FORMS

- To define the data use easy to complete forms
- Forms should be numbered with an appropriate code, and a reference shall be made in the procedure with regard to the associated form.

VALIDATION

- For accreditation of a test procedure, the validation data must be available for inspection during the accreditation audit.

IMPLEMENTATION

- The implementation process should be led by a working group appointed by the management.
- The group shall be formally trained for ISO 17025 accreditation.
- The Quality Manual and the associated procedures should be written by the Quality Manager and the team, in consultation with management.
- The laboratory procedures should be written by the laboratory staff.
- All procedures should be reviewed by the working group.

APPLICATION FOR ACCREDITATION
(BY LABORATORY)

ACKNOWLEDGEMENT AND SCRUTINY OF APPLICATION
(BY ACCREDITATION BODY SECRETARIAT)

ADEQUACY OF QUALITY MANUAL
(BY LEAD ASSESSOR)

STAGE 1 OF AUDIT LABORATORY
(OPTIONAL)

FINAL ASSESSMENT OF LABORATORY
(BY ASSESSMENT TEAM)

SCRUTINY OF ASSESSMENT REPORT
(ACCREDITATION AGENCY SECRETARIAT)

RECOMMENDATION FOR ACCREDITATION
(BY ACCREDITATION COMMITTEE)

APPROVAL FOR ACCREDITATION
(BY CHAIRMAN OF ACCREDITATION BODY)

ISSUE OF ACCREDITATION CERTIFICATE
(BY ACCREDITATION BODY SECRETARIAT)

- *FEEDBACK BY LABORATORY AND REQUIRED CORRECTIVE ACTION BY LABORATORY*

ISO ACCREDITATION OF LABORATORIES AND METHODS

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REQUIREMENTS FOR 'OFFICIAL' LABORATORIES

The local body shall designate laboratories that may carry out the analysis of samples taken during 'official' controls.

ISO 17025 accreditation for 'official' control laboratories is required by the local body, and for the international acceptance of the test data.

STANDARDS

- EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories
- EN 45002 on 'General criteria for the assessment of testing laboratories
- EN 45003 on 'Calibration and testing laboratory accreditation system – General requirements for operation and recognition

ISO 17025 ACCREDITATION COVERAGE

ISO 17025 accreditation is specific to individual test methods and, for a laboratory involved in testing for a wide range of analytes.

BENEFITS OF ACCREDITATION

- Increased professional recognition of the quality of the services provided.
- The documentation prepared in support of the accreditation is a useful training tool for the new staff.

REGIONAL ACCREDITATION BODIES

A number of organisations authorized to assess the status of laboratories and confer accredited status exist worldwide.

The accreditation procedure starts with the engagement of a recognized accreditation body that will provide the necessary service.

This body will liaise with the organisation applying for accreditation, and a timescale for the submission of the primary documentation (the Quality Manual) will be agreed.

THE QUALITY MANUAL

The Quality Manual describes the organisation and its operation including:

- MANAGEMENT STRUCTURE
- MANAGEMENT RESPONSIBILITIES
- MANAGEMENT REVIEW
- ROLE OF THE QUALITY MANAGER
- FINANCE
- PROCUREMENT OF EQUIPMENT AND MATERIALS
- PROCEDURES FOR RECRUITMENT OF STAFF
- STAFF TRAINING
- CERTIFICATION OF STAFF COMPETENCE
- RELATIONS WITH THE CLIENT
- SITE SECURITY AND CLIENT CONFIDENTIALITY
- SAMPLE ACCEPTANCE AND RECEPTION
- DATA STORAGE
- ARCHIVING AND RETENTION OF RECORDS
- PREPARATION, CERTIFICATION, AND DESPATCH OF TEST REPORTS
- QUALITY ASSURANCE INCLUDING PROFICIENCY TEST
- INTERNAL AUDITS
- PREVENTIVE ACTIONS
- COMPLAINTS PROCEDURE
- CORRECTIVE ACTIONS
- AUTHORIZATION, REVIEW, AND WITHDRAWAL OF PROCEDURES

LABORATORY PROCEDURES (STANDARD OPERATING PROCEDURES - SOPs)

- SOP for the cleaning of glassware (chemistry or microbiology)
- SOP for the calibration of volumetric glassware
- SOP for the calibration of thermometers
- SOP for the calibration of balances
- SOP for the calibration of the pH meter
- SOP for the measurement and recording of operating temperatures in ovens, refrigerators, freezers, and autoclaves
- SOP for use and maintenance of each main item of equipment
- SOP for sample storage and disposal
- SOP for the retention of reagents and the disposal of waste/obsolete materials