Cross Reference to Laboratory Management System

Laboratory Name _____Laboratory Number:_____

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	_____
5.6 Responsibility for management system	_____
5.7 Communication from lab management on:	_____
• Effectiveness of management system	_____
• 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	_____
• Documentation of 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	_____

Rating Guide Item (A02)	Cross reference
6.4 Equipment (Continued)	
• Calibration programme	_____
• Labelling of Equipment	_____
• Subject to mishandling or overloading	_____
• Intermediate checks	_____
• Reference values or Correction factors	_____
• Unintended adjustments	_____
• Records	_____
6.5 Metrological traceability	
• 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	_____
• 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	_____
7.4 Handling of test or calibration items	
• Procedure	_____
• System for identification	_____
• Deviations from conditions	_____
• Storage conditions	_____
7.5 Technical Records	
• Sufficient information	_____
• Amendments to technical records	_____

Rating Guide Item (A02)	Cross reference
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	_____
• 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	_____
• 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	_____
• 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

8.1 Options
- 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 _____

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 _____
- Audit criteria defined _____
- Reporting of outcomes _____
- Follow-up _____
- Record retention _____

8.9 Management reviews
- Objectives and frequency _____
- Inputs _____
- Outputs _____