

ASSESSOR CHECKLIST: GENERAL CRITERIA

The following pages present the criteria from ISO/IEC Guide 25-1990, "General Requirements for the Competence of Calibration and Testing Laboratories" in a checklist format. The laboratory's policies and procedures must meet these requirements. Quality system documentation and supporting records must be available for the assessor's review.

Before the assessment, the laboratory is asked to complete all the unshaded document reference identifiers in the checklist's second column (labelled "Doc. Ref.") and place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. This serves to help both the laboratory and the assessors prepare for the assessment and may save a significant amount of assessment time and cost. The appropriate "document reference" should include quality manual, laboratory manual, SOP, etc. references. The noted references should specify procedure number, page number and section number, if possible, where each checklist item is addressed.

Assessor Instructions: Review the laboratory's documented quality system to verify compliance with the applicable Guide 25 documentation requirements. Assess to verify that the documented quality system is indeed implemented as described. Record comments related to any requirement on the space provided. Assess the laboratory's technical competence to perform specific tests or specific types of tests. Record comments related to tests on separate sheets and/or on the draft scope(s) of accreditation. All deficiencies must be identified and explained in the assessor deficiency report.

Laboratory Name: \_\_\_\_\_ City: \_\_\_\_\_  
State: \_\_\_\_\_

Personnel Information (Names, Titles, and Responsibilities):

Technical Manager: \_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Quality Manager: \_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Key Technical Staff and Their Unique Capability\*: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\* 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.

ISO/IEC Guide 25 - 1990  
Checklist

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
<b>4. ORGANIZATION AND MANAGEMENT</b>					
4.1 The laboratory shall be legally identifiable.					
It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements.					
<b>4.2 The laboratory shall:</b>					
a) have managerial staff with the authority and resources needed to discharge their duties;					
b) have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;					
c) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;					
d) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of tests;					
e) provide supervision by persons familiar with the test methods and procedures, the objective of the test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
f) have a technical manager (however named) who has overall responsibility for the technical operations;					
g) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;					
h) nominate deputies in case of absence of the technical or quality manager;					
i) where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;					
j) where appropriate, participate in interlaboratory comparisons and proficiency testing programs. [Attach the last two copies of proficiency test results for every program in which the laboratory should be enrolled.]					
<b>5. QUALITY SYSTEM, AUDIT AND REVIEW</b>					
5.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of testing activities it undertakes.					
The elements of this system shall be documented.					
The quality documentation shall be available for use by the laboratory personnel.					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
The laboratory shall define and document its policies and objectives for, and its commitment to good laboratory practice and quality of testing services.					
The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned.					
The quality manual shall be maintained current under the responsibility of the quality manager.					
5.2 The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements. The quality manual and related quality documentation shall also contain:					
a) a quality policy statement, including objectives and commitments, by top management;					
b) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;					
c) the relations between management, technical operations, support services and the quality system;					
d) procedures for control and maintenance of documentation;					
e) job descriptions of key staff and reference to the job descriptions of other staff;					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
f) identification of the laboratory's approved signatories (where this concept is appropriate)					
g) the laboratory's procedures for achieving traceability of measurements;					
h) the laboratory's scope of tests;					
i) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;					
j) reference to the test procedures used;					
k) procedures for handling test items;					
l) reference to the major equipment and reference measurement standards used;					
m) reference to procedures for calibration, verification and maintenance of equipment;					
n) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;					
o) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;					

Requirement	Compliance			Document Reference	Comments
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p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;					
q) procedures for dealing with complaints;					
r) procedures for protecting confidentiality and proprietary rights;					
s) procedures for audit and review.					
5.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.					
5.4 The quality system shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.					

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5.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.					
5.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:					
a) internal quality control schemes using whenever possible statistical techniques;					
b) participation in proficiency testing or other interlaboratory comparisons; [attach the last two proficiency testing results for every program in which the laboratory should be enrolled]					
c) regular use of certified reference materials and/or in-house quality control using secondary reference materials;					
d) replicate testings using the same or different methods;					
e) re-testing of retained items;					
f) correlation of results for different characteristics of an item.					
6. PERSONNEL					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
6.1 The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.					
6.2 The laboratory shall ensure that the training of its personnel is kept up-to-date.					
6.3 Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.					
<b>7. ACCOMMODATION AND ENVIRONMENT</b>					
7.1 Laboratory accommodation, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of tests.					
7.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.					
7.3 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the tests concerned.					

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	Y	N	NA		
7.4 There shall be effective separation between neighboring areas when the activities therein are incompatible.					
7.5 Access to and use of all areas affecting the quality of these activities shall be defined and controlled.					
7.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.					
Supplemental Inquiry. The laboratory should have a chemical hygiene plan per 29 CFR 1910.1450.					
<b>8. EQUIPMENT AND REFERENCE MATERIALS</b>					
8.1 The laboratory shall be furnished all items of equipment (including reference materials) required for the correct performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements are met.					
8.2 All equipment shall be properly maintained.					
Maintenance procedures shall be documented.					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous tests.					
8.3 Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.					
8.4 Records shall be maintained of each major item of equipment and all reference materials significant to the tests performed. The records shall include:					
a) the name of the item of equipment;					
b) the manufacturer's name, type identification, and serial number or other unique identification;					
c) date received and date placed in service;					
d) current location, where appropriate;					
e) condition when received (e.g. new, used, reconditioned);					
f) copy of the manufacturer's instructions, where available;					

Requirement	Compliance			Document Reference	Comments
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g) dates and results of calibrations and/or verifications and date of the next calibration and/or verification;					
h) details of maintenance carried out to date and planned for the future;					
i) history of any damage, malfunction, modification or repair.					
<b>9. MEASUREMENT TRACEABILITY AND CALIBRATION</b>					
<p>9.1 All measuring and testing equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service.</p> <p>The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.</p>					
9.2 The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
9.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.					
9.4 Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.					
9.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement.  There shall be a program of calibration and verification for reference standards.					
9.6 Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.					
9.7 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.					
10.0 TEST METHODS					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
<p>10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the tests.</p> <p>All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.</p>					
<p>10.2 The laboratory shall use appropriate methods and procedures for all tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of test data).</p> <p>They shall be consistent with the accuracy required, and with any standard specifications relevant to the tests concerned.</p>					
<p>10.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.</p>					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
10.4 Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.					
10.5 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.					
10.6 Calculations and data transfers shall be subject to appropriate checks.					
10.7 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:					
a) all applicable requirements are complied with;					
b) computer software is documented and adequate for use;					
c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;					
d) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of test data;					

Requirement	Compliance			Document Reference	Comments
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e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.					
10.8 Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.					
11. HANDLING OF TEST ITEMS					
11.1 The laboratory shall have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time.					
<p>11.2 Upon receipt, the condition of the test item, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded.</p> <p>Where there is any doubt as to the item's suitability for test, where the item does not conform to the description provided, or where the test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding.</p> <p>The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.</p>					

Requirement	Compliance			Document Reference	Comments
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<p>11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the test item, during storage, handling, preparation, and test; any relevant instructions provided with the item shall be followed.</p> <p>Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.</p>					
<p>11.4 The laboratory shall have documented procedures for the receipt, retention or safe disposal of test items, including all provisions necessary to protect the integrity of the laboratory.</p>					
12. RECORDS					
<p>12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations.</p>					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the test certificate, or test report for an appropriate period.					
The records for each test shall contain sufficient information to permit their repetition.					
The records shall include the identity of personnel involved in sampling, preparation, or testing.					
12.2 All records (including those pertaining to test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.					
<b>13. CERTIFICATES AND REPORTS</b>					
<p>13.1 The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the test methods.</p> <p>The results should normally be reported in a test report or test certificate and should include all the information necessary for the interpretation of the test results and all information required by the method used.</p>					
13.2 Each certificate or report shall include at least the following information:					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
a) a title, e.g. "Test Report", or "Test Certificate";					
b) name and address of laboratory, and location where the test was carried out if different from the address of the laboratory;					
c) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;					
d) name and address of client, where appropriate;					
e) description and unambiguous identification of the item tested;					
f) characterization and condition of the test item;					
g) date of receipt of test item and date(s) of performance of test, where appropriate;					
h) identification of the test method used, or unambiguous description of any non-standard method used;					
i) reference to sampling procedure, where relevant;					
j) any deviations from, additions to or exclusions from the test method, and any other information relevant to a specific test, such as environmental conditions;					

Requirement	Compliance			Document Reference	Comments
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k) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;					
l) a statement of the estimated uncertainty of the test result (where relevant);					
m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;					
n) where relevant, a statement to the effect that the results relate only to the items tested;					
o) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.					
13.3 Where the certificate or report contains results of tests performed by sub-contractors, these results shall be clearly identified.					
13.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of test carried out, but the headings shall be standardized as far as possible.					

Requirement	Compliance			Document Reference	Comments
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<p>13.5 Material amendments to a test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report [or Test Certificate], serial number . . . [or as otherwise identified]", or equivalent form of wording.</p> <p>Such amendments shall meet all the relevant requirements of clause 13.2.</p>					
<p>13.6 The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or test certificate or amendment to a report or certificate.</p>					
<p>13.7 The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements are met and that confidentiality is preserved.</p>					

Requirement	Compliance			Document Reference	Comments
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<b>14. SUB-CONTRACTING OF TESTING</b>					
14.1 Where a laboratory sub-contracts any part of the testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect to the work being sub-contracted. The laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party.					
14.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting.					
<b>15. OUTSIDE SUPPORT AND SUPPLIES</b>					
15.1 Where the laboratory procures outside services and supplies, in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
<p>15.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements.</p> <p>The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the tests concerned.</p>					
<p>15.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.</p>					
16. COMPLAINTS					
<p>16.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities.</p> <p>A record shall be maintained of all complaints and of the actions taken by the laboratory.</p>					

Requirement	Compliance			Document Reference	Comments
	Y	N	NA		
16.2 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or otherwise concerning the quality of the laboratory's tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 5.3.					