

A Guide for Writing the Quality Manual for a Testing/Calibration Lab

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1. Introduction

The following document, published by IAS, is a guide to help testing/calibration laboratories create documentation to satisfy the requirements of ISO 17025. Such documentation is a necessity for accreditation by IAS and is the first step to be taken by a laboratory in its march towards public recognition of its competence in the testing/calibration disciplines. Accreditation by IAS, recognized the world over because of its Mutual Recognition Agreement with APLAC/ILAC, helps laboratories enhance their business opportunities both inside and outside the U.S.

2. Structure of the Documentation

A quality manual serves as a working document for the entire operation of a testing/calibration laboratory. Its application to day-to-day work results in uniformity, consistency and quality improvement in the operations of the laboratory.

This document gives broad guidelines. The operational details will depend upon the size/activities of the laboratory.

Generally, laboratories need two levels of documentation. A quality manual describing the laboratory's quality system policies and objectives and a procedures manual, should be sufficient for a small or medium sized laboratory, although laboratories are free to adopt several levels of documentation if their operations are large enough to justify extensive documentation.

3. General Advice

- a) Make a start. Do not get scared. Do not procrastinate. Remember, even a thousand-mile journey starts with the first step.
- b) Go through the 17025 Standard. If you feel sleepy while reading, take a nap. But continue – never give up. Much harder tasks have been completed in this world.
- c) As you go through the standard, concentrate on, contemplate and comprehend each clause. Try to understand what the standard requires for your operation.
- d) If your laboratory has been functioning for a while, some kind of quality system must already be in place. Maybe just some modification, some reorientation, some refinement is needed. Try to fine-tune the system that you already have.

- e) The quality manual generally needs to be written by some senior level person, and needs the approval of the quality manager. Sometimes, that the same person will wear both hats. Either way is okay.
- f) It is better if the procedural manuals are written by the personnel performing the actual technical procedures, then edited/fine-tuned by senior personnel and the quality manager.
- g) Write the manual in the present tense and do not use “shall” or “will” in the manual. Use ‘is’ and ‘are’ extensively. Never copy lines from the 17025 Standard into the manual.
- h) Use simple, concise and grammatically correct language. Get to the point of the 17025 clauses. Avoid wordiness and unnecessary language.
- i) As far as possible, set up your manual so that the clauses and subclauses follow the same sequence as the 17025 Standard. This is not mandatory but makes the manual more user-friendly. If, for some compelling reason, the sequence of clauses cannot be followed, provide a cross-reference table (listing all the clauses and subclauses) at the end of quality manual.
- j) Address each clause/subclause of the standard *briefly* in the quality manual. If you need to spell out too much detail, make a separate numbered document and *refer* to the document number in the quality manual.
- k) Use double spacing.
- l) Make the following part of the quality manual.
 - i. A title page giving both the physical and electronic addresses of your organization/laboratory.
 - ii. An authorization from the CEO for a particular person, by name and designation, to function as the quality manager, having the overall responsibility for establishing, implementing and maintaining the laboratory’s quality system.
 - iii. A page providing the issue details of the manual revision number, issue number, date of issue, copy number, copy holder, and status (controlled or uncontrolled), etc.
 - iv. An amendment record providing, in tabular form, information on changes to the manual: clause number; date of the amendment; nature of the change; brief reason for the amendment; person approving the change; etc.
- m) Start each clause/subclause on a new page. This will be of great help, in the future, if you need to amend or add pages to address the clause/subclause. Also, in numbering pages, bunch together the pages for each clause/subclause, and number the pages in the fashion “page...of...” Leave a couple of pages blank at the end of each clause and mark the blank pages “Intentionally Left Blank”. Include these blank sheets in the numbering of the pages. These blank sheets will be of help, in future, if there is a need for some amendment requiring additional space. By paginating in this way, you will be able to amend individual clauses without changing the entire manual, and introducing amendments will be much easier and faster. This also makes document control easier.

- n) Use the same format for all pages of the manual. Text should appear on only one side of the page. The page format should include the company name, its logo (if there is one), the clause number which the page addresses, the manual revision number, issue number, the date of issue, the page number, and signatures of persons who prepared the manual and who approved the manual. A typical format is shown below:

Company Logo	Quality Manual Of	Revision Number
		Issue No. & Date
4. Quality System		Page No. ...of...
Company's Name and Address		Prepared by: Signature (Name)
Copy Status:		Approved by: Signature (Name)
<p>This manual is the property of...; No corrections/amendments are to be made except by the person authorized. The holder to return the manual when he leaves the organization or when he has no further use for it.</p>		

- o) Once the manual is ready, make one "Master Copy." The master copy must at all times be resident with the quality manager, who should make copies and distribute after stamping (for example) "Controlled When in Red" or "Uncontrolled". Remember to send only "uncontrolled" copies to outside assessors or accrediting bodies.
- p) Any amendment should be made only on the Master Copy with copies then made for distribution to persons holding the manual.
- q) If manuals/documents are maintained electronically, they should be controlled through "password," "Read only" means.

4. **Now about the actual documentation**

Read and understand how the clauses apply to the activities in your organization. Get both "macro" and "micro" picture of the activities.

Read the first clause. Understand what needs to be addressed. Close the standard. Ponder again and get a clear picture. Write down, in your own words, how you would address the clause. Come directly to the point (no blah blahs or unnecessary wording). Keep your organization's activities focused in your mind while you write. Continue in a similar way for other clauses.

- 5. Use the first three clauses of the manual to introduce your organization and its vision, the activities of the laboratory in some detail.
- 6. Address each clause/subclause/sub-sub-clause, even if it does not apply your laboratory's activities and give a reason for its nonrelevance.

For example, if sampling (clause 5.7) does not apply to your laboratory (generally, it does not apply to calibration activities), make some statement such as this: "Since the laboratory calibrates every instrument it receives and does not resort to sampling practice, this clause does not apply." In such a case, the subclauses (5.7.2 & 5.7.2) would need not to be addressed.

7. **Organization:**

Provide a complete but brief description of the organization. Provide details of the laboratory organization down to the technician/operator level. Show the direct link of the Quality Manger to top management.

Address impartiality, integrity, confidentiality, client's rights clauses.

Include the responsibility of staff to follow documented policies and procedures. Make a statement that any deviation from documented policies and procedures should be first endorsed by the senior management in charge of quality before the deviation takes place.

Assign deputies for the Quality Manager and key technical staff.

Include duties and responsibilities of the Quality Manager and the technical staff of the laboratory.

8. **Quality System**

Briefly describe the quality system and its aims and objectives.

Quality Policy: This must be a statement from top management, endorsed by the CEO of the organization. Avoid use of superlatives in the statement. Include intended quality of service, activities complying with 17025, staff familiarizing themselves with policy, commitment to staff training, and continuous improvement. Remember, every word of the policy statement is auditable. Carefully choose words and KISS (Keep It Short and Sharp). Preferably, the quality statement should not be more than a page.

9. Document Control

Know the difference between documents and records. Documents are distributed/made known to the personnel of the laboratory, to be understood and followed. Records are data/information generated by the personnel during the course of following the instructions in a document. While quality manuals, procedure manuals, instructional manuals, normative standards, policy documents, test/calibration methods, etc., are documents, calibration/test results, nonconformance's observed and reported, audit findings, management review minutes, etc., are records.

Make a document "distribution list" a part of the quality manual under this clause. A typical table would be as below:

No.	Copy No.	Copy Holder	Copy Status
1	Master Copy	Quality Manager	-
2	01	CEO	Controlled
3	02	Quality Manager	Controlled
-	03	Lab-in-charge/Supervisor	Controlled
-	-	-	-
-	-	-	-
n	06	Accreditation Body Assessor	Uncontrolled

Maintain an issue register with signatures of recipients. The Quality Manager can sign for the documents sent to accreditation bodies and assessors. Make the Quality Manager responsible for controlling and maintaining all the documents related to the quality system. Control should include distribution, distribution of amendments, approval and incorporation of amendments, and removal of obsolete documents and their disposal.

10. Review of Requests, Tenders and Controls

More popularly known as "contract review," this clause is an important one. It aims at greatly reducing (or almost eliminating) any disputes that might arise between customers and the laboratory, after the test/calibration is over. It is intended to link what the customer expects the laboratory to do and what the lab actually does, so there is no discrepancy between "customer-expectation" and "laboratory delivery."

For example, if a customer submits a sample to be tested using a standardized procedure (say ASTM...), and the laboratory, for some reason, intends to deviate from the procedure,

the customer must be informed of the deviation and his consent obtained, before the work is started. The deviation and the customer acceptance have to be documented.

Make statements about understanding the client's requirements having available the required resources (personnel, equipment, reference standards, analysis capabilities, time, etc.) to handle the work, documentation of the contract review, etc.

11. Purchasing

Address purchase of services for calibration of the laboratory's equipment from an NMI or another accredited laboratory. Address purchase of calibration equipment and critical consumables, if any.

12. Complaints

Maintain a register of complaints. The register should provide information about the date the complaint was received, the nature of the complaint, how it was resolved, etc.

Address working with the customer (to assure continued business) in the case of valid complaints.

13. Nonconformances, Corrective Actions, Cause Analysis

Address stoppage of work when a nonconformance is observed. As regards the nonconformance, address evaluation of significance, cause analysis, development of corrective action, corrective action implementation, and resumption of work under authorization. Address the responsibility of the person authorizing resumption of work.

14. Internal Audits

Address the frequency (at least once a year) and scope of audits. Address auditor selection (qualifications/experience/training), responsibility for auditor selection (usually Quality Manager), audit procedures, audit review, and corrective actions.

15. Management Reviews

Address all ten elements of the clause. A management review meeting is to be held within a reasonable time after every internal/external audit.

16. Personnel

State the minimum qualifications/experience of technical personnel handling testing/calibration work. Address supervision of work. Prepare "Authorized Signatories" list of the persons who can approve release of reports. Address programs aimed at improving employees' skills, like education programs, training, hands-on training.

Identify the responsibilities of technical personnel, supervisory personnel.

For all personnel, keep records of academic qualifications, experience, professional qualifications, training programs attended, special skills, certificates acquired for special skills, etc.

Address adequacy of supervision by stating the ratio of supervisors to technical personnel.

17. Accommodation and Environment

State the environmental conditions maintained in the laboratory. (The environmental conditions are more stringent if yours is a dimensional calibration laboratory. For a dimensional calibration laboratory, the base temperature should be 20°C (68°F) with a tolerance of 1 to 3°C (2 to 5.5°F) depending on the level of operation. Humidity should be around 50 ± 5% RH, and the room should be at a positive pressure.) Give layout of the lab in a sketch indicating the position of each piece of major equipment. Provide information about the area of the laboratory. Describe controls on access to the laboratory. Describe the procedures used to monitor and document environmental conditions. (If it is dimensional calibration lab, state the frequency at which the temperature is monitored and recorded.) Address cleanliness and good housekeeping.

18. Test and Calibration Methods

Refer to methods briefly in the quality manual and address in detail in procedures/work instructions. Write procedures for all the testing/calibration done by the laboratory. Include handling and preparation of materials for test/calibration. For non-standard methods, address validation.

19. Uncertainty of Measurement

Provide a procedure as a separate document, and briefly explain the procedure in the quality manual.

In the procedure, provide information about all the factors considered for type 'B' method adopted for type 'A' values, and provide a step-by-step evaluation process.

Provide an uncertainty evaluation format for each family of instruments.

20. Control of Data

Address procedures for error-free data transfer. Address software access and control through passwords. Address software validation.

21. Equipment

Provide a list of major equipment including name, identification number, range, resolution, uncertainty, frequency of calibration, traceability. Address maintenance, availability of instruction manuals, history cards, etc.

22. Traceability

State how the laboratory's measurements are traceable to the national level.

23. Calibration

State usage of SI units and how work in non-SI units is handled to provide traceability.

24. Reference Standards

Provide a list of physical reference standards maintained by the laboratory (if applicable), and provide similar information to that listed under item 21 above.

25. Assuring Quality of Test and Calibration Results

Address use of physical reference standards; calibration of standards by an NMI; calibration of standards by an accredited laboratory; traceability; periodic recalibration; proficiency testing; interlaboratory comparisons; replicate checking; reproducibility.

26. Reports

State the contents of testing/calibration reports. Provide a format for each of them. Address how reporting is handled if testing/calibration is subcontracted. Provide a list of authorized signatories, including name, title and sample signature. Address amendments to a report. Address supplements to a report.

In the format, provide for disclaimer clauses such as: (1) This report pertains to the item supplied and the stated conditions of testing/calibration; (2) This report should not be reproduced except in full.

27. Opinions and Interpretations

Address the conditions under which opinions/interpretations are given, and also the basis on which they are given.

28. Results from Subcontractor

State that the results from a subcontractor will be clearly identified in the test/calibration report.

29. Electronic Transmission of Results

State that electronic transmission (by fax or e-mail) is provided when specifically requested by the customer. State that even if reports are electronically transmitted, a hard copy will eventually follow; and that any disputes should involve the values in the hard copy.

30. Conclusion

State that all efforts will be made to provide the results of testing/calibration with honesty and integrity and without any bias. State that all efforts have been made to present the facts in the manual, and that any questionable items will be attended to as soon as it is noticed, by amendments or rewriting.