



The following pages present the criteria from standard ISO/ IEC 17025: 2005, "General Requirements for the Competence of Calibration and Testing Laboratories" in a checklist format. Quality Management System (QMS) documentation and supporting quality records must be available for the assessor's review.

**Assessor Instructions:**

Every checklist item must be accompanied by a tick mark in the yes (Y), no (N), or not applicable (NA) space. Submit this checklist as part of the assessment documentation. This serves to help you as assessor and the laboratory and may save a significant amount of assessment time and cost.

Review the laboratory's documented QMS to verify compliance with the applicable Standard documentation requirements. Assess to verify that the documented QMS is indeed implemented as described. Record comments related to any requirement in the space provided and sign on the appropriate line below. Assess the efficiency of the laboratory's QMS and technical competence to perform specific tests or specific type of tests. All deficiencies must be identified and explained in the Deviation Reports.

Laboratory Name: -----  
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Personnel information (Names, Titles, and Responsibilities):  
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Quality Manager: -----

Technical Manager: -----

Key Technical Staff and Their Unique Capability<sup>1</sup>:  
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*I, hereby, attest that all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of ISO/IEC 17025 (section no. 4 and 5). Any areas of noncompliance have been fully described in the Deviation Report.*

Assessor Signature: -----

Date: -----

<sup>1</sup> A "Key technical staff person" is anyone whose absence or departure would reduce the laboratory's competence to carry out one or more specific tests, and would necessitate removal from the laboratory's Scope of Accreditation, any tests or types of tests for which that person has unique capability.

## 4. Management requirements

	The Requirements	Compliance			Remarks
		Yes	No	NA	
<b>4.1 Organization</b>					
4.1.1	Legally responsible entity				
4.1.2	The laboratory's responsibility is to carry out testing and calibration according to ISO 17025				
4.1.3	Permanent and mobile facilities covered by the laboratory management system				
4.1.4	Responsibilities of key personnel if the laboratory is part of an organization performing other activities than testing/calibration				
4.1.5	The laboratory shall have(requirement to organization):				
a	<b>Managerial and technical personnel with authority and resources to carry out duties and to identify departures</b>				
b	Management and personnel free from undue internal and external pressure and influences				
c	Policies and procedures to protect the customer confidential information and proprietary rights, including procedures for electronic storage and transmission of results				
d	Policies and procedures to avoid the involvement in activities that would diminish confidence in the laboratory's competence, impartiality, independence				
e	Definition of the organization and management structure				
f	Specification of responsibility and authority for all relevant personnel				
g	Adequate supervision of testing and calibration staff				
h	Technical management with overall responsibility				
i	Quality manager and reference to management making decisions on the laboratory's policy or resources				
j	Appointed deputies for key managerial personnel				
k	<b>Personnel aware of their contribution to objectives</b>				
4.1.6	<b>Top management ensures appropriate communication of management system effectiveness</b>				

	The Requirements	Compliance			Remarks
		Yes	No	NA	
<b>4.2 Management system requirements</b>					
4.2.1	Management system appropriate and implemented				
	Documented quality policy				
	Procedures and instructions to the extent necessary				
	System documentation available to staff				
<b>4.2.2</b>	<b>Overall objectives are established and reviewed during management review.</b> Quality policy shall include:				
a	Laboratory management's commitment				
b	The management statement of the laboratory's standard of services				
<b>c</b>	<b>Purpose of management system related to quality</b>				
d	A requirement that the staff implement the policy and procedures in their work				
<b>e</b>	<b>The management's commitment to comply with ISO 17025 and continually improve effectiveness of management system</b>				
<b>4.2.3</b>	<b>Evidence of commitment to development and continual improvement</b>				
<b>4.2.4</b>	<b>Communication to organization of importance of meeting customer and statutory requirement</b>				
4.2.5	The quality manual's reference to supporting procedures and description of the system documentation				
4.2.6	Definition of roles and responsibilities of technical management and quality manager				
<b>4.2.7</b>	<b>Integrity of management system is maintained in case of changes</b>				
<b>4.3 Document control</b>					
4.3.1	Procedure to control all documents (internal and external) of the quality system				
	Regulations				
	Standards				
	Normative documents				
	Test and/or calibration methods				
	Further instructions, manuals, drawings, software and specifications				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	The Requirements	Compliance			Remarks
		Yes	No	NA	
<b>4.3.2-3 Document approval, issue and changes</b>					
4.3.2.1	Approval of all documents by authorized persons- establishment and availability of a master list/procedure for document control identifying status and distribution				
4.3.2.2	The procedure(s) shall ensure:				
a	Availability of relevant documents				
b	Periodically review and revision of documents				
c + d	Removal of invalid documents and suitable marking of retained obsolete documents				
4.3.2.3	Unique identification of documents including date/revision, page numbering and responsible				
4.3.3.1	Document changes approved by authorized personnel				
4.3.3.2	Identification of altered or new text if possible				
4.3.3.3	Procedure for amendment of documents by hand, if permitted				
4.3.3.4	Procedure for changing and control of documents maintained in computerized systems				
<b>4.4 Review of requests, tenders and contracts</b>					
4.4.1	Procedures of review for requests, tenders and contracts shall ensure;				
a	Definition of requirements, including methods				
b	That the laboratory has the capability and resources to meet the requirements				
c	Appropriate test and/or calibration method				
	Accept of differences between request and tender				
4.4.2	Records of reviews, including changes of contract with customer				
4.4.3	Subcontracted works covered by the review				
4.4.4 +4.4.5	Customer is informed of any deviation. Same review of amended contracts				
<b>4.5 Subcontracting of tests and calibrations</b>					
4.5.1	Competent subcontractor, e.g. complying with ISO 17025				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	The Requirements	Compliance			Remarks
		Yes	No	NA	
4.5.2	Advise of customer in writing, and approval from customer				
4.5.3	The laboratory's responsibility to the customer- unless the subcontractor is specified by customer or authority				
4.5.4	Register of subcontractors				
<b>4.6 Purchasing services and supplies</b>					
4.6.1	Policy and procedures for purchasing of services and supplies, affecting the quality to tests and calibration				
	Procedures for purchasing of reagents and consumable materials, relevant for tests and calibrations				
4.6.2	Inspection of purchased supplies and reagents – records of actions check of compliance				
4.6.3	Content of purchasing documents – review and approval				
4.6.4	The laboratory's evaluation of suppliers of critical consumables and recording of this evaluation				
<b>4.7 Services to the client</b>					
4.7.1	Clarification of the customers request				
	The customer witnessing of tests				
	Ensuring of confidentiality to other customers				
<b>4.7.2</b>	<b>Feedback seeked, used and analyzed for improvement</b>				
<b>4.8 Complaints</b>					
4.8	Policy and procedure for resolution of complaints				
	Records of complaints, investigations and corrective actions				
<b>4.9 Control of nonconforming testing and/or calibration work</b>					
4.9.1	Policy and procedures for nonconforming testing and/or calibration work				
a + e	Responsibilities and authorities for management of nonconforming work				
b	Evaluation of the significance of the deviation				
c	Immediate correction				
d	Notification of customer and recalling of work, where necessary				

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	The Requirements	Compliance			Remarks
		Yes	No	NA	
4.9.2	Implementation of corrective actions according to 4.11, if necessary				
<b>4.10 Improvement</b>					
<b>4.10</b>	<b>Continual improvement of quality system effectiveness</b>				
<b>4.11 Corrective actions</b>					
4.11.1	Policy and procedures for corrective actions				
4.11.2	Cause analysis				
4.11.3	Selection and implementation of corrective actions – appropriate to the magnitude and risk of the problem				
4.11.4	Monitoring of results of corrective actions				
4.11.5	Additional audit if relevant				
<b>4.12 Preventive actions</b>					
4.12.1	Identification of needed improvements and potential sources of nonconformance				
4.12.2	Procedures for preventive actions and control to ensure efficiency				
<b>4.13 Control records</b>					
4.13.1	General				
4.13.1.1	Procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records				
4.13.1.2	Legibility and retrievability of records – suitable training of documents – retention times of records				
4.13.1.3	Records held secure and in confidence				
4.13.1.4	Procedures to protect and back-up of electronically stored records				
4.13.2	Technical records				
4.13.2.1	Records of original observations, derived data and sufficient information to establish and audit trail – copy of reports/certificates- identification of factors affecting the uncertainty – identity of personnel				
4.13.2.2	Records identifiable to the specific task				
4.13.2.3	Signing of alterations to records – similar to electronically stored records				

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	The Requirements	Compliance			Remarks
		Yes	No	NA	
<b>4.14 Internal audits</b>					
4.14.1	Procedures and time schedule for internal audit – the quality manager's responsibility				
	Trained, qualified and independent audit personnel				
4.14.2	Corrective actions – notifying customer if results are affected				
4.14.3	Recording of audits and corrective actions				
4.14.4	Follow-up audits to verify effectiveness of corrective actions				
<b>4.15 Management reviews</b>					
4.15.1	Procedure and time schedule for review				
	Suitability of policy and procedures				
	Reports from managerial and supervisory personnel				
	Outcome of recent internal audits				
	Corrective and preventive actions				
	Assessment by external bodies				
	Results of interlaboratory comparisons or proficiency tests				
	Changes in volume and type of the work				
	Customer feedback				
	Complaints				
	<b>Recommendation for improvement</b>				
	Other relevant factors, e.g. quality control activities, resources and staff training				
4.15.2	Records of evaluations and actions–time scale for actions				

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**5. Technical requirements**

	The requirements				Remarks
		Yes	No	NA	
<b>5.2 Personnel</b>					
5.2.1	Ensuring of competence of testing/calibrating personnel, of personnel who operate specific equipment, evaluate results or sign reports/certificates				
	Supervision of personnel undergoing training				
5.2.2	Policy and procedures for identifying training needs and providing training. <b>Training effectiveness is evaluated</b>				
5.2.3	Personnel employed or under contract – personnel under contract competent, supervised and working in accordance with the quality system				
5.2.4	Job description maintained for managerial, technical and key support personnel				
5.2.5	Authorization of personnel to specific tasks, and recording of authorizations, including date confirmation				
<b>5.3 Accommodations and environmental conditions</b>					
5.3.1	Laboratory facilities ensuring correct performance of tests/calibrations – including sampling and onsite testing/calibration				
5.3.2	Monitoring, controlling and recording of environmental conditions if required – biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound- and vibration levels				
5.3.3	Effective separation between neighboring areas with incompatible activities				
5.3.4	Control of access to and use of laboratory areas				
5.3.5	Measures to ensuring good housekeeping				
<b>5.4 test and calibration methods and method evaluation</b>					
5.4.1	Use of appropriate methods for all tests/calibrations, including sampling, handling, transport, storage and preparation of items – for estimation of uncertainty and analysis of testing/calibration data				
	Instructions for use and operation of equipment				
	Instructions for handling and preparation of items				
	Updating and availability of relevant instructions				

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	<b>The requirements</b>				<b>Remarks</b>
		<b>Yes</b>	<b>No</b>	<b>NA</b>	
5.4.2	Selection of methods				
	Use of standard methods – supplemented with details to ensure consistent application				
	Confirmation of properly operated standard methods				
	Information to customer if proposed methods are inappropriate or out of date				
5.4.3	Plan for introduction of laboratory-developed methods – qualified personnel with adequate resources				
5.4.4	Non-standard methods – the customer's agreement and specification of the customer's requirements				
5.4.5.2	Validation of non-standard methods, laboratory-designed/developed methods, standard methods used outside their scope				
	Recording of validation results, procedure and a statement on fitness for use				
5.4.5.3	Results of validation relevant to the customer's needs – uncertainty, detection limit, selectivity, linearity, limit of repeatability, limit of repeatability and/or reproducibility., robustness and/or cross reproducibility				
<b>5.4.6 Estimation of uncertainty of measurement</b>					
5.4.6.1	Procedure to estimate uncertainty for all calibrations performed by the laboratory				
5.4.6.2	Procedure to estimate uncertainty for a testing laboratory – all components				
5.4.6.3	Estimation of uncertainty – analysis of all components of importance				
<b>5.4.7 Control of data</b>					
5.4.7.1	Systematic and appropriate checks of calculations and data transfer				
5.4.7.2	Ensuring, when computers or automatic equipment is used:				
a	Documentation and validation of computer software				
b	Implementation of a procedure for protection of data				
c	Maintenance of computers and automatic equipment to ensure proper functioning				

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	The requirements				Remarks
		Yes	No	NA	
<b>5.5 Equipment</b>					
5.5.1	The laboratory's disposal equipment necessary for correct performance of testes/calibrations				
	Ensuring compliance with ISO 17025 of equipment outside the laboratory's permanent control				
5.5.2	Calibration programs for all relevant equipment compliance with the specifications/uncertainty				
	Calibration or check of equipment before use – the laboratory's specification requirements				
5.5.3	Operation by authorized personnel – instructions available				
5.5.4	Unique identification of each equipment/software				
5.5.5	Recording of equipment including:				
a	Identification of equipment				
b	Manufacturer, type, and serial number				
c	Checks of compliance with specifications				
d	Current location, where appropriate				
e	Manufacture's instruction, or reference to this				
f	All information relating to calibration, adjustments, acceptance criteria, and next calibration				
g	Maintenance plan, if appropriate, and maintenance carried out				
h	Damage, malfunction, modification or repair				
5.5.6	Procedure for handling, transport, storage, use, and planned maintenance – prevention of contamination				
5.5.7	Labeling or isolation of defective equipment – examination of the effect on previous tests/calibrations				
5.5.8	Indication of calibration status – date of recalibration				
5.5.9	Ensuring correct function and calibration of equipment gone outside the laboratory's direct control				
5.5.10	Procedure for possible intermediate checks				
5.5.11	Procedure for updating of copies of possible calculations of correction factors by calibration				
5.5.12	Safeguarding from invalidating adjustments of equipment, hardware and software				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	The requirements				Remarks
		Yes	No	NA	
<b>5.6 Measurement traceability</b>					
5.6.1	Procedure and program for calibration of equipment before being put into service				
	<i>Specific requirements to calibration laboratories</i>				
5.6.2.1 .1	Traceability by unbroken chain to relevant primary standards of SI units – calibration certificates stating measurement results, including uncertainty and/or a statement of compliance with a metrological specification				
5.6.2.1 .2	Where traceability to SI-unit s not possible – use of reference materials, specified methods and/or consus standard				
	Participation in interlaboratory comparisons				
	<i>Specific requirements to testing laboratories</i>				
5.6.2.2 .1	Requirements of 5.6.2.1.1 shall be complied with, unless the contribution from calibration contributes little to the uncertainty of the measurement result				
5.6.2.2 .2	Where traceability to SI-unit is not possible – use of reference materials, specified methods and/or consus standards for calibration laboratories, cf. 5.6.2.1.2				
<b>5.6.3 Reference standards and reference materials</b>					
5.6.3.1	Procedure and program for traceable calibration of reference standards				
5.6.3.2	Reference materials traceable to SI-units if possible				
5.6.3.3	Defined procedure and time schedules fro checks to maintain calibration status of reference standards and reference materials				
5.6.3.4	Procedure for handling, transport storage and use of reference standards and reference materials				
<b>5.7 Sampling</b>					
5.7.1	Sampling plan and procedure for sampling				
5.7.2	Recording of possible deviations from sampling procedure				
5.7.3	Recording of sampling data and operations – procedure, sampler, environment conditions, location				
<b>5.8 Handling of test and calibration items</b>					
5.8.1	Procedure for transport, receipt, handling, protection, storage and/or disposal of items				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	<b>The requirements</b>				<b>Remarks</b>
		<b>Yes</b>	<b>No</b>	<b>NA</b>	
5.8.2	Identification of items, including subdivision of groups of items if relevant				
5.8.3	Recording of departures from normal or specified conditions – consultation of customer, if necessary				
5.8.4	Procedure and facilities to ensure the condition and integrity of the items				
	Recording of specified environmental conditions				
<b>5.9 Assuring the quality of test and calibration results</b>					
5.9.1	Procedure for monitoring the validity of tests and calibrations – recording of data				
	Monitoring may include:				
a	Regular use of certified reference materials and/or internal quality control by secondary reference materials				
b	Participation in interlaboratory comparisons or proficiency testing programs				
c	Replicate tests or calibrations using same or different methods				
d	Retesting or recalibration				
e	Correlation of results for different characteristics of an item				
5.9.2	Analysis of quality control data and planned actions when they are not acceptable				
<b>5.10.1-2 Reporting of results – General – Test reports and calibration certificates</b>					
5.10.1	Accurate, clear and objective reporting of results in accordance with the specified method				
5.10.2	Test reports/calibration certificates shall include:				
a	Title				
b	Name and address of laboratory, possibly location				
c	Unique identification of report and each page				
d	Name and address of customer				
e	Method used				
f	Unambiguous identification of the test/calibration item and description of condition				
g	Date of receipt of item, if relevant, and date of test/calibration				
h	Reference to procedure and sampling plan relevant to the validity of the results				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	The requirements				Remarks
		Yes	No	NA	
i	Test/calibration results				
j	Name, function and signature or equivalent identification of person(s) responsible for the report				
k	A statement that the results relate only to the items tested/calibrated, if relevant				
<b>5.10.3 Test reports</b>					
5.10.3.1	Test reports in addition to 5.10.2, if necessary for the interpretation, include:				
a	Deviations, including additions or exclusions, from test method, and test conditions				
b	A statement of compliance with specifications, where relevant				
c	The estimated uncertainty, if relevant				
d	Opinions and interpretations, where appropriate				
e	Additional information required				
	<i>Additional requirements to reports containing results of sampling</i>				
5.10.3.2	If sampling is performed, further:				
a	Date of sampling				
b	Unambiguous identification of the sampled material				
c	Location of sampling(diagrams, sketches, photos)				
d	References to sampling plan and procedure				
e	Environmental conditions, if relevant				
f	Specification of method, deviations and additions				
<b>5.10.4 Calibration certificates</b>					
5.10.4.1	Calibration certificates shall in addition to 5.10.2, if necessary for the interpretation, include:				
a	Conditions, e.g. environmental, which may influence the calibration results				
b	Uncertainty of measurement and/or statement of compliance with an identified metrological specification				
c	Evidence of the traceability of measurements				
5.10.4.2	Declaration of compliance with reference to specifications and taking into account uncertainty				

**Note:** the paragraphs in bold indicate the new requirements in the ISO/IEC17025:2005

	<b>The requirements</b>				<b>Remarks</b>
		<b>Yes</b>	<b>No</b>	<b>NA</b>	
5.10.4.3	Reporting results before and after calibration if the instrument is adjusted				
5.10.4.4	Calibration label/interval				
<b>5.10.5-9 Additional requirements</b>					
5.10.5	<i>Opinion and interpretations</i> Documentation of the basis for possible opinions and interpretations				
5.10.6	<i>Testing and calibration results obtained from subcontractors</i> Identification of results from subcontractors				
	Issue of calibration certificate from subcontractor				
5.10.7	<i>Electronic transmission of results</i> Compliance with ISO 17025 by electronic transmission of test or calibration results				
5.10.8	<i>Format of reports and certificates</i> Appropriate design of reports to minimize misunderstanding or misuse				
5.10.9	<i>Amendments to test reports/calibration certificates</i> Issue of a further document – compliance with ISO 17025				

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