DOCUMENT REVIEW REPORT FOR LABORATORIES – ISO/IEC 17025

Initial Assessment ☐ Scope Extension ☐ Accreditation Renewal ☐ Other ☐

ORGANIZATION	
DOCUMENTATION RECEIVED *(Enter date of receipt)*	
DOCUMENT REVIEW BY *(List Names of Team Leader & Assessors/Technical Experts conducting the Document Review)*	
NAME & SIGNATURE *(Team Leader)*	
DATE OF REPORT SUBMISSION	

1. INTRODUCTION

The supplied documentation (Quality Manual) was reviewed against the standard requirements, SADCAS requirements, ILAC P9 – Policy on Participating in Proficiency Testing Activities, ILAC P10 - Policy on Metrological Traceability of Measurement Results and ILAC P 14 - Policy for Measurement Uncertainty in Calibration

2. REVIEW AGAINST ISO/IEC 17025 REQUIREMENTS FOR TESTING/CALIBRATION LABORATORIES

4. GENERAL REQUIREMENTS

SECTION 4.1: IMPARTIALITY

SECTION 4.2: CONFIDENTIALITY

5. STRUCTURAL REQUIREMENTS

6. RESOURCE REQUIREMENTS

SECTION 6.1 GENERAL

SECTION 6.2 PERSONNEL

SECTION 6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

SECTION 6.4 EQUIPMENT ILAC P10; ILAC P 14

SECTION 6.5 METROLOGICAL TRACEABILITY ILAC P10; ILAC P 14

SECTION 6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

7. PROCESS REQUIREMENTS

SECTION 7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

SECTION 7.2 SELECTIONM VERIFICATION AND VALIDATION OF METHODS
SECTION 7.3 SAMPLING

SECTION 7.4 HANDLING OF TESTS OR CALIBRATION ITEMS

SECTION 7.5 TECHNICAL RECORDS

SECTION 7.6 EVALUATION OF MEASUREMENT UNCERTAINTY ILAC P14

SECTION 7.7 ENSURING THE VALIDITY OF RESULTS ILAC P9

SECTION 7.8 REPORTING OF RESULTS

SECTION 7.9 COMPLAINTS

SECTION 7.10 NONCONFORMING WORK

SECTION 7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

8. MANAGEMENT SYSTEM REQUIREMENTS

SECTION 8.1 OPTIONS

SECTION 8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

SECTION 8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS (OPTION A)

SECTION 8.4 CONTROL OF RECORDS

SECTION 8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)

SECTION 8.6 IMPROVEMENT (OPTION A)

SECTION 8.7 CORRECTIVE ACTIONS (OPTION A)

SECTION 8.8 INTERNAL AUDITS (OPTION A)

SECTION 8.9 MANAGEMENT REVIEWS (OPTION A)

3. GENERAL COMMENTS

Below are some examples of general comments for different situations encountered. Follow your instincts and use this general comments section to highlight areas you feel may require specific attention.

Example 1: This could be where you notice from the application form or date on documents that the system has only been documented/ implemented for a short period of time. Or where it is clear that there is no clear direction given in the documentation, no "how" described.

Please note that for the initial assessment sufficient records generated by the system must be available to demonstrate the implementation of the system to give confidence that the laboratory can consistently ensure the quality of its results.

Example 2: Quality documentation is meant to be of benefit to a laboratory. The policies set by management give the overall direction of the laboratory. The objectives are always in line with the policies, usually measurable by some means, more specific to areas and may change. The procedures are the instruction manual defining how the laboratory operates to enable it to achieve the set objectives and thus continue moving in the planned direction as defined by the policies.

Example 3: Although the documentation submitted appeared to be written in accordance with the standard, there was very little direction given to the user thereof. Statements of fact were generally made but detail on how the laboratory was to achieve these requirements was lacking.

Example 4: The specific notes made during the evaluation are not necessarily non-compliances but sometimes areas of lack of clarity that could become obvious during the on-site assessment.

Example 5: The documentation submitted was deemed to be assessable and appeared to be in general compliance with the requirements of ISO/IEC 17025. Whether the laboratory's actual operational procedures are reflected in the Quality documentation can only be determined on-site at the initial assessment.

Example 6: Use of terms that are open to interpretation, such as "where appropriate" and "if possible", are not suitable as they do not give clear direction to the user to ensure consistency within the laboratory.

Be wary of stating that the manual is excellent / in full compliance with the standards as this may cause problems when the site visit reveals weaknesses overlooked during the document review.

4. RECOMMENDATION

Example 1: The deviations listed should be incorporated into the quality manual after an initial assessment of the laboratory may be arranged.

Example 2: The manual requires revision and re-submission for evaluation after which an initial assessment of the laboratory may be arranged.

Example 3: The deviations listed require a submission of additional documents or information to conclude the Document review process after which an Initial assessment may be arranged.

REVIEW OF ADDITIONAL DOCUMENTS
Comments on adequacy: Reviewer Name: _____ Date: _____ Review Signature: _____