities and environmental conditions		
General		
6.3.1.1	The facilities and environmental conditions shall be suitable for the laboratory activities and shall: a) not adversely affect the validity of results, or the safety and privacy of patients, visitors, laboratory users, and personnel; b) comply with institutional and/or national Work Health and Safety guidelines; c) be confirmed as fit for purpose and safe for resuscitation of patients. Testing rooms must be of an adequate size and design to allow staff to perform their duties safely and not impeded in their movements in the event of a medical or other emergency; d) provide separate patient reception and testing areas. NOTE 1: 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. NOTE 2: This clause applies to all sites (fixed and mobile) where tests are performed. NOTE 3: Where ad-hoc testing is undertaken away from the laboratory, such as in hospital wards, and the testing location does not meet the requirements as listed above, a risk minimisation strategy must be employed.	

Clause	Requirement	Comments
6.3.1.2	Facility controls shall be specified, implemented, recorded, monitored, periodically reviewed, and shall include: a) control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples; b) prevention of contamination, interference, or adverse influences on laboratory activities that can arise from ambient conditions, energy sources, lighting, ventilation, noise, water and waste disposal; c) prevention of cross-contamination, where test procedures pose a risk, or where work can be affected or influenced by lack of separation; d) provision of safety and emergency facilities and devices, where applicable and regularly verifying their functioning; e) maintenance of laboratory facilities including electrical safety in a functional and reliable condition (see 6.4.9). NOTE 1: Ambient conditions (temperature, humidity, barometric pressure). NOTE 2: Electrical supply to the electric monitoring equipment attached directly to patients must be at minimum body protected standard (class B (AS specification)).	
6.3.1.3	The laboratory must be clearly identified by appropriate wayfinding processes, telephone, and stationery so that it can be easily found and/or accessed.	
Primary service areas		
6.3.2.1	These must include the areas set aside for test systems, and workspace for the performance of specific tests or procedures.	
6.3.2.2	Where aerosol generating actions or loud vocal coaching is likely to occur, testing must occur in separate fully enclosed rooms with effective ventilation, and patients must not be tested concurrently in the same room.	
Administrative space		
6.3.3.1	There shall be adequate space for administrative duties for laboratory operation.	
6.3.3.2	Administrative space should include a Medical Director's office, Scientific Director's office (if appointed), separate workspaces for scientific staff and space for administrative activities.	

Clause	Requirement	Comments
Storage facilities		
6.3.4.1	Storage space, with conditions that ensure the continuing integrity and safe storage of equipment, reagents, gas cylinders, consumables, documents and records, shall be provided.	
6.3.4.2	Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of the materials in the context of any statutory or regulatory requirements.	
Personnel facilities		
6.3.5.1	There shall be adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment, clothing and personal effects.	
6.3.5.2	Space for personnel activities, such as meetings, quiet study and a rest area, must be provided.	
Reception facilities		
6.3.6.1	Patient reception and waiting facilities shall consider privacy, comfort and needs (e.g. disabled access, toilet facility, inpatient waiting) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during testing.	
Mobile laboratories		
6.3.7.1	Mobile providers must ensure that they have access to a dedicated space suitable for testing at any given site.	
Infection prevention and control		
6.3.8.1	The facility shall have infection control procedures developed in accordance with current state and/or national standards.	
6.3.8.2	Where there is a hospital infection control department they must be engaged in the development and endorsement of these procedures.	

Clause	Requirement	Comments
6.3.8.3	Infection control procedures shall address, at a minimum, the following: a) cleaning and/or sterilisation of patient testing equipment (critical, semi-critical and noncritical equipment); b) single-patient use equipment; c) ventilation management of patient testing and waiting areas; d) use of in-line bacterial filters; e) procedures for storage of re-usable equipment such as cleaned mouthpieces; f) details regarding standard and transmission-based precautions; g) patients with known infectious diseases, including but not limited to, Multi-resistant Organisms.	
6.3.8.4	Room ventilation should be monitored in accordance with current TSANZ-ANZSRS guidelines.	
Safety procedures		
6.3.9.1	The laboratory must meet standards of laboratory safety consistent with national workplace health and safety legislation (see 6.3.1.1 b).	
6.3.9.2	Emergency procedures meeting local requirements must be documented.	
6.3.9.3	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.	
Equipment		
6.4.1	The laboratory shall have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration.	
6.4.2	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.	
6.4.3	The equipment used for the conduct of respiratory function and related tests must be suitable for the purpose and must meet ERS/ATS Standards.	

Clause	Requirement	Comments
6.4.4	Where the equipment used is outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management shall ensure that the requirements of this document are met. NOTE: For example, where a service is utilising equipment owned by a third party, this equipment must meet the requirements of this standard.	
6.4.5	Each item of equipment that can significantly influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained. NOTE: Examples of 'uniquely labelled' can include asset number, serial number, permanently affixed ID label, but does not include printers, scanners etc.	
6.4.6	The laboratory shall maintain and replace equipment as needed to ensure the quality of test results.	
6.4.7	The laboratory shall verify that the equipment conforms to specified acceptability criteria before being placed or returned into service. Equipment used for measurement shall be capable of achieving the measurement accuracy required to provide a valid result (see 7.5.3 and 7.5.4 for details).	
6.4.8	The laboratory shall: a) have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate test results; b) ensure equipment shall be operated by trained, authorised, and competent personnel; c) ensure instructions for the use of equipment, including those provided by the manufacturer, shall be readily available; d) guarantee equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.5.4).	

Clause	Requirement	Comments
6.4.9	The laboratory shall: a) have preventive maintenance programmes, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded; b) ensure equipment be maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorised personnel; c) ensure equipment that is defective or outside specified requirements, be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate actions when non-conforming work occurs (see 7.7); d) when applicable, decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.	
6.4.10	Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required. The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.	

Clause	Requirement	Comments
6.4.11	Records shall be maintained for each item of equipment that influences the results of laboratory activities. These records shall include the following, where relevant: a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware; b) dates of receipt, acceptance testing and entering into service; c) evidence that equipment conforms with specified acceptability criteria; d) the current location; e) condition when received (e.g. new, used or reconditioned); f)manufacturer's instructions; g) the programme for preventive maintenance; h) any maintenance activities performed by the laboratory or approved external service provider; i) damage to, malfunction, modification, or repair of the equipment; j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results; k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete. These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in 8.4.4.	

Clause	Requirement	Comments
Equipment calibration and metrological traceability		
6.5.1	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.	
6.5.2	The laboratory shall have procedures for the verification of equipment performance that directly or indirectly affects test results. The procedures shall specify: a) conditions of use, manufacturer's instructions and ERS/ATS standards; b) frequency of performance; c) recording of results; d) handling of situations when routine quality control testing indicates that the method is out of the specified range, and protocols specifying the courses of action to be followed for diagnosis and correction. Quality control data shall be recorded in a manner which allows trends and shifts to be identified. *NOTE: Guidelines for the calibration and quality control of most routine lung function tests are available in ERS/ATS Standards.*	
6.5.3	Calibration check procedures must be done on at least a daily basis when that instrumentation is in use, or whenever accuracy is in doubt.	
6.5.4	In addition to daily calibration checks of equipment, non-biological control measures must be utilised to verify the overall performance of the equipment (refer to Appendix A). 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 are outlined in Appendix A. NOTE: Tests not described in Appendix A must be checked in-line with manufacturer's recommendations and ERS/ATS Standards.	
6.5.5	In addition to non-biological control measures, biological control measurements may be performed for each of the common respiratory function tests (on each separate piece of equipment). The table (in Appendix B) outlines the recommendations and interval for testing. When performing biological controls, subjects must be healthy and free of cardiopulmonary disease.	

Clause	Requirement	Comments
6.5.6	Where resourcing allows, laboratories operating in a hospital (or other host institution) environment should work with administration to: a) ensure that the equipment used to undertake spirometry throughout the institution undergoes appropriate quality checks (calibration and/or validation) and maintenance. b) play an active role in the training of all staff to correctly perform spirometry using this equipment.	
Reagents and consumables		
6.6.1	The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables. NOTE: Reagents and consumables include substances which are commercially supplied or prepared in-house, reference materials (calibrators and QC materials), mouthpieces, filters, nose pegs, blood collection equipment etc.	
6.6.2	The laboratory shall store reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant.	
6.6.3	When the laboratory is not the receiving facility, it shall verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.	
6.6.4	Consumables that can affect the quality of tests shall be confirmed for performance before placing into use. NOTE: For example, confirmation of gas mix concentrations.	
6.6.5	The laboratory shall establish an inventory management system for reagents and consumables that can affect the quality of tests.	
6.6.6	Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available. Reagents and consumables shall be used according to the manufacturer's specifications. If they are intended to be used for other purposes, see 7.5.4.	
6.6.7	Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.	
6.6.8	The laboratory shall have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.	

Clause	Requirement	Comments
6.6.9	Records shall be maintained for each critical reagent and consumable that significantly contributes to the performance of tests. These records shall include, but not be limited, to the following: a) identity of the reagent or consumable; b) manufacturer's information, including instructions, name and batch code or lot number; c) date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service; d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use. NOTE 1: Criticality of reagents and consumables is determined based on risk. NOTE 2: Examples of critical reagents and consumables may include allergens and gases.	
6.6.10	Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.	
Service agreements		
6.7.1	The laboratory shall have a procedure to establish and periodically review agreements for providing laboratory activities. The procedure shall ensure that: a) the requirements are adequately specified; b) the laboratory has the capability and resources to meet the requirements; c) when applicable, the laboratory advises the laboratory user of the specific activities to be performed by referral laboratories and consultants.	
6.7.2	Laboratory users shall be informed of any changes to an agreement that can affect test results.	
6.7.3	Records of reviews, including any significant changes, shall be retained.	
6.7.4	Service agreements between the laboratory and other parts of the organisation using laboratory supported equipment, shall ensure that respective responsibilities and authorities are specified and communicated.	

Clause	Requirement	Comments
Externally provided products and services		
6.8.1	The laboratory shall ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are: a) intended for incorporation into the laboratory's own activities; b) provided, in part or in full, directly to the laboratory user by the laboratory, as received from the external provider; c) used to support the operation of the laboratory. It may be necessary to collaborate with other organisational departments or functions to fulfil this requirement. NOTE: Services may include, calibration services, facility and equipment maintenance services, external quality assurance programmes and external consultancies.	
6.8.2	The laboratory shall communicate its requirements to consultants who provide interpretations and advice, for: a) the procedures, tests, reports and consulting activities to be provided; b) management of critical results; c) any required personnel qualifications and demonstration of competence. A list of all consultants shall be maintained.	
6.8.3	The laboratory shall have procedures and retain records for: a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services; b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of the external providers; c) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the laboratory user; d) taking any actions arising from evaluations of the performance of the external providers.	

Clause	Requirement	Comments
Process requirements		
General		
7.1.1	The laboratory shall identify potential risks to patient care in the pre-test, test and post-test processes. These risks shall be assessed and mitigated to the furthest extent possible. The residual risk shall be communicated to laboratory users as appropriate.	
7.1.2	The identified risks and effectiveness of the mitigation processes shall be monitored and evaluated according to the potential harm to the patient.	
7.1.3	The laboratory shall also identify opportunities to improve patient care and develop a framework to manage these opportunities (see 8.5).	
Pre-test processes		
7.2.1	The laboratory shall have procedures for all pre-test/assessment activities and make them accessible to relevant personnel. NOTE: The pre-test processes can influence the outcome of the intended test.	
7.2.2	The laboratory shall have appropriate information available for its laboratory users and patients. The information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements. The information shall include as appropriate: a) the location(s) of the laboratory, operating hours and contact information; b) the procedures for requesting tests/assessments; c) the scope of laboratory activities and time for expected availability of results; d) the availability of personnel to provide advice on testing services and result interpretation; e) requirements for patient consent; f) factors known to significantly impact the performance of the test or the interpretation of the results; and g) the laboratory complaint process.	

Clause	Requirement	Comments
Requests for laboratory tests		
7.3.1	Each request accepted by the laboratory for test(s) shall be considered an agreement.	
7.3.2	The test request shall provide sufficient information to ensure: a) unequivocal traceability of the patient to the request; b) identity and contact information of requester; c) test(s) requested; d) informed clinical and technical advice and interpretation can be provided; e) the test request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the laboratory user; f) where necessary for patient care, the laboratory shall communicate with laboratory users or their representatives, to clarify the laboratory user's request.	
7.3.3	The laboratory shall have a procedure for managing oral requests for tests, if applicable, that includes the provision of documented confirmation (hard copy or electronic) of the test request to the laboratory, within a given timeframe.	
7.3.4	Procedures must exist for: a) prompt, efficient handling of patient referrals; b) the laboratory's criteria for acceptance; c) communication with the referring doctor, where necessary; d) triaging of referrals, including timeframes for triaging categories, definition of priority categories and timeframes for testing to be performed (see 5.5.4).	
7.3.5	The procedures for allocation of appointments must be appropriate and clearly defined.	
7.3.6	The laboratory shall provide information and instructions for pre-testing activities with sufficient detail to ensure that the integrity of the test is not compromised. This shall include: a) preparation of the patient (e.g. instructions to caregivers and patients); b) provision of clinical information relevant to, or affecting, test performance or result interpretation (e.g. medication use); c) the laboratory's criteria for proceeding with the test (e.g. patient compliance with pre-test instructions, patient health status).	

Clause	Requirement	Comments
Patient reception procedures		
7.4.1	To ensure safe, accurate and clinically appropriate patient testing, the laboratory shall have instructions for: a) verification of the identity of the patient for whom testing is to be conducted; b) verification and when relevant, recording that the patient meets pre-test requirements [e.g. fasting status, medication status (time of last dose, cessation)].	
7.4.2	The laboratory shall obtain consent from the patient for all procedures carried out on the patient.	
7.4.3	If obtaining consent is not possible in emergency situations, the laboratory may carry out necessary procedures, provided they are in the patient's best interest. NOTE 1: For most routine laboratory tests, consent can be inferred when the patient willingly submits to the test. NOTE 2: Invasive tests, or those with an increased risk of complications to the test, may need a more detailed explanation and, in some cases, written consent.	
7.4.4	The laboratory shall have a process that considers the best interests of the patient in receiving care, when a test has been compromised due to: a) incorrect patient identification; b) incorrect patient file attribution; c) when a patient is tested under another patient's identification; d) failure to meet test acceptability criteria; e) pre-test requirements are not met.	
7.4.5	When a compromised test is accepted, after consideration of the risk to patient safety and clinical need, the final report shall indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected.	
7.4.6	Laboratory procedures shall include how to handle additional testing not identified on the referral. NOTE: Examples of application of additional tests may to help address the clinical question, or where the referring doctor adds additional test retrospectively to original test order.	

Clause	Requirement	Comments
Test methodology		
Documentation of test procedures		
7.5.1.1	The laboratory shall: a) document its test procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results; b) ensure procedures are written in a language understood by laboratory personnel and be available in appropriate locations; c) explain implications to laboratory users when validated changes to a test procedure are made that which could affect the interpretation of results; d) ensure all documents associated with the performance of tests, are document controlled. NOTE: This includes working instructions, flow process diagrams or similar systems that summarise key information.	
7.5.1.2	Information from product instructions for use, that contain sufficient information, can be incorporated into procedures by reference.	
7.5.1.3	Each test shall be separately described and include the following information: a) the purpose and clinical indications for performance of the test; b) contraindications to testing; c) a description of the equipment used and, where appropriate, reference to equipment specifications and their applicability to the measurement; d) the procedure for performance of the test must be fully described, with adequate reference to published guidelines and/or manufacturer's manuals; e) where the same test is performed on multiple devices, a separate methodology must be documented for each device; f) troubleshooting to remedy problems that might be encountered with test performance; g) 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; h) cleaning and maintenance requirements; i) infection control issues relevant to the test, and any other safety requirements; j) methods for production of interim and finalised test reports; k) appropriate references, including reference values and, if test techniques are based upon unpublished work, copies of relevant documents should be included as appendices.	

Clause	Requirement	Comments
Test method selection		
7.5.2.1	The laboratory shall select and use test methods which have been validated for their intended use to assure the clinical accuracy of the test for patient testing.	
7.5.2.2	Test protocols for routine clinical assessment of spirometry, carbon monoxide transfer factor, lung volume measurement, bronchial provocation testing and performance of field walking tests must comply with the most recent ERS/ATS Standards. NOTE 1: Preferred methods are those specified in ERS/ATS Standards (where available) or those that have been published in established/authoritative textbooks, peer-reviewed texts, or journals, or in international and national consensus standards or guidelines, or national or regional regulations. NOTE 2: Where an ERS/ATS Standard is available but is NOT used, adequate explanatory notes and rationale must be included in the laboratory manual and validation of these methodologies must be provided	
7.5.2.3	The performance specifications for each test method shall relate to the intended purpose of that test and its impact on patient care.	
7.5.2.4	All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and be readily available to personnel (see 8.3).	
7.5.2.5	Personnel shall follow established procedures and the identity of persons performing test processes shall be recorded, including POCT operators.	
7.5.2.6	Authorised personnel shall periodically review the test methodologies used by the laboratory to ensure they follow best practice and are clinically appropriate for Intended patient population.	
Verification of test methods		
7.5.3.1	The laboratory shall have a procedure to verify that it can properly perform test methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method, can be achieved.	
7.5.3.2	The performance specifications for the test method confirmed during the verification process shall be those relevant to the intended purpose of the test results.	
7.5.3.3	The laboratory shall ensure the extent of the verification of test methods is sufficient to ensure the consistent validity of results pertinent to clinical decision making.	
7.5.3.4	Personnel with the appropriate authorisation and competence shall review the verification results and record that the results meet the specified requirements.	

Clause	Requirement	Comments
7.5.3.5	If a method is revised by the issuing body, the laboratory shall repeat verification to the extent necessary.	
7.5.3.6	The following records of verification shall be retained: a) performance specifications to be achieved; b) results obtained; and c) a statement of whether the performance specifications were achieved and if not, action taken.	
Validation of test methods		
7.5.4.1	The laboratory shall validate test methods derived from the following sources: a) laboratory designed or developed methods; b) methods used outside their originally intended scope (i.e. outside of the manufacturer's instructions for use, or original validated measurement range, and where no validation data is available); c) validated methods subsequently modified.	
7.5.4.2	The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the test method have been fulfilled.	
7.5.4.3	The laboratory shall ensure the extent of validation of a test method is sufficient to ensure the consistent validity of results pertinent to clinical decision making.	
7.5.4.4	Personnel with the appropriate authorisation and competence shall review the validation results and record that the results meet the specified requirements.	
7.5.4.5	When changes are proposed to a validated test method, the clinical impact shall be reviewed, and a decision made as to whether to implement the modified method.	
7.5.4.6	The following records of validation shall be retained: a) the validation procedure used; b) specific requirements for the intended use; c) determination of the performance specifications of the method; d) results obtained; and e) a statement on the validity of the method, detailing its fitness for the intended use.	

Clause	Requirement	Comments
Reference values and clinical decision limits		
7.5.5.1	Reference values and clinical decision limits, when needed for interpretation of test results, shall be specified and: a) their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients. b) be periodically reviewed. c) be communicated to laboratory users including when any changes are made to them.	
7.5.5.2	When changes are made to a test method, the laboratory shall review the impact on associated reference values and clinical decision limits and communicate to the laboratory users when applicable. NOTE 1: Z scores must be used where the reporting system allows. NOTE 2: Global Lung Function Initiative (GLI) reference sets should be used where available, and justification must be provided where they are not in use.	
7.5.5.3	When a laboratory chooses a set of references values, the following must be taken into account: a) predictions of expected reference 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); b) the equipment and techniques used by a laboratory and those used to obtain reference values should, to the extent possible, be similar; 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; d) ethnic factors, smoking habits and respiratory symptoms should be accounted for, if possible; e) the equipment and methods used to obtain and analyse the data must be appropriate and clearly described.	
7.5.5.4	Age (in years) and height (in cm) must be recorded to one (1) decimal place to minimise reference interval errors.	

Clause	Requirement	Comments
Validity of results		
7.5.6.1	The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed. NOTE: Validity includes equipment validity, test performance and skill of the operator.	
Internal quality control		
7.5.7.1	The laboratory shall have an IQC procedure for monitoring the ongoing validity of test results, according to specified criteria, that verifies the attainment of the intended quality and ensures consistent validity pertinent to clinical decision making. NOTE: Consideration of inter-operator variability and lot-to-lot variation.	
7.5.7.2	The laboratory shall select IQC materials/methods that are fit for its intended purpose/s and aligned to ERS/ATS Standards where available. When selecting IQC material/methods, factors to be considered shall include: a) stability with regard to the properties of interest; b) the IQC material provides a clinically relevant challenge to the test method, has concentrations or physical characteristics that covers the measurement range of the test method.	
7.5.7.3	If appropriate IQC material is not available, the laboratory shall consider the use of other methods for IQC. NOTE: Examples of other methods may include the use of biological controls.	
7.5.7.4	IQC shall be performed at a frequency that is: a) described in a relevant technical standard; or b) based on the stability and robustness of the test method and the risk of harm to the patient from an erroneous result.	
7.5.7.5	The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.	
7.5.7.6	IQC data shall be reviewed with specified acceptability criteria, at regular intervals and in a time frame, which allows a meaningful indication of current performance.	

Clause	Requirement	Comments
7.5.7.7	When IQC defined acceptability criteria are not fulfilled, the patient results that were examined after the last successful IQC event shall be evaluated, impact understood, and relevant patients retested after the error has been corrected, where required.	
7.5.7.8	In the event that patient results have been significantly altered by the IQC error, and the results have already been released, the laboratory shall have a process for notifying the referrer.	
Post-test processes		
Reporting		
7.6.1.1	The laboratory shall: a) ensure that test results are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the test procedure. The report shall include all available information necessary for the interpretation of the results; b) have a procedure to notify laboratory users when test results are delayed, based on the impact of the delay on the patient; c) ensure that all information associated with issued reports is retained in accordance with management system requirements (see 8.4). NOTE: It is recommended that the report format should follow ERS/ATS Standards (15). NOTE: For the purposes of this document, reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.	
7.6.1.2	Reports and correspondence must be completed within five (5) working days following each patient contact. NOTE: Reporting turnaround times must be reported in absolute time. Use of average or median values are not acceptable.	
7.6.1.3	Where the report turn-around times are non-conforming (i.e. above 5 working days), the laboratory must implement strategies to reduce these timeframes.	
7.6.1.4	The laboratory shall ensure that authorised personnel review the results of tests and evaluate them against IQC and, as appropriate, available clinical information and previous test results.	
7.6.1.5	Responsibilities and procedures for how test results are released for reporting, including by whom and to whom, shall be specified.	
7.6.1.6	All laboratory test results must be reported and signed off by a qualified clinician and/or scientist.	

Clause	Requirement	Comments
7.6.1.7	The laboratory shall: a) ensure interpretation algorithms are documented to minimise potential for inter-reporter variability. b) clearly state definitions of normality/abnormality, which are based upon statistically valid techniques.	
7.6.1.8	There should be adequate recognition of problems with certainty/uncertainty associated with test results close to limits of the normal range. Note 1: Where available, interpretation algorithms should be supported by published guidelines and references quoted. Note 2: Monitoring of interpretations and opinions can be achieved through regular peer review of test results.	
Critical result reports		
7.6.2.1	When test results fall within critical decision limits established by the laboratory: a) the referrer or other authorised person is notified as soon as relevant, based on clinical information available; b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification; c) the laboratory shall have an escalation procedure for laboratory personnel when a referrer or other responsible person cannot be contacted.	
Special consideration for results		
7.6.3.1	When agreed with the laboratory user, the results may be reported in a simplified way. Any information listed in 7.6.4 that is not reported to the laboratory user shall be readily available.	
7.6.3.2	When results are transmitted as a preliminary report, the final report shall always be forwarded to the laboratory user.	
7.6.3.3	Records shall be kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.6.2 b). Such results shall always be followed by a report.	

Clause	Requirement	Comments
Requirements for reports		
7.6.4.1	Each report shall include the following information, unless the laboratory has documented reasons for omitting any items: a) unique patient identification, the date and time of test and the date of the issue of the report, on each page of the report; b) identification of the laboratory issuing the report; c) name or other unique identifier of the referrer; d) clinical indications for the test requested; e) clear, unambiguous identification of the test performed; f) identification of the test method used, where relevant; g) test results with, where appropriate, the units of measurement; h) reference values, z-scores or graphical representation of data supporting clinical decision limits as necessary; i) identification of tests undertaken as part of a research or development programme and for which no specific claims on measurement performance are available; j) identification of the person (name and position) authorising the release of the report; k) identification of any results that need to be considered as preliminary; l) interpretative summary to include: i. indications of any critical results; ii. addressing of the clinical question, where possible; iii. sample quality and suitability that can compromise the clinical value of test results; iv. discrepancies when tests are performed by different procedures (e.g. POCT) or in different locations; v. possible risk of misinterpretation when different units of measurement, different reference values, or different definitions of bronchodilator response are in use regionally or nationally; vi. result trends or significant changes over time. m) page number to total number of pages. Note: Comparisons to 95% confidence intervals, rather than with fixed percentage of reference values, are required, and the laboratory report form must facilitate these comparisons by including appropriate normal ranges (upper and lower limits of normal).	
Amendments to reported results		

Clause	Requirement	Comments
7.6.5.1	Procedures for the issue of amended or revised results shall ensure that: a) the reason for the change is recorded and included in the revised report, when relevant; b) revised results shall be delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and patient's identity in the original report shall be indicated; c) the laboratory user is made aware of the revision; d) when it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference and traceability to the original report that it replaces; e) when the reporting system cannot capture revisions, a record of such shall be kept.	
Non-conforming work		
7.7.1	The laboratory shall have a process for when any aspect of its laboratory activities or test results do not conform to its own procedures, quality specifications, or the laboratory user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The process shall ensure that: a) the responsibilities and authorities for the management of nonconforming work are specified; b) immediate and long-term actions are specified and based upon the risk analysis c) tests are halted, and reports withheld when there is a risk of harm to patients; d) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on test results which were or could have been released prior to identification of the nonconformance; e) a decision is made on the acceptability of the nonconforming work; f) when necessary, test results are revised, and the laboratory user is notified; g) the responsibility for authorising the resumption of work is specified.	
7.7.2	The laboratory shall implement corrective action commensurate with the risk of recurrence of the nonconforming work (see 8.7).	
7.7.3	The laboratory shall retain records of nonconforming work and actions as specified in 7.7.1 a) to g).	

Clause	Requirement	Comments
Control of data and information management		
Control of data		
7.8.1.1	The laboratory shall have access to the data and information needed to perform laboratory activities. NOTE 1: In this document, "laboratory information systems" includes the management of data and information contained in both computer and non-computerised systems. Some of the requirements can be more applicable to computer systems than to non-computerised systems. NOTE 2: Risks associated with computerised laboratory information systems are discussed in ISO 22367:2020, A.13. NOTE 3: The information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information, are listed in ISO/IEC 27001:2013, Annex A Reference control objectives and controls.	
7.8.1.2	The laboratory shall ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care. The laboratory is ultimately responsible for the laboratory information systems.	

Clause	Requirement	Comments
Information systems management		
7.8.2.1	The system(s) used for the collection, processing, recording, reporting, storage or retrieval of test data and information shall be: a) validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory non-biological configuration or modifications to commercial off-the shelf software, shall be authorised, documented and validated before implementation; b) documented, and the documentation readily available to authorised laboratory users, including that for day-to-day functioning of the system; c) implemented taking cybersecurity into account, to protect the system from unauthorised access and safeguarded data against tampering or loss; d) operated in an environment that complies with supplier specifications or, in the case of non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription; e) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions; and f) calculations and data transfers shall be checked in an appropriate and systematic manner. NOTE 1 Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as laboratory equipment, hospital patient administration systems and systems in primary care. NOTE 2 Commercial off-the-shelf software used within its designed application range can be considered sufficiently validated (e.g. word processing and spreadsheet software, and quality management software programs).	
Downtime plans		
7.8.3.1	The laboratory shall have planned processes in the event of failure or during downtime in information systems that affects the laboratory's activities.	
Off-site management		
7.8.4.1	When the laboratory information system(s) are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.	

Clause	Requirement	Comments
Complaints		
7.9.1	The laboratory shall have a process for handling complaints that shall include at least the following: a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response; b) tracking and recording of the complaint, including the actions undertaken to resolve it; c) ensuring that appropriate action is taken. NOTE The resolution of complaints can lead to implementation of corrective actions (see 8.7) or be used as input into the improvement process (see 8.6).	
7.9.2	Upon receipt of a complaint, the laboratory shall: a) confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint (see 8.7.1); b) be responsible for gathering all necessary information to determine whether the complaint is substantiated; c) whenever possible, acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.	
7.9.3	The laboratory shall ensure investigation and resolution of complaints shall not result in any discriminatory actions.	
7.9.4	The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.	
Continuity and emergency preparedness planning		
7.10.1	The laboratory shall ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.	

Clause	Requirement	Comments
7.10.2	Plans shall be periodically tested and the planned response capability exercised, where practicable. The laboratory shall: a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel; b) provide information and training as appropriate to relevant laboratory personnel; c) respond to actual emergency situations; d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.	

Clause	Requirement	Comments
Management system requirements		
General Requirements		
8.1.1	The laboratory shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document. As a minimum, the management system of the laboratory shall include the following: a) responsibilities (8.1) b) objectives and policies (8.2) c) documented information (8.2, 8.3 and 8.4) d) actions to address risks and opportunities for improvement (8.5) e) continual improvement (8.6) f) corrective actions (8.7) g) evaluations and internal audits (8.8) h) management reviews (8.9)	
8.1.2	The laboratory may meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001). This quality management system shall support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.	
8.1.3	The laboratory shall ensure that persons doing work under the laboratory's control are aware of: a) relevant objectives and policies; b) their contribution to the effectiveness of the management system, including the benefits of improved performance; c) the implications of not conforming with the management system requirements.	
Management system documentation		
8.2.1	Laboratory management shall establish, document, and maintain objectives and policies for the fulfilment of the purposes of this document and shall ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organisation. NOTE: The management system documents can, but are not required to, be contained in a quality manual.	
8.2.2	The objectives and policies shall address the competence, quality and consistent operation of the laboratory.	
8.2.3	Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	

Clause	Requirement	Comments
8.2.4	All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.	
8.2.5	All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.	
Control of management system documentation		
8.3.1	The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.	
8.3.2	The laboratory shall ensure that: a) documents are uniquely identified; b) documents are approved for adequacy before issue by authorised personnel who have the expertise and competence to determine adequacy; c) documents are periodically reviewed and updated as necessary; d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; e) changes and the current revision status of documents are identified; f) documents are protected from unauthorised changes and any deletion or removal; g) documents are protected from unauthorised access; h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose; i) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements. NOTE: In this context, "document" can be policy statements, procedures and related job aids, flow charts, instructions for use, specifications, manufacturer's instructions, calibration tables, reference values and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as laws, regulations, standards and textbooks from which test methods are taken, documents describing personnel qualifications (such as job descriptions), etc. These can be in any form or type of medium, such as hard copy or digital.	
Control of records		
8.4.1	The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements of this document. Records shall be created at the time each activity that affects the quality of a test is performed. NOTE: Records can be in any form or type of medium.	

Clause	Requirement	Comments
8.4.2	Test records must contain all information needed to show unambiguously what has been done, by whom and when; including: a) date and time of test; b) identity of the testing officer; c) identity of the test method; d) any variations from the standard method; e) identification of the subject; all test data (including units) and any necessary calculations; f) final results; g) any other information required by test method; and h) any pertinent observations of the testing officer.	
8.4.3	The laboratory shall ensure that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.	
8.4.4	The laboratory shall: a) implement the procedures needed for the identification, storage, protection from unauthorised access and changes, back-up, archive, retrieval, retention time, and disposal of its records; b) specify retention times for records; c) ensure reported test results are retrievable for as long as necessary or as required; d) ensure all records are accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (see 8.9). NOTE: In addition to requirements, where not legislated, retention times can be chosen based on identified risks.	
Actions to address risks and opportunities for improvement		
8.5.1	The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to: a) prevent or reduce, undesired impacts and potential failures in the laboratory activities; b) achieve improvement, by acting on opportunities; c) assure that the management system achieves its intended results; d) mitigate risks to patient care; e) help achieve the purpose and objectives of the laboratory.	

Clause	Requirement	Comments
8.5.2	The laboratory shall: a) prioritise and act on identified risks. Actions taken to address risks shall be proportional to the potential impact on laboratory test results, as well as patient and personnel safety. b) record decisions made and actions taken on risks and opportunities. c) integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness. NOTE 1: Options to address risks can include identifying and avoiding threats, eliminating a risk source, reducing the likelihood or consequences of a risk, transferring a risk, taking a risk in order to pursue an opportunity for improvement or retaining risk by informed decision. NOTE 2: Although this document requires that the laboratory identifies and addresses risks, there is no requirement for any particular risk management method. Laboratories can use ISO 22367 and ISO 35001 for guidance. NOTE 3: Opportunities for improvement can lead to expanding the scope of the laboratory activities, applying new technology, or creating other possibilities to fulfil patient and laboratory user needs.	
Improvement		
8.6.1	The laboratory shall: a) continually improve the effectiveness of the management system, including the pre-test, test and post-test processes as stated in the objectives and policies; b) identify and select opportunities for improvement and develop, document, and implement any necessary actions. Improvement activities shall be directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5); c) evaluate the effectiveness of the actions taken; d) ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care; e) ensure improvement plans and related goals are communicated to personnel by laboratory management. NOTE: Opportunities for improvement can be identified through risk assessment, use of the policies, review of the operational procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and laboratory users, analysis of data and EQA results.	
8.6.2	The laboratory shall seek feedback from its patients, laboratory users, and personnel. The feedback shall be analysed and used to improve the management system, laboratory activities and services to laboratory users.	

Clause	Requirement	Comments
8.6.3	Records of feedback shall be maintained including the actions taken.	
8.6.4	Communication shall be provided to personnel on actions taken arising from their feedback.	
Nonconformities and corrective action		
8.7.1	When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: i. take immediate action to control and correct the nonconformity; ii. address the consequences, with a particular focus on patient safety including escalation to the appropriate person; b) determine the cause(s) of the nonconformity; c) evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by: i. reviewing and analysing the nonconformity; ii. determining whether similar nonconformities exist or could potentially occur; iii. assessing the potential risk(s) and effect(s) if the nonconformity recurs; d) implement any action needed; e) review and evaluate the effectiveness of any corrective action taken; f) update risks and opportunities for improvement, as needed; g) make changes to the management system, if necessary.	
8.7.2	Corrective actions shall be appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s).	
8.7.3	The laboratory shall retain records as evidence of the: a) nature of the nonconformities, cause(s) and any subsequent actions taken, and b) evaluation of the effectiveness of any corrective action.	
Evaluation and audits		
8.8.1	The laboratory shall conduct evaluations at planned intervals to demonstrate that the management, support, and pre-test, test, and post-test processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.	
8.8.2	The process of monitoring quality indicators (see 5.5 d)) shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring.	

Clause	Requirement	Comments
8.8.3	The indicators shall be periodically reviewed, to ensure continued appropriateness.	
8.8.4	The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system: a) conforms to the laboratory's own requirements for its management system, including the laboratory activities; b) conforms to the requirements of this document; and c) is effectively implemented and maintained.	
8.8.5	The laboratory shall plan, establish, implement and maintain an internal audit programme that includes: a) priority given to risk to patients from laboratory activities; b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities; c) specified audit objectives, criteria and scope for each audit; d) selection of auditors who are trained, qualified and authorised to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited; e) ensuring objectivity and impartiality of the audit process; f) ensuring that the results of the audits are reported to relevant personnel; g) implementation of appropriate correction and corrective actions without undue delay; h) retention of records as evidence of the implementation of the audit programme and audit results.	
Management reviews		
8.9.1	Laboratory management shall review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.	

Clause	Requirement	Comments
8.9.2	The inputs to management review shall be recorded and shall include evaluations of at least the following: a) status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources; b) fulfilment of objectives and suitability of policies and procedures; c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies; d) patient, laboratory user and personnel feedback and complaints; e) quality assurance of result validity; f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement; g) performance of external providers; h) results of participation in interlaboratory comparison programmes; i) evaluation of POCT activities; j) other relevant factors, such as monitoring activities and training.	
8.9.3	The output from the management review shall be a record of decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; d) improvement of services to patients and laboratory users; e) any need for change.	
8.9.4	Laboratory management shall ensure that actions arising from management review are completed within a specified time frame.	
8.9.5	Conclusions and actions arising from management reviews shall be communicated to laboratory personnel.	