ISO/IEC 17025 ASSESSMENT WORKSHEET

Self-assessment

This self assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

4 GENERAL REQUIREMENTS

4.1 Impartiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1.1	Laboratory activities • shall be undertaken impartially and structured and safeguarded to ensure impartiality	
4.1.2	Laboratory management • shall be committed to impartiality	
4.1.3	Laboratory responsibility • commercial, financial or other pressures must not compromise impartiality with regard to laboratory activities	
4.1.4	Risk identification • the laboratory to undertake this on an ongoing basis and include those arising from – its activities – its relationships – relationships of personnel	
4.1.5	Risk mitigation • the laboratory shall demonstrate how risk to impartiality is eliminated or minimised	

4.2 Confidentiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.2.1	Laboratory responsibility • through legally enforceable commitments, manage all information obtained or created during the performance of laboratory activities • inform the customer in advance of the information it intends to place in the public domain • maintain all customer information as confidential, except for that information the customer makes public or that agreed to be made public between the laboratory and customer	
4.2.2	Release of customer information • must not occur unless – when required by law – authorised by contractual arrangements • customer to be notified of information provided (unless prohibited by law)	
4.2.3	Customer information from other sources • shall be confidential between the customer and laboratory • the source of this information shall remain confidential to the laboratory	
4.2.4	Confidentiality obligations of personnel • shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law	

5 STUCTURAL REQUIREMENTS

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.1	Legal status • the laboratory shall be a legal entity, or a defined part of a legal entity	
5.2	Laboratory management • identify management that has overall responsibility for the laboratory	
5.3	Scope of laboratory activities • the laboratory to define and document the range of activities which it claims conformity to the Standard – cannot include laboratory activities which are provided externally on an ongoing basis	
5.4	Conduct of laboratory activities and premises • to be performed to meet the requirements of – the Standard – customer requirements – regulatory authorities – NATA • activities include those conducted at – permanent facilities – sites away from permanent facilities – temporary or mobile facilities – customer premises	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.5	Structure, personnel and documentation a) define the laboratory's place in any parent organisation, the relationship between management, technical operations and support services b) specify the responsibilities, authorities and interrelationships of those who manage, perform or verify work affecting the results of laboratory activities c) document procedures to the extent necessary to ensure consistent conduct of laboratory activities and the validity of results	
5.6	Personnel authorities and resources a) available to implement, maintain and improve the management system b) able to identify deviations in the management system or laboratory activity procedures c) able to initiate actions to prevent or minimise deviations d) report to laboratory management the performance of the management system and needs for improvement e) ensure the effectiveness of laboratory activities	
5.7	Laboratory management responsibilities a) ensure communication on the effectiveness of the management system and meeting customers' and other requirements b) ensure integrity of the management system is maintained when changes are planned and implemented	

6 RESOURCE REQUIREMENTS

6.1 General

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1	Available resources • laboratory to have available personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities	

6.2 Personnel

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.1	Competence and impartiality • all personnel (internal or external) associated with the laboratory that could influence the laboratory activities to be competent and act impartially in accordance with the management system	
6.2.2	Documentation of competency requirements • to include education, qualification, training, technical knowledge, skills and experience for each role which influence the laboratory activities	
6.2.3	Competency • ensure personnel are competent to perform laboratory activities for which they are responsible and to evaluate the significance of deviations	
6.2.4	Duties, responsibilities and authorities • ensure these are communicated	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.5	Procedures and records a) for the determination of the competence requirements b) for the selection of personnel c) for training d) for supervision e) for authorisations f) for the monitoring of competence	
6.2.6	Authorisations to perform specific activities a) develop, modify, verify and validate methods b) analyse results, including statements of conformity or opinions and interpretations c) report, review and authorise result	

6.3 Facilities and environmental conditions

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.3.1	Suitability of facilities and environmental conditions • appropriate and not adversely affect the validity of results	
6.3.2	Document • the requirements for facilities and environmental conditions to perform laboratory activities	
6.3.3	Monitor, control and record • the environmental conditions in accordance with the relevant specifications, methods and procedures or when they influence the validity of results	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.3.4	Measures to control facilities • to be implemented, monitored and periodically reviewed, including but not limited to a) access to and use of areas affecting laboratory activities b) prevention of contamination interference or adverse influences on laboratory activities c) effective separation between areas with incompatible laboratory activities	
6.3.5	Sites outside laboratory's permanent control • ensure facilities and environmental conditions comply with requirements of the Standard	

6.4 Equipment

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.1	Availability of equipment • laboratory has access to equipment for correct performance of laboratory activities	
6.4.2	Equipment outside control of laboratory • the requirements of the Standard are met	
6.4.3	Procedure • is available for handling, storage, use and planned maintenance to ensure proper functions and to prevent contamination or deterioration	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.4	Verification • ensure equipment conforms to specified requirements before being placed or returned into service	
6.4.5	Accuracy and/or measurement uncertainty (MU) • to provide a valid result, equipment must be capable of achieving the required – measurement accuracy; and/or – MU	
6.4.6	Calibration • equipment shall be calibrated when – measurement accuracy or MU affects the validity of the results; and/or – the equipment is necessary to establish metrological traceability of the results	
6.4.7	Calibration program • shall be established and reviewed and adjusted as necessary in order to maintain confidence in the status of calibration	
6.4.8	Labelling • all equipment which requires calibration or has a defined period of validity shall be labelled, coded or otherwise identified	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.9	Out-of-service • overloaded, mishandled or poorly functioning equipment shall be isolated and not reused until verified that it performs correctly • the effect of such defective equipment shall be investigated and the management of non-conforming work initiated	
6.4.10	Intermediate checks • shall be carried out when necessary to confirm performance of the equipment • in accordance with a procedure	
6.4.11	Correction factors • when calibration and reference material data include reference values or correction factors, these are to be updated and implemented, as appropriate, to meet specified requirements	
6.4.12	Unintended adjustment • practicable measures are taken to prevent these from occurring and invalidating results	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.13	Records • shall be retained for equipment which can influence laboratory activities, including: – identity, including software / firmware version – manufacturer's name, type and serial number or other identification – evidence of verification – location – calibration dates and results, results of adjustments, acceptance criteria, due date of next calibration or interval – documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity – maintenance plan and maintenance performed – details of damage, malfunction, modifications or repair	

6.5 Metrological traceability

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.1	Establish metrological traceability • the laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.2	Measurement results traceable to SI units • to be established through a) calibration provided by a competent laboratory; or b) certified values of CRMs from a competent producer with stated traceability to SI units; or c) direct realisation of the SI units ensured by comparison with national or international standards	
6.5.3	Traceability to SI units not technically possible • where this occurs, metrological traceability to an appropriate reference shall be demonstrated, for example a) certified values of CRMs provided by a competent producer to non SI values b) results of reference measurement procedures, specified methods or consensus standards that are accepted as providing measurement results fit for their intended use and ensured by suitable comparison	

6.6 Externally provided products and services

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.6.1	Use of externally provided products and services • Only suitable products and services are used when a) incorporated into the laboratory's own activities b) provided directly to the customer by the laboratory as received from the external provider c) used to support the operation of the laboratory	
6.6.2	Procedure and records for a) defining, reviewing and approving the laboratory's requirements for externally provided products and services b) defining criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers c) ensuring that prior to laboratory use or supply to customers, the products and services conform to the laboratory's requirements or where relevant to the Standard d) actions to take arising from evaluations, monitoring or re-evaluations of external providers	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.6.3	Communication of requirements to external providers • These include a) the products and services to be provided b) the acceptance criteria c) competence, including any required qualification of personnel d) activities that the laboratory, or its customer, intends to perform at the external provider's premises	

7 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.1.1	Procedure Shall ensure a) requirements are defined, documented and understood b) laboratory has the capability and resources to meet the requirements c) where external providers are used, the customer is advised and approves d) appropriate methods or procedures are selected	
7.1.2	Inappropriate method requested • customer is informed, including if method is out-of-date	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.1.3	Statement of conformity requested • specification or standard and the decision rule are clearly defined • unless inherent in the specification or standard, the decision rule is agreed with the customer	
7.1.4	Differences between requests and contract • are resolved prior to laboratory activities commencing • contract to be acceptable to both the laboratory and customer • deviations requested do not impact on the laboratory's integrity or the validity of result	
7.1.5	Deviations from the contract • customer is informed	
7.1.6	Amendments to contracts • contract review is repeated after work commences and amendments communicated to all affected personnel	
7.1.7	Cooperation with customers • laboratory to clarify requests and to allow the customer to monitor its performance	
7.1.8	Records of reviews • are retained, including changes to contracts and discussions had with the customer	

7.2 Selection, verification and validation of methods

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.1 Selection and verification of methods		
7.2.1.1	Methods and procedures • to be appropriate for all laboratory activities, including where necessary, for evaluation of measurement uncertainty and statistical techniques for data analysis	
7.2.1.2	Currency of methods and procedures • to be kept up-to-date and made available to personnel	
7.2.1.3	Method version • latest valid versions to be used unless it is not appropriate or possible • where necessary, supplemented with additional details for consistent application	
7.2.1.4	Method selection • the laboratory to select an appropriate method and inform the customer when the customer has not specified the method	
7.2.1.5	Method verification • before introducing methods, the laboratory must verify that it can achieve the required performance • records of verification must be kept • verification to be repeated when changes to the methods are made by the issuing body/ies	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.1.6	Method development • as proceeds, periodic review to occur to confirm the needs of the customer are still satisfied • changes to the development plan to be approved and authorised	
7.2.1.7	Deviations from methods • shall only occur if the deviation is technically justified, documented, authorised and accepted by the customer	
7.2.2 Validation of methods		
7.2.2.1	Validation • non-standard methods, laboratory developed methods and standard methods used outside their scope or modified shall be validated	
7.2.2.2	Changes made to validated method • the influence of such changes shall be determined and if they affect the original validation, then the method must be revalidated	
7.2.2.3	Method performance characteristics • satisfy the customers needs and specified requirements	
7.2.2.4	Validation records a) the validation procedure used b) specification of the requirements c) performance characteristics of the method d) results obtained e) a statement on the validity of the method, and its fitness for the intended use	

7.3 Sampling

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.1	Sampling plan and method • method addresses factors to be controlled to ensure validity of subsequent testing or calibration • plan and method available at sampling site • sampling plans based on statistical methods whenever reasonable	
7.3.2	Method • describes a) selection of samples or sites b) sampling plan c) preparation and treatment of samples from a substance, material or product	
7.3.3	Records of sampling data • include a) reference to the sampling method b) date and time of sampling c) data to identify and describe the sample d) identification of the personnel e) identification of the equipment used f) environmental or transport conditions g) diagrams or other means to identify the sampling location when appropriate h) deviations, additions or exclusions from the method or sampling plan	

7.4 Handling of test and calibration items

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.1	Procedure • ensures the protection of integrity of the item and the interests of the laboratory and customer and covers – transportation – receipt – handling – protection – storage – retention and/or disposal • precautions taken to avoid deterioration, contamination, loss or damage • handling instructions provided with the item to be followed	
7.4.2	Identification • system is in place for the unambiguous identification of items, including, if relevant, the subdivision and transfer of items	
7.4.3	Item deviations • upon receipt, deviations from specified conditions are recorded • if there is doubt about suitability of item, or it does not conform to description provided, ensure that the customer is consulted and that the instructions are recorded • when deviation is acknowledged and customer instructs to proceed with testing or calibration, the laboratory is to include a disclaimer in the report indicating that the results may be affected	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.4	Storage conditions • to be maintained, monitored and recorded	

7.5 Technical Records

Clause No.	General Requirements	Evidence (outcome of discussions with staff, observations; procedures & documentation reviewed)
7.5.1	Records • for each laboratory activity include – results – report – factors affecting the results and its measurement uncertainty – date – identity of personnel conducting the laboratory activity and checking data and results • allow repetition of the laboratory activity • original observations, data and calculations to be recorded at the time they are made and be identifiable with the specific task	
7.5.2	Amendments • can be traced to original observations or previous version of records • original and amended data – to be retained – include the date – an indication of the altered aspects – the personnel responsible	

7.6 Evaluation of measurement uncertainty

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.6.1	Contributions of MU • shall be identified • significant contributions taken into account when evaluating MU, including those from sampling	
7.6.2	Calibration • MU for all calibrations performed shall be evaluated	
7.6.3	Testing • where the test method precludes rigorous evaluation, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method	

7.7 Ensuring the validity of results

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.7.1	Procedure • for monitoring validity of results is in place • data from monitoring activities are recorded in a manner which allows the detection of trends with statistical methods applied, where possible, for review of the results • monitoring is to be planned and reviewed and include, where appropriate a) use of reference materials or quality control materials b) use of alternative calibrated instrumentation providing traceable results c) functional checks of measuring and testing equipment d) use of check or working standards with control charts e) intermediate checks on measuring equipment f) replicate tests or calibrations g) retesting or recalibration of retained items h) correlation of results for different characteristics of an item i) review of reported results j) intra-laboratory comparisons k) testing of blind sample(s)	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.7.2	Comparison of results with other laboratories • shall be used to monitor the laboratory's performance • monitoring shall be planned and reviewed and include participation in either or both a) proficiency testing b) inter-laboratory comparisons	
7.7.3	Analysis of monitoring data • used to control and improve, where applicable, laboratory activities • appropriate action is taken to prevent incorrect results from being reported when monitoring data is found to be outside of pre-defined criteria	

7.8 Reporting of results

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.1 General		
7.8.1.1	Review and authorisation of results • shall occur prior to release	
7.8.1.2	Reports • results are provided accurately, clearly, unambiguously and objectively • include all the information agreed with the customer and necessary for the interpretation of the results • issued reports are retained as technical records	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.1.3	Simplified reports • when agreed with the customer • all information not reported to customer and covered by 7.8.2 to 7.8.7 must be readily available	
7.8.2	**Common requirements for reports (test, calibration or sampling)**	
7.8.2.1	Report content a) title b) name and address of the laboratory c) location where the laboratory activities were performed d) unique identification that all components are recognised as a portion of a complete report and a clear identification of the end e) name and contact information of the customer f) method used g) a description, unambiguous identification, and if necessary, the condition of the item h) date of receipt of the item or date of sampling of the item where critical to the validity and application of the results i) date(s) of the performance of the laboratory activity j) date of the issue of the report k) reference to the sampling plan and sampling method if relevant to the validity and application of the results l) statement to the effect that results only relate to the item tested, calibrated or sampled m) the results with the units of measurement, where appropriate	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	n) additions, deviations or exclusions from the method o) identification of the person authorising the report p) clear identification when the results are from external providers	
7.8.2.2	Laboratory responsibility • for all information provided in the report except when provided by the customer – customer information to be clearly identified and a disclaimer included when information supplied can affect the validity of results • when customer is responsible for sampling, the report is to state that the results apply to the sample as received (also refer to 7.4.3)	
7.8.3	**Specific requirements for test reports**	
7.8.3.1	Additional information • for the interpretation of the test results, in addition to 7.8.2, reports to include where necessary a) information on specific test conditions, such as environmental conditions b) where relevant, a statement of conformity with requirements or specifications c) where applicable, the MU in the same units as the measurand or in a term relative to the measurand when – relevant to the validity or application of the results – customer's instruction	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	– MU affects conformity to a specification limit d) where appropriate, opinions and interpretations e) additional information which may be required by specific methods, authorities, customers or groups of customers	
7.8.3.2	Sampling • when the laboratory is responsible for sampling, test reports shall meet the requirements of 7.8.5 where necessary	
7.8.4	**Specific requirements for calibration certificates**	
7.8.4.1	Additional information • in addition to 7.8.2, calibration certificates to include a) the MU of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand b) the conditions under which the calibrations were made that have an influence on the measurement results c) a statement to indicate how the measurements are metrologically traceable d) results before and after any adjustments or repair e) where relevant, a statement of conformity with requirements or specifications f) where appropriate, opinions and interpretation	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.4.2	Sampling • when the laboratory is responsible for sampling, calibration certificates shall meet the requirements of 7.8.5 where necessary	
7.8.4.3	Calibration certificates or labels • shall not include any recommendation on calibration intervals, unless agreed with the customer	
7.8.5	**Reporting sampling - specific requirements**	
7.8.5	Additional information • when the laboratory is responsible for the sampling, in addition to 7.8.2, reports to include a) date of sampling b) unique identification of the item or material sampled c) location of sampling, including any diagrams, sketches or photographs d) reference to the sampling plan and sampling method e) details of any environmental conditions that affect the interpretation of the results f) information required to evaluate MU for subsequent testing or calibration	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.6	**Reporting statements of conformity**	
7.8.6.1	Decision rule • to be documented and applied, taking into account the associated risk, when a statement of conformity is provided to a customer	
7.8.6.2	Statement of conformity • includes a) which results the statement of conformity applies to b) which specifications, standards or parts thereof are met or not met c) the decision rule applied (unless it is inherent in the requested specification or standard)	
7.8.7	**Reporting opinions and interpretations**	
7.8.7.1	Authorised personnel • opinions and interpretations are only made by authorised personnel and the basis upon which they have been made shall be documented	
7.8.7.2	Based on results • opinions and interpretations are based on the results obtained and clearly identified as such in reports	
7.8.7.3	Direct verbal communication • when opinions and interpretations are verbally communicated to the client, a record is retained	
7.8.8	**Amendments to reports**	
7.8.8.1,	Amendments to reports	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.8.2, 7.8.8.3	• are clearly identified • where appropriate, the reason for the change is included in the report • a further report is issued and referenced as amended, is uniquely identified and makes reference to the original report it replaces	

7.9 Complaints

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.9.1	Documented process • is available for receiving, evaluating and making decisions on complaints	
7.9.2	Availability of documented process and responsibility • is available to any interested party • when a complaint is received, the laboratory is to confirm whether it relates to laboratory activities it is responsible for and action it • laboratory is responsible for all decisions relating to complaints handling	
7.9.3	Content of complaints process a) a description of the process for receiving, validating, investigating and deciding what actions are to be taken in response to it b) tracking and recording complaints, including actions taken c) ensuring that any appropriate action is taken	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.9.4	Gathering and verifying information • the laboratory is responsible in order to validate the complaint	
7.9.5	Acknowledging receipt • whenever possible, the laboratory does this and provides the complainant with progress reports and the outcome	
7.9.6	Communication of outcomes • to be made by, or reviewed and approved by, an individual(s) not involved in the original laboratory activities in question	
7.9.7	Formal notice of end of complaint • whenever possible, the laboratory to advise the complainant	

7.10 Non-conforming work

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.10.1	Procedure • is available and implemented when any aspect of the laboratories activities does not conform to its own procedures or the agreed requirements of the customer a) defines the responsibilities and authorisations for the management of non-conforming work b) actions are based upon the risk levels established by the laboratory	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	c) an evaluation is made of the significance of the non-conforming work, including an impact analysis on previous results d) a decision is taken on the acceptability of the non-conforming work e) where necessary, the client is notified and work is recalled f) defines the responsibility for authorising the resumption of work	
7.10.2	Records • are retained of non-conforming work and the actions taken	
7.10.3	Implementation of corrective action • shall be taken when the non-conforming work could recur, or there is doubt with the laboratory's operations with its own management system	

7.11 Control of data and information management

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.11.1	Access to data and information • data and information needed to perform laboratory activities is available	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.11.2	Laboratory information management system • the system for collecting, processing, recording, reporting, storing and retrieving data is validated, including interfacing with other laboratory systems before being used • changes to the system are authorised, documented and validated before used	
7.11.3	Protection, safeguard and maintenance • the information system a) is protected from unauthorised access b) is safeguarded against tampering and loss c) is operated in an environment that complies with supplier or laboratory specifications or, for non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription d) is maintained in a manner which ensures the integrity of the data and information e) includes the recording of system failures and the appropriate immediate and corrective actions	
7.11.4	Off-site systems • laboratory ensures that the provider or operator complies with all applicable requirements of the Standard	
7.11.5	Instructions, manuals and reference data • are readily available to personnel	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.11.6	Calculations and data transfers • are checked in an appropriate and systematic manner	

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.1.1 General		
8.1.1	Management system • supports and demonstrates the consistent achievement of the requirements of the Standard • assures the quality of the laboratory results • allows the requirements of clauses 4 to 7 to be met • is in accordance with either Option A or Option B	

Option A

The laboratory must address clauses 8.2 to 8.9.

Option A: 8.2 Management system documentation

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.1	Policies and objectives • are established, documented for the fulfilment of the Standard • are acknowledged and implemented at all levels of the laboratory	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.2	Competence, impartiality consistent operations • are addressed by the policies and objectives	
8.2.3	Laboratory management • provides evidence of commitment to the development of the management system • continually improves the management system's effectiveness	
8.2.4	Reference to the management system • of all documentation, processes, systems and records	
8.2.5	Access to parts of the management system • is available to personnel	

Option A: 8.3 Control of management system documents

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.1	Control of documents • both internal and external documents relating to the fulfilment of the requirements of the Standard	
8.3.2	Document control process a) documents are approved by authorised personnel prior to issue b) documents are periodically reviewed and updated as necessary c) changes and current revision status of documents are identified	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	d) relevant versions of documents are available and their distribution controlled as necessary e) documents are uniquely identified f) unintended use of obsolete documents is prevented	

Option A: 8.4 Control of records

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.4.1	Records retention • to demonstrate fulfilment of the requirements of the Standard	
8.4.2	Controls • are implemented for – identification – storage – protection – back-up – archive – retrieval – retention times – disposal • are established for – retention periods to satisfy contractual obligations – confidentiality commitments – access and availability	

Option A: 8.5 Actions to address risks and opportunities

Note: There is no requirement for formal methods for risk management or a documented risk management process

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.5.1	Risks and opportunities are considered a) to assure the management system achieves its intended goals b) to achieve the laboratory objectives c) to prevent (or minimise) undesired impacts and potential failures d) to achieve improvement	
8.5.2	Plan a) actions to address risks and opportunities b) how to – implement actions into the management system – evaluate the effectiveness of actions	
8.5.3	Actions to address risks and opportunities • are proportional to the potential impact on the validity of the laboratory results	

Option A: 8.6 Improvement

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.1	Opportunities • are identified and any necessary action implemented	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.2	Customer feedback • both positive and negative are sought, analysed and used to improve the management system, laboratory activities and customer service	

Option A: 8.7 Corrective actions

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.1	Nonconformities • when occur, the laboratory shall a) react and, as applicable, take action, correct the issue and address the consequences b) evaluate the need for action to eliminate the cause so that it does not recur c) implement any action necessary d) review the effectiveness of any corrective action e) update any risk and opportunities f) makes any necessary changes to the management system	
8.7.2	Corrective action taken • is appropriate to the effects of the nonconformity	
8.7.3	Records retained a) of the nature of the nonconformity, cause(s) and any action(s) taken b) of the outcomes of corrective action	

Option A: 8.8 Internal audits

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.1	Conducted at planned intervals • to establish whether the management system a) conforms to – the laboratory's requirements, including laboratory activities – the requirements of the Standard b) is effectively implemented and maintained	
8.8.2	Audit requirements a) is planned and implemented, including frequency, defined responsibilities and reporting, taking into account – the importance of the laboratory activities concerned – changes affecting the laboratory – the results of previous audits b) audit criteria and the scope of each audit are defined c) audit results are reported to relevant management d) corrective actions, where necessary, are implemented promptly e) records of the audit program, including outcomes, are retained	

Option A: 8.9 Management reviews

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.1	Review of management system • is conducted at planned intervals by laboratory management to ensure – continued suitability, adequacy and effectiveness – covers the stated policies and objectives related to the fulfilment of the Standard	
8.9.2	Records of inputs • including information related to a) changes in internal and external issues b) fulfilment of objectives c) suitability of policies and procedures d) status of actions from previous reviews e) outcomes of recent internal audits f) corrective actions g) assessment by external bodies h) changes in volume, type and range of laboratory activities i) customer and personnel feedback j) complaints k) effectiveness of any implemented improvements l) adequacy of resources m) results of risk identification n) outcomes of the assurance of validity of results o) any other relevant factors	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.3	Records of outputs • include all decisions and actions relating to a) effectiveness of the management system b) improvement of the laboratory activities relating to satisfying the requirements of the Standard c) provision of required resources d) any need for change(s)	

Option B

Where 1) to 6) cannot be confirmed, then assessment of the laboratory's management system shall be against Option A requirements.

If the laboratory has adopted Option B	Evidence
1) evidence the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).	
2) evidence that the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA).	
3) copies of the most recent certification audit report(s) issued by the CB covering the laboratory's management system in full.	
4) confirmation from the CB of the close out of any nonconformities raised during certification audits.	

5) evidence the certification of the management system covers the laboratory activities covered by its NATA scope of accreditation.	
6) supports the facility fulfilling consistently the requirements of ISO/IEC 17025 to assure the quality of results.	