A18-2017 – CROSS REFERENCE TO LABORATORY MANAGEMENT SYSTEM

Revision 2.1

March 23, 2022

Laboratory Name: _____

Laboratory Number:_____

CALA
Trust, measured accurately

Rating Guide Item (A02)	Cross reference
4 General Requirements	
4.1 Impartiality	
• Structured and managed	
• Management commitment	
• Impartiality of lab activities	
• Identification of risks	
• Elimination or minimizing risk	
4.2 Confidentiality	
• Management of information	
• Release of confidential information	
• Information from third parties	
• Personnel external to the laboratory	
5 Structural Requirements	
5.1 Legal Entity	
5.2 Management with overall responsibility	
5.3 Range of Activities	
5.4 Meeting requirements	
5.5 Organization and management structure	

Rating Guide Item (A02)	Cross reference
5 Structural Requirements	
5.6 Responsibility for management system	
5.7 Communication regarding effectiveness of management system and;	
• ensuring integrity of management system is maintained for planned changes.	
6 Resource Requirements	
6.1 General	
6.2 Personnel	
• Requirements for internal or external staff	
• Document competence requirements	
• Competence	
• Communication of duties & responsibilities	
• Procedures and records	
• Authorizations	
6.3 Facilities and environmental conditions	
• Suitability	

Rating Guide Item (A02)	Cross reference
• Documentation of requirements	
6 Resource Requirements	
• Monitor, control and record conditions	
• Measures to control facilities	
6.4 Equipment	
• Access	
• Outside the lab's permanent control	
• Procedure(s) for equipment	
• Conformance to requirements	
• Capability to produce valid results	
• Equipment is calibrated	
• Calibration programme	
• Labelling of Equipment	
• Subject to mishandling or overloading	
• Intermediate checks	
• Reference values or Correction factors	
• Unintended adjustments	
• Records	

Rating Guide Item (A02)	Cross reference
6 Resource Requirements	
6.5 Metrological traceability	
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• Established and maintained	
• Traceability to the SI	
• When traceability to the SI is not possible	
6.6 Externally provided products and services	
• Use of suitable products and services	
• Procedures and records	
• Communication of requirements	
7 Process Requirements	
7.1 Review of requests, tenders and contracts	
• Procedure	
• Inappropriate method requested	
• Statement of conformity	
• Differences between request and contract	
• Customer informed of deviations	
• Amendments	

Rating Guide Item (A02)	Cross reference
7 Process Requirements	
• Clarification of requests	
• Records of review	
7.2 Selection, verification and validation of methods	
• Appropriate methods and procedures	
• Current and available	
• Latest valid version in use	
• Lab selection of methods	
• Verification of standard methods	
• Method development	
• Deviations from methods	
• Validation of methods	
• Changes to validated methods	
• Fit-for-purpose	
• Records of validation	
7.3 Sampling	
• Sampling plan and method	
• Sampling method content	
• Records	

Rating Guide Item (A02)	Cross reference
7 Process Requirements	
7.4 Handling of test or calibration items	
• Procedure	
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• System for identification	
• Deviations from conditions	
• Storage conditions	
7.5 Technical Records	
• Sufficient information	
• Amendments to technical records	
7.6 Evaluation of measurement uncertainty	
• Identification of contributions	
• Evaluation of MU for all calibrations	
• Evaluation of MU for quantitative results	
• Estimation of MU for other types of tests	
7.7 Ensuring the validity of results	
• Procedure for monitoring	
• Data recorded to detect trends	

Rating Guide Item (A02)	Cross reference
7 Process Requirements	
• PT or inter-laboratory comparisons	
• Analysis of data to control and improve	
• Data outside pre-defined criteria	
7.8 Reporting of results	
• Results reviewed and authorized	
• Results reported clearly, unambiguously	
• Simplified reports	
• Common requirements for reports	
• Specific requirements for testing	
• Calibration certificates	
• Reporting sampling	
• Statements of conformity	
• Opinions and interpretations	
• Amendments to reports	
7.9 Complaints	
• Documented process	
• Availability of process	

Rating Guide Item (A02)	Cross reference
7 Process Requirements	
• Content of process	
• Responsibility	
• Acknowledgement of complaint	
• Impartiality of outcomes	
• Formal notice of end of process	
7.10 Nonconforming work	
• Responsibilities and authorities	
• Actions based on risk levels	
• Evaluation of significance	
• Decision on acceptability	
• Customer is notified or work recalled	
• Responsibility for resumption of work	
• Record retention	
• Need for corrective action	
7.11 Control of data and information management	
• Access to data and information	
• Validation of LIMS	

Rating Guide Item (A02)	Cross reference
7 Process Requirements	
• Protected from unauthorized access	
• Safeguarded	
• Complies with specifications	
• Maintenance	
• System failures	
•	
• Off-site providers or operators	
• Availability of manuals etc…	
• Calculations and data transfers	

Rating Guide Item (A02)	Cross reference
8.0 Management System Requirements	
• Option A	
• Option B	
8.2 Management System Documentation	
• Policies and objectives	
• Management commitment	
• Supporting procedures and processes	
• Access by personnel	
8.3 Control of management system documents	
• Control of documents	
• Approval of documents	
• Periodic review	
• Changes identified	
• Distribution	
• Uniquely identification	
• Obsolete documents	
8.4 Control of records	
• Requirement to retain records	
• Record integrity	

Rating Guide Item (A02)	Cross reference
8.0 Management System Requirements	
8.5 Risk	
• Consideration of risks and opportunities	
• Actions to address risks and opportunities	
• Actions proportional to impact	
8.6 Improvement	
• Identify and Select	
• Feedback	
8.7 Corrective actions	
• Correction	
• Evaluation of need for corrective action	
• Implement corrective action	
• Effectiveness	
• Update risks and opportunities	
• Changes to system, if necessary	
• Appropriateness	
• Record retention	
8.8 Internal audits	
• Objectives and frequency	

Rating Guide Item (A02)	Cross reference
8.0 Management System Requirements	
• Audit criteria defined	
• Reporting of outcomes	
• Follow-up	
• Record retention	
8.9 Management reviews	
• Objectives and frequency	
• Inputs	
• Outputs	