

YOUR TEST LAB NAME HERE

 **ISO/IEC 17025**

ISO 17025 Quality Manual

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4. Management Requirements

4.1. Organization

- 4.1.1. (test lab name) is incorporated as an (S-Corp, LLC) corporation in the state of (STATE NAME) and is headquartered in (CITY NAME), USA. Our business plan details the specifics of our corporation.
- 4.1.2. (test lab name) is committed to conducting testing and calibration services that satisfy our customer requirements, the requirements of ISO 17025 and requirements of our accrediting body.
- 4.1.3. The management system as outlined within this quality manual applies and will be followed regardless of where services are rendered (on or offsite).
- 4.1.4. (test lab name) only provides testing and calibration services and is committed to providing reliable, unbiased test results and interpretations. (User note: this default statement only applies to independent laboratories. If not true, you may need to explain how the lab's activities will be protected against undue internal pressures).
- 4.1.5. (test lab name) personnel
- 4.1.5.a. The managerial and technical personnel have the authority and resources to carry out their duties; including implementing, maintaining, and improving this management system (site org. charts, budgets, workload metrics and capital plans). The managerial and technical personnel are committed to identifying departures from this management system, our accrediting body's requirements, testing/calibration procedures and customer requirements.
- Policy: Although (test lab name) is committed to making reasonable attempts to prevent and minimize such departures, we recognize that departures will occasionally occur. Therefore, it is our policy that any departures shall be explicitly documented and promptly reported to the appropriate parties.
- 4.1.5.b. (test lab name) recognizes the risk that personnel may be subjected to commercial, financial, scheduling, and other pressures that may influence their quality of work. Therefore, employees are not permitted to accept gifts or gratuities from clients. Furthermore, (test lab name) employees are not permitted to work for another lab. (test lab name) is committed to conducting business in an ethical manner and will not tolerate any form of bribery or coercion that would compromise the integrity of our calibration and/or test results. Any undue pressures shall be promptly reported to top management.
- 4.1.5.b.1. Since there is no practical means of completely insulating our employees from these pressures, the following policies shall be applied in situations where undue pressure affects the quality of work.
- 4.1.5.b.2. If undue pressure exists, employees are encouraged to submit a written complaint to the quality manager. QP-006 outlines the formal procedure to be followed when handling complaints and/or concerns.
- 4.1.5.b.3. In the unlikely circumstance that laboratory personnel deliberately compromise the quality and integrity of their work, the individual will be held accountable for such conduct as deemed appropriate by lab management.
- 4.1.5.c. (test lab name) understands the confidential and proprietary nature of our customer's materials, processes and information. It is our policy to protect each customer's information by honoring confidentiality agreements. QP-006: Ensuring Confidentiality during Visits outlines the procedure for ensuring and maintaining customer confidentiality.
- 4.1.5.d. (test lab name) is committed to the highest ethical and quality standards. Not only is the management system outlined within this quality manual evidence of our commitment, but also our actions demonstrate these values.
- 4.1.5.e. Refer to section 4.1.1 of this quality manual for a definition of the organization. The structure is outlined in the following organizational chart. (User note: Depending on the size of your organization, you may either insert an image, embed an object or simply provide a textual reference to your actual organizational chart)
- (insert organizational chart or link to chart here)
- Figure 1: Organizational Chart
- 4.1.5.f. ISO designated roles are defined in the organizational chart. Each role has the authority to oversee testing and calibration activities and is required to verify results and ensure the overall quality of work.
- 4.1.5.g. (test lab name)'s management team has over 50 years of combined experience in testing. All personnel, including trainees, are under the direct supervision of, and supported by, the management team and/or their designated consultants.
- 4.1.5.h. The designated technical manager is responsible for technical operations and plans the appropriate resources in the business plan or other appropriate budgets.
- 4.1.5.i. The quality manager, technical manager and deputy, when appropriate, are identified in the organizational chart.
- 4.1.5.j. Additions and changes to the management system are disseminated to laboratory personnel through the QP-008: Management System Change Notification Process. The effectiveness of the management system is



4.14. Internal Audit Policy and Procedure

Purpose	The purpose of the internal audit policy and procedure is to define a standard approach and frequency for auditing the management system and testing and calibration activities.	
Scope	Internal audits encompass all testing and calibration activities included in the scope of accreditation.	
Definitions	Auditor	Individual conducting the audit.
Responsibility	Quality Manager	Ensure that internal audits are completed on a timely basis, at the frequency specified by the management system, by qualified personnel.
	Auditor	Perform an audit of the management. Document concerns and nonconformance and supply an audit report.

4.14.1. Internal and external audits shall be performed using ISO/IEC 17025 as the basis of the audit. Whenever possible, internal audits shall be conducted by an independent and impartial third party. The lab shall provide appropriate accommodations for auditing activities. Internal quality system audits shall be conducted annually between the months of September and October (User note: audits should be scheduled based on your specific needs – the key is to make sure the audit actually occurs). Internal audits shall adhere to the following rotation schedule to assure that all tests, within the scope of accreditation, are audited within two internal audit cycles.

<u>Audit Cycle</u>	<u>Scope of Audit</u>
Odd Year Audits	ISO 17025 Section 4.1 - 4.15 Tests A, B, C, D
Even Year Audits	ISO 17025 Section 5.1 - 5.10.9 Tests W, X, Y, Z

4.14.2. The Quality Manager is responsible for initiating and completing corrective and/or preventive actions per sections 4.11 and 4.12. If nonconforming work is discovered, Section 9.1: Control of Nonconforming Testing and/or Calibration work shall be employed.

4.14.3. The results of any audit performed shall be submitted in writing to the Quality Manager.

4.14.4. A follow up audit at the appropriate time in the corrective action process will be conducted to validate effectiveness of the corrective action(s).



5.2. Procedure for Ensuring Competent Personnel

Purpose	The purpose of the competent personnel procedure is to ensure, maintain and develop competency in all areas of test and calibration. In addition the procedure should enable smooth transfers of responsibility and mitigates the risk of losing key personnel.	
Scope	Includes all activities related to testing and calibration, the application of the management system and management.	
Definitions	Trainee	Individual undergoing training to develop competency in a specific area.
Responsibility	Quality Manager	Institute a training program and ensure the requirements of this procedure are met.
	All personnel	Seek the appropriate support when uncertain of skills and competence.
	Trainee	Document training activities and plans in the appropriate locations.

5.2.1. (test lab name) ensures the competence of all personnel performing testing and/or calibration activities. Activities include performing tests and calibrations, evaluating results, signing test reports and calibration certificates.

5.2.1.a. (test lab name) assesses competence through a variety of means as appropriate. Such means include:

- Education
- Training
- Experience
- Demonstration of skills

5.2.1.b. In areas that require technical certification, (test lab name) will fulfill the requirements as required.

5.2.2. (test lab name) shall assess the knowledge, skills and attitudes of personnel performing test and calibration activities. Such assessments evaluate the effectiveness of training and shall result in a training plan that satisfies the identified need. General educational and training goals include:

- More than 1 individual trained and competent to perform tests under the scope of accreditation.
- Evaluate competence through internal audits
- Actively seek and participate in proficiency testing offered within our field.
- Personnel attend in two training seminars per year (as appropriate)

5.2.3. Only personnel who are employed by or contracted to (test lab name) shall perform test and calibration activities. All work shall be supervised and completed in accord with this management system. Any contracted personnel shall supply a resume detailing education, training and previous experience. In addition, contracted personnel should supply personnel references prior work.

5.2.4. Job descriptions for employees are maintained in the EIR-019: Job Descriptions Repository.

5.2.4.a. At a minimum, these job descriptions include:

- Responsibilities while performing tests and/or calibrations;
- Responsibilities while planning tests and/or calibrations and evaluating results;
- Responsibilities for reporting opinions and interpretations;
- Responsibilities for developing, modifying and validating new methods;
- Required expertise and experience
- Qualifications and training programs
- Managerial Duties (if any)

5.2.5. Personnel are authorized to perform work upon satisfactory demonstration of competence. Records of authorizations are maintained in individual training records.



5.4. Test and Calibration Methods and Method Validation Policy and Procedure

5.4.1. General Method Policies and Procedure

- 5.4.1.a. (test lab name) uses methods and procedures that are appropriate for all the tests and calibrations for testing and calibration activities.
- 5.4.1.b. When the absence of a work instruction jeopardizes the results of a test or calibration, work instructions that detail procedures for operating equipment, and handling and preparation of items are provided.
- 5.4.1.c. Work instructions, standards, manuals and reference data are maintained in a current state and subject to the document control procedure in section 4.3. Section 4.4 details handling and reporting deviations from procedures.

5.4.2. Method Selection Policy

- 5.4.2.a. (test lab name) only uses methods which meet the needs of the customer and are appropriate for the tests and/or calibration services provided.
- 5.4.2.b. Unless otherwise specified, (test lab name) only uses internationally, nationally or regionally accepted standards. Any methods selected by the laboratory shall be approved for use by the customer prior to test or calibration. As noted under section 4.4, (test lab name) will perform the appropriate review of its capability prior to recommending standards.
- 5.4.2.c. Unless otherwise specified, only the latest version of the standard will be used. As appropriate, methods will be supplemented with additional details to ensure consistent application and interpretation.
- 5.4.2.d. (test lab name) will notify its customers if a selected method is considered inappropriate or becomes out of date.
- 5.4.2.e. (test lab name) does not develop methods for its own use under the scope of accreditation.

5.4.3. In House Method Development Policy

- 5.4.3.a. (test lab name) does not develop test or calibration methods for its own use under the scope of accreditation.

5.4.4. Non Standard Methods Policy

- 5.4.4.a. (test lab name) does not offer nonstandard tests under the scope of accreditation.
- 5.4.4.b. Any nonstandard test or calibration services provided shall be documented with enough detail to sufficiently reproduce the test.

5.4.5. Validation of Non Standard Methods Policy and Procedure

- 5.4.5.a. (test lab name) does not offer test or calibration services under the scope of accreditation.

5.4.6. Estimation of Measurement Uncertainty Policy and Procedure

- 5.4.6.a. QP-001: Estimating Measurement Uncertainty outlines the procedure used for estimating measurement uncertainty.

5.4.7. Control of Data Policy and Procedure

- 5.4.7.a. QP-003: Control of Data outlines the procedure used for controlling calculated data and WI-003 outlines the procedure for transmitting electronic data. (User note: This requires much more detail that is specific to practices of your lab. Consider adding more content to QP-003 and this section to elaborate on how data is controlled in your lab.)



5.10.3. Test Report Policy and Procedure

- 5.10.3.a. In addition to the requirements outline in 5.10.2, test reports shall include the following as required to interpret results:
- a) Any deviation (additions, exclusions or otherwise alterations) from the test method and or environmental conditions.
 - b) Where required, a statement of compliance/non-compliance with relevant requirements or acceptance criteria.
 - c) Where applicable, a statement of measurement uncertainty (as determined in 5.4.6). Measurement uncertainty shall be reported according to QP-002: Reporting Measurement Uncertainty.
 - d) When appropriate, opinions and interpretations of the results.
 - e) Additional information required by specific methods or customers.
 - f) Details of the environmental conditions during sampling that may affect the interpretation of results.
 - g) Any standard or specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification.



Change Control Section

<u>Version</u>	<u>Rev. Date</u>	<u>Section</u>	<u>Change Control Comments</u>	<u>Approver</u>
1	07.17.2009	NA	Created new document.	First name Last Name