



Quality Manual

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1 Scope

- 1.1 This ISO 17025 Quality Manual specifies the competence, impartiality and operational requirements that have been adopted and implemented by click or tap here to enter laboratory name.
- 1.2 This Quality Manual is applicable to all laboratory activities identified in EIR-022-01: Scope of Laboratory Activities.
- 1.3 Laboratory customers, regulatory authorities, peer-assessments, accreditation bodies, and others shall use this Quality Manual to confirm and recognize the competence of click or tap here to enter laboratory name to perform testing and calibration activities.

2 Normative References

- 2.1 This Quality Manual has been developed to conform with the requirements of ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.

3 Management System Structure

- 3.1 This management system has been systematically designed to enable users to easily cross reference the various elements. The basic architecture is illustrated in Figure 1.

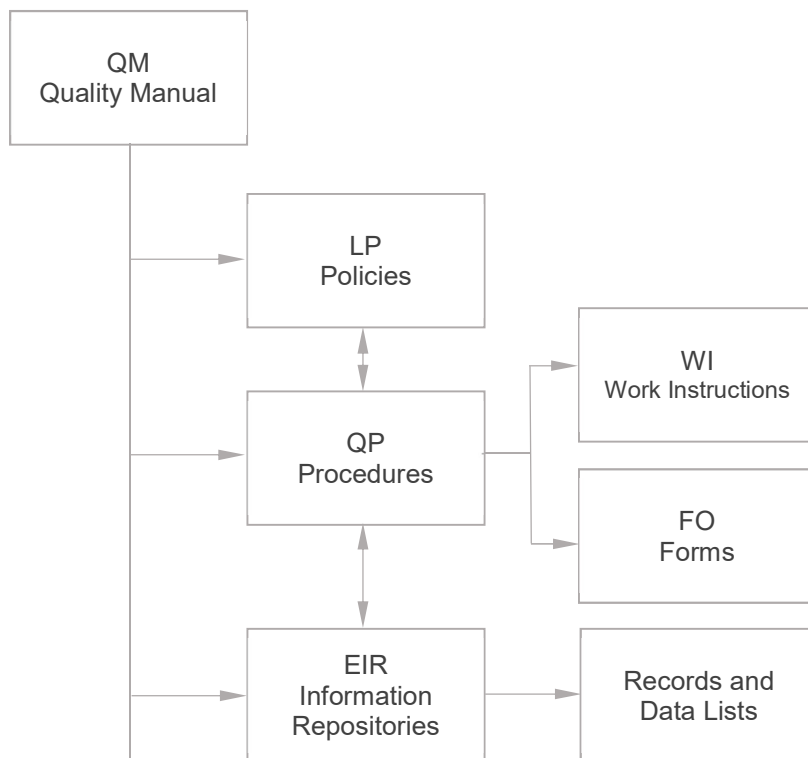


Figure 1: Management System Document Structure

4 General

4.1 Impartiality

- 4.1.1 It is the policy and commitment of click or tap here to enter laboratory name to appropriately structure and manage activities in a manner that protects and preserves impartiality.
- 4.1.2 Our lab demonstrates commitment to impartiality by:
- Providing a policy statement that explicitly expresses our commitment (clause 4.1.1 of this quality manual).
 - Providing a Code of Conduct (LP-001) for members of management and all laboratory personnel.
 - Establishing procedures for ensuring impartiality, evaluating risks, and periodically reevaluating the risks. Refer to QP-012: Ensuring Impartiality for more information.
 - Maintaining records of risk assessments and by implementing countermeasures to prevent or minimize the identified risks.
 - Systematically incorporating steps, throughout the relevant policies and procedures, that prevent or minimize identified risks and expose situations when impartiality is compromised.
 - Ensuring all laboratory personnel are aware, through orientation and ongoing training of:
 - LP-001: Code of Conduct Policy
 - QP-012: Ensuring Impartiality Procedure
 - The risks they may face by reviewing the Risk Assessment
 - Providing personnel with access to top management to report behaviors or incidents thought to compromise impartiality.
- 4.1.3 click or tap here to enter laboratory name assumes full responsibility for being impartial and for preventing commercial, financial, and other pressures.
- 4.1.4 click or tap here to enter laboratory name identifies, reassess, prevents and minimizes risks to impartiality according to QP-012: Ensuring Impartiality.

4.2 Confidentiality

- 4.2.1 click or tap here to enter laboratory name assumes full responsibility for the confidentiality of all information obtained through laboratory activities. We express our commitment to members of management and laboratory personnel through LP-001: Code of Conduct. click or tap here to enter laboratory name is legally bound to maintain confidentiality through various non-disclosure agreements, confidentiality agreements, and other similar agreements as required by our customers. QP-013: Handling Confidential Information shall be followed when a customer's information is released to the public.
- 4.2.2 QP-013: Handling Confidential Information shall be followed when releasing confidential information.
- 4.2.3 QP-013 Handling Confidential Information shall be followed when obtaining confidential information about customers from other sources such as complainants, regulators, etc.
- 4.2.4 All personnel, including external resources, shall keep information obtained through laboratory activities confidential and shall follow QP-013.

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6.6 Externally Provided Products and Services

- 6.6.1 click or tap here to enter laboratory name ensures only suitable products and services are supplied to the laboratory through QP-015: Ensuring Quality of External Products and Services.
- 6.6.2 Procedures and records for externally provided products and services
 - a) QP-015: Ensuring Quality of External Products and Services shall be followed when defining, reviewing, and approving requirements for externally provided products and services.
 - b) QP-015: Ensuring Quality of External Products and Services shall be followed when defining criteria for evaluation, selection, monitoring performance, and re-evaluation of external providers.
 - c) QP-015: Ensuring Quality of External Products and Services shall be followed to ensure externally provided products and services conform to the applicable requirements.
 - d) QP-015: Ensuring Quality of External Products and Services shall be followed when authorizing the use of externally provided products and services and when responding to non-conforming products and services.
- 6.6.3 Requirements are communicated to authorized providers according to QP-009: Procuring Products and Services.

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7.6 Evaluating Measurement Uncertainty

- 7.6.1 [click or tap here to enter laboratory name](#) estimates uncertainty according to QP-001: Estimating Measurement Uncertainty.
- 7.6.2 The uncertainty is assessed for internal calibration methods that affect activities identified in EIR-022-01: Scope of Laboratory Activities according to QP-001: Estimating Measurement Uncertainty.
- 7.6.3 The uncertainty is assessed for all test methods included in EIR-022-01: Scope of Laboratory Activities according to QP-001: Estimating Measurement Uncertainty.

7.7 Ensuring the Validity of Results

- 7.7.1 QP-019: Ensuring the Validity of Results shall be used to specify the assessment procedures for monitoring the validity of results. Records of resulting method assessments shall be retained in EIR-023: Method Assessments within the method's designated folder.
- 7.7.2 Other performance monitoring schemes, such as, proficiency testing and interlaboratory comparisons, shall be identified according to QP-019: Ensuring the Validity of Results in the Method Assessment Procedure.
- 7.7.3 Data, analysis and results from method assessments shall be recorded as specified by the Method Assessment Procedures.
- 7.7.4 Nonconforming results and negative trends shall be investigated by performing a method assessment according to QP-019: Ensuring the Validity of Results.

8.5 Actions to Address Risks and Opportunities

- 8.5.1 QP-022: Risks Opportunities and Actions Assessment shall be followed to identify risks and opportunities for improvement.
- 8.5.2 Actions to address risks and opportunities are identified in RA-002: Process Risks and Opportunities Assessment.
- 8.5.3 Actions shall be prioritized as specified by QP-022: Risks Opportunities and Actions Assessment and shall be proportional to the potential impact of the effects.
- 8.5.4 Plans to implement prioritized actions shall be created as specified by QP-022: Risks Opportunities and Actions Assessment.

8.6 Improvement

- 8.6.1 click or tap here to enter laboratory name shall regularly monitor and continuously improve the effectiveness of the management system. Monitoring activities shall include:
 - a) Quality objectives;
 - b) Customer feedback;
 - c) Complaints;
 - d) Audit results;
 - e) Proficiency testing;
 - f) Review of Corrective and Preventative Actions;
 - g) Management Review
- 8.6.2 QP-021: Customer Service specifies the periodic solicitation of customer feedback. The feedback is reviewed and used to improve the management system, laboratory activities and customer service.
- 8.6.3 QP-022: Risks Opportunities and Actions Assessment shall be followed when opportunities for improvement are identified.
- 8.6.4 Additions and changes to the management system are disseminated to laboratory personnel as outlined in QP-008: Management Change Notification.

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9 Authorization

9.1 This Quality Manual has been reviewed and determined to conform with the requirements of ISO 17025, this laboratory's accrediting body, and the requirements of this ISO 17025 Management System. This Quality Manual is authorized for use.

Date of Authorization:

Authorizer's Name:

Authorizer's Signature:

[input authorizer's name]

10 Change Control

<u>Version</u>	<u>Rev. Date</u>	<u>Change Control Comments</u>	<u>Revised by:</u>
1	01.01.2018	Created new document.	(author's name)