Self-examination for compliance with ISO 17025

The questions in the self-examination questionnaire in the following pages go through the key requirements of ISO 17025; they are the kind of questions which you should be asking yourself, as a laboratory, as you try to decide where you are ISO 17025 compliant. This will give pointers to where you need to make changes. It cannot be emphasized too strongly that there are no standard ways of achieving compliance; rather there are hundreds of approaches to complying with any particular requirement. You need to focus on the requirement itself and to find the most convenient and cost-effective way to meet it in your particular situation.

With each question, tick one of the boxes numbered 1 to 4, based on the following code:

1 mark	No we do not meet this requirement at all
2 marks	We meet some parts of this requirement- some level of implementation is in place
3 marks	We meet most parts of this requirement- some level of implementation and documentation is in place
4 marks	We meet this requirement fully- all requisite documents and implementation requirements have been met

The numbers in brackets in the questionnaire refer to the relevant clauses in ISO17025:2005

The higher your total score on this questionnaire, the less you will have to do to become compliant. However, this questionnaire is only intended to form an *initial* assessment in key areas and does not cover the whole of ISO 17025, so even if your answers are all 4s this does not mean that you already comply—but you are very well placed to make the final adjustments. The maximum score is 300 by the way!

Some general thoughts to bear in mind

ISO 17025 is very much a standard to which you adhere by your own efforts. You document how you will meet the requirements of the standard and how you will manage your activities to maintain compliance. You then commit to monitoring your own compliance through audit and related activities and to taking corrective action when you move out of compliance.

When you are assessed, the recognition body will, of course, determine whether you are compliant on the day of assessment. However, the assessors will be far more interested in satisfying themselves that you have a robust management system which will maintain compliance on a routine basis. The assessors normally visit only once a year so the steps which you take to maintain and monitor compliance between visits are a key issue with them.

A well-managed quality system should pay for itself by reducing the amount of re-testing or re-calibration a laboratory needs to do and by improving its clients' confidence and hence its success as a business.

NOTE: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hardcopy or electronic, and they may be digital, analog, photographic or written.

Key to understanding your level of implementation

Mostly 1s	Further training and implementation need to be taken up
Mostly 2s	You can begin the initial recognition application process, but training should be taken up to document the system
Mostly 3s	You are ready for the recognition application process, but you should focus on establishing consistency in operations
Mostly 4s	You are ready for the recognition application process, and you should focus on continual improvement

SNo.	Clause Reference	ISO 17025 Requirement	Score (1-4)	Objective evidence (name the document)
	4.1	**Organization**		
1.		Is the laboratory managed in such a way that it operates independently and is free from external influences?		
	4.1.5, 4.2	**Management requirements**		
2.		Is senior management committed to a quality system, including compliance with ISO 17025, and agreed that resources will be provided to establish and maintain it?		
3.		Do staff at all levels recognize that, irrespective of workload and other pressures, the requirements of the quality system must be followed at all times?		
4.		Is there a person who is responsible for establishing and monitoring compliance with the quality system on a day-to-day basis?		
5.		Is there a documented specification of the quality management system, for example in a quality manual, with clear assignment of authority and responsibility such that the managers who supervise work have authority to ensure the quality of the work which they supervise?		
	4.3	**Document control**		
6.		Are there documents available that give work instructions so that staff have a source of reference to enable them to conduct their work properly and consistently?		
7.		Are all documents controlled, which means can you answer 'yes' to the following:		
8.		Are all documents giving instructions or used to record data authorized by defined management personnel?		
9.		Is a record of the issue of all documents kept and procedures adopted so that, when amendments are made, every copy can be retrieved to be updated?		
	4.5	**Subcontracting of tests and calibrations**		
10.		Do you have a list of approved subcontractors?		
11.		Do you have a record of the accreditations of the subcontractors?		
12.		Where subcontractors are not accredited do you have other evidence that they are competent?		

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	4.6	**Purchasing services and supplies**		
13.		Do you have a list of approved suppliers and a policy for inclusion of a supplier on the list?		
14.		Does this policy ensure that purchased materials and services will be good enough to ensure that the quality of your data is not threatened?		
	4.7, 4.8	**Service to clients and complaints**		
15.		Do clients know how to contact you and who to speak to about the progress of their work?		
16.		Do you follow up complaints from clients and learn from them so that you can take steps to ensure that the problem does not happen again?		
	4.9	**Control of nonconforming work** Nonconforming work occurs when data or services are detected which do not meet the laboratory's agreed standard of quality. This may be detected internally or externally.		
17.		Do you have a procedure for ensuring that work, or release of data, is stopped immediately nonconforming work is identified?		
18.		Do you follow up on nonconforming work in order to learn from it and take action to ensure that the problem cannot happen again?		
	4.11	**Corrective action**		
19.		Where quality problems are identified do you have a procedure for ensuring that prompt corrective action is taken?		
20.		Do you ensure that the corrective action taken addresses the root cause of the problem, i.e. do you think that you normally make it unlikely that the problem will happen again?		
21.		Do you follow up to ensure that the corrective action has been effective, for example after a period of settling in?		
	4.12	**Preventive action**		
22.		Do you track trends in data so that you can respond to deterioration in quality before it reaches unacceptable levels?		
23.		Do you hold regular meetings of senior technical staff to discuss areas of concern about quality and consider proposals for improvement?		
24.		Do you track measurable items, for example turnaround times, numbers of re-tests necessary, and respond when performance appears to be		

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		deteriorating?		
	4.13	**Control of Records**		
25.		Where your documentation requires a procedure to be followed do you have records which show whether it was actually done or not?		
26.		Would your records enable you to identify the person who did each piece of work?		
27.		Would your records enable you to identify the equipment used?		
28.		Would your records enable you to prove that the equipment was properly calibrated and functioning correctly?		
	4.14, 4.15	**Internal audits and management review**		
29.		Do you carry out and record regular inspections to check that the procedures which you have defined and documented are, in fact, being followed?		
30.		Does senior management carry out reviews to determine whether the quality system continues to meet the needs of the organization?		
	5.2	**Personnel**		
31.		Do you have appropriate numbers and types of staff so that work can be carried out without having to rush so much that quality may be compromised?		
32.		Do you formally check if all persons performing technical functions possess the required educational/professional qualifications and experience?		
33.		Are there clearly defined job descriptions set out for each of the persons working in the laboratory?		
34.		Do you have a procedure for regular performance evaluation to assess their competence?		
35.		Do you have a procedure for training staff in testing and/or calibration?		
	5.3	**Accommodation and environmental conditions**		
36.		Does the accommodation provide adequate separation of functions to minimize the possibility of cross contamination? (Give a lab floor plan?)		
37.		Are you confident that the conditions and standard of housekeeping in your laboratory are adequate to ensure that the quality of data is not being compromised?		

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38.		Are there measures to provide uninterrupted services (electricity, gas, water)?		
39.		Are there measures to restrict the entry of unwanted materials and persons into the laboratory?		
40.		Are there appropriate storage facilities to provide integrity of samples before and after testing?		
	5.4, 5.9	**Test and calibration methods and method validation;** **Assuring the quality of test and calibration results, validation**		
41.		Do you use only standard, internationally accepted methods for testing?		
42.		Are all methods documented to the extent necessary to enable them to be performed properly and consistently?		
43.		Do you have validation data which shows the performance characteristics, for example accuracy and precision, of all of the methods which you carry out?		
44.		Are quality control procedures in place to ensure that the performance characteristics established for the methods continue to be met on a routine basis?		
45.		Is the laboratory staff trained in sampling?		
46.		Where these are available, does the laboratory make regular measurements on certified reference materials to confirm the accuracy of its measurements?		
47.		Where available, does the laboratory participate in inter-laboratory comparison exercises, i.e. exchange of samples with other laboratories and comparison of results?		
	5.4.7	**Control of data and data integrity**		
48.		Is all raw data recorded at the time of observation and traceable, for example by being signed, to the person who made the observation?		
49.		Are transfers of data between documents, or between documents and computers, subject to checks?		
	5.5, 5.6	**Equipment, calibration and traceability**		
50.		Are operational procedure charts available with each of the equipment?		
51.		Where the concept is applicable, has equipment		

SNo.	Clause Reference	ISO 17025 Requirement	Score (1-4)	Objective evidence (name the document)
		been calibrated to ensure traceability to the SI system of units through an unbroken and, if necessary, international chain?		
52.		Are regular cleaning and maintenance checks performed?		
53.		Do you have evidence to show that calibration is carried out often enough to ensure that drift between calibrations is not so large as to undermine data quality?		
54.		Where practicable, is equipment checked between calibrations and records kept to confirm that it has not drifted and lost its calibration?		
55.		Is all equipment which is subject to regular checks or calibrations labelled to show when the next calibration or check is due?		
56.		Is there a record of all equipment and particularly of its cleaning, maintenance and calibration history?		
	5.8	**Handling of test and calibration items**		
57.		Do you have a system for uniquely labelling and numbering items so that the number remains with all samples and sub-samples as the item moves through the laboratory?		
58.		Do you have procedures for identifying samples which require special storage or preservation and for ensuring that appropriate action is taken?		
	5.10	**Reporting** Check your typical reports against this list and assess the degree of compliance		
59.		The basic required contents of a report are as follows:- (a) Name and address of the laboratory; (b) Name and address of client; (c) Unique identifier of certificate or report (such as serial number); (d) On each sheet of the certificate or report, a unique form of sheet identifier (such as the serial number of the certificate or report, with a unique page number in the form "page -- of -- pages"); (e) Date of receipt of calibration or test item, and date(s) of performance of calibration or test, as appropriate;		

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		(f) Date of issue of certificate or report; (g) Signature and legible name of approved signatory or signatories taking responsibility for the content of the certificate or report, or equivalent form of technical authorization; (h) Unambiguous identification of item(s) calibrated or tested (including name of manufacturer of item(s), any model or type designation and any relevant serial numbers, as appropriate); (i) Any abnormalities or departures from standard conditions; (j) Reference to calibration or test method and procedure used; (k) Any standard or other specification relevant to the calibration or test method or procedure, and deviations, additions to or exclusions from the specification concerned; (l) Where relevant to the validity or application of the calibration or test result(s), details of any sampling, item preparation, or data analysis; (m) Calibration or test result(s); (n) Any design or performance specifications met or failed; (o) Estimated uncertainty of the calibration or test result (this information need only appear in test reports and test certificates where it is relevant to the validity or application of the test result, where a client's instructions so require, or where uncertainty affects compliance to a specification or limit); (p) Any other available information requested by a client relevant to the validity or applicability of the calibration or test result.		
Total Score out of 300				