Guidance for Documenting and Implementing ISO/IEC 17025:2005 & Laboratory Guidance

(Revision 2 — 02/15/06)

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### REVISION HISTORY

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Introduction

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories sets out the criteria for laboratories wishing to demonstrate that they are technically competent, operate an effective quality system, and are able to generate technically valid calibration and test results. The standard will form the basis for the accreditation of competence of laboratories by accreditation bodies.

A transition period has been established during which laboratories currently operating to the preceding standards ISO/IEC 17025:1999 change to operating to the requirements of ISO/IEC 17025:2005. Similarly, accreditation bodies may need to adapt existing assessment and accreditation practices in order to minimize the period during which accreditation to different standards may exist. The International Laboratory Accreditation Cooperation (ILAC) has confirmed that there will be a transition period of two years for full implementation of ISO/IEC 17025:2005. Accreditation bodies shall require that the laboratories for which they grant and maintain accreditation comply with the requirements of the standard within not more than two years from the date of publication of the standard, which was May 15, 2005. Accreditation bodies shall confirm that the laboratories comply with the standard at the next surveillance activity following this period.

PURPOSE

To help laboratories establish a program for a laboratory management system that is suitable for their size and workload, and that will meet their clients needs. This guidance document will help the laboratory develop and implement a laboratory management system that is in compliance with ISO/IEC 17025.

AUTHORSHIP

Laboratory Accreditation Bureau created this document as a guidance document for training programs for laboratories. Laboratories interested in developing a system compliant with ISO/IEC 17025 will use this document as guidance. The guidance provided will provide interpretations used by LAB when evaluating laboratories.

The five categories under the “needs assessment” section, listed “a” through “e”, are based upon the Procedure described in A2LA’s Interim Policy on Measurement Uncertainty for Testing Laboratories, dated August 28, 2000
1. GENERAL INFORMATION

1.1 Structure of the Guidance and Evidence of Fulfillment of Requirements

The text of the clauses of the standard is not included so that copyright is not breached. It is necessary to use this guidance in conjunction with the ISO/IEC 17025.

Cross-references between the clauses of ISO/IEC 17025, and ISO/IEC Guide 25 are given in Table 1.

This document will give guidance on ways that a laboratory may choose to fulfill the requirements of ISO/IEC 17025. Assessors shall note that this guidance is not all-inclusive, and a laboratory may choose another method to fulfill these requirements. The assessor will have to evaluate the appropriateness of the method chosen by the laboratory to fulfill the requirements.

2. Guidance to Clauses of ISO/IEC 17025

Clause 1 Scope

Laboratory Accreditation Bureau will ensure that the accreditation certification that they issue to laboratories clearly indicates that an accredited laboratory complies with the requirements of ISO/IEC 17025, and thereby operates a quality management system that also meets the requirements of ISO 9001 when the laboratory engages in the design/development of new methods, and/or develops test programs combining standard and non-standard test and calibration methods, and ISO 9002 when the laboratory only uses standard methods.

Clause 2 Normative References

Clause 3 Terms and Definitions

Clause 4 Management Requirements
Clause 4.1 Organization and Management

E-Clause 4.1.1— Entity can be held legally responsible. To show compliance with this requirement, the laboratory can provide the accreditation body with one of the following documents:

- Articles of Incorporation
- Partnership Agreements
- Tax ID
- Other

E-Clause 4.1.2— This paragraph encompasses the whole system. To fulfill this requirement, the laboratory should ensure that it meets the requirements of ISO/IEC 17025, and fulfills the needs of their clients. The evidence needed is the Quality Management System (QMS) itself.

E-Clause 4.1.3— The QMS must be designed to cover all activities for which the laboratory is seeking accreditation, regardless of the location.

E-Clause 4.1.4— This is also quite subjective, however, alarms should go off if the quality person is reporting to the person who is directly in charge of the actual testing. In a large organization that also includes manufacturing. Laboratory personnel should not report to the head of manufacturing.

E-Clause 4.1.5—

a) Establish by organization chart what the authority is for all of management. You will also need to prove to an assessor that the managers have the authority and resources, i.e. personnel, equipment, time to carry out their duties. This also includes the implementation, maintenance and improvement of the management system. The assessors will be noting whether the managers can identify departures from procedures for performing test/calibration, and whether they can initiate corrective and preventive actions. See clauses 4.11 and 4.12. The job descriptions for the managers should include the responsibilities listed above, and the initiation of corrective and preventive actions.

b) The best way to fulfill the requirements of this clause is to establish a training or orientation program that includes the company's policy with regard to undue commercial, financial or other pressures that would adversely affect employee's work. There should be a policy that addresses this issue. The policy may be in the QA, HR, or even corporate documentation. Many companies have established an agreement that employees sign when they are hired that clearly defines the company's policies on this subject and may also include a policy on conflict of interest reporting.
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c) There should be a policy statement in the QA manual and procedure(s) to protect the client’s proprietary information and rights. This requirement may not apply to laboratories that only do testing for their own benefit. This should be part of a new employee’s training/orientation. A record of the training/orientation should be part of the employee’s records. This clause also requires the establishment of procedure(s) for electronic media storage and transmission. Further requirements of this nature are addressed later in the document, and should be considered when developing a policy regarding electronic media.

d) The company should develop a policy by which their employees must report any possible conflict of interest they may have when it is discovered. At no time should a laboratory allow an individual to perform an activity for which they have a known conflict of interest. See comments on 4.1.5 b). Typically, this is also part of the training/orientation, and should be recorded as a part of the employees’ records. Many laboratories are establishing a Conflict of Interest form that is signed by the employee on the first day of employment, to assure that the employee is aware of the policy.

e) There should be an organization chart that defines the structure of the company, and the relationship between other divisions of the company. The QMS should indicate what the relationship is between quality management, technical operations and support services. This should go hand-in-hand with assuring that the authority of the individual function is not undermined or influenced in a negative manner by one of the others, and the organization chart and QMS policy should provide the evidence for compliance.

f) There should be documentation for all technical personnel that define their authority and interrelationships (reporting structure). This can be documented in any manner that defines this information, but most generally will be given in a job description. The organization chart will be a visual aid in evaluating the relationships. The QMS document should give a brief description of each key position along with its responsibility and authority as regards the QMS.

g) There must be a person(s) of authority who is familiar with the methods and procedures, the objective, and assessment of results of the tests or calibrations performed. This should be documented and may include: technical resumes, training records, or other such documentation. The ratio of supervisory to non-supervisory personnel is subjective, but should be sufficient to provide adequate oversight, especially where trainees are involved. The laboratory will have to convince the assessment team that the supervision is adequate for its particular circumstance.

h) At a minimum, one individual must be in charge of the technical aspects of the operations. In some larger laboratories, it is possible that more than one
individual will have this responsibility. This individual is responsible for assuring that the laboratory has the necessary resources to ensure the required quality of the laboratory operations. This authority should be addressed in the job description, with a brief description in the quality manual. This individual’s title need not be Technical Manager, but it must be clear in the documentation that he or she is responsible for the activities described in this clause.

i) One individual must be in charge of the quality management system. The responsibility and authority must be defined, and is best done in the job description, with a brief description in the quality manual. The organization chart should show that this individual has access to the highest level of authority when acting as the quality manager. In small organizations, it is possible that the technical manager and the quality manager are the same individual; however, this is not recommended for larger organizations due to possible conflicts of interest.

j) Where it is possible, deputies must be appointed for key personnel. Individuals may have more than one function and it may be impractical to appoint deputies for every function. In the absence of these key people, the deputies would perform their tasks to assure continued compliance with the QMS and competent performance of tests.

k) Personnel must be aware of the importance of their activities and how they contribute to the achievement toward the objectives of the management system. This may be done by including personnel in management review activities and outcomes and through performance evaluations. Additionally meetings may be established to involve personnel in improvement through the establishment of preventative actions and the corrective action process.

E-Clause 4.1.6— Top management shall ensure that communication processes regarding the effectiveness of the management system are established. Communicating the results of management reviews or refresher training on management system issues may do this. Capturing meetings (even those informal ones) may assist in providing evidence of the needed communication for the assessor. Top management is considered to be those individuals who have the authority and can provide the resources necessary to make changes to any aspect within the laboratory.

Clause 4.2 Quality system

E-Clause 4.2.1— The quality management system may be very elaborate in a large laboratory, but very informal in smaller ones. The quality policies, system, programs, procedures and instructions shall be documented. These documents can be arranged in any hierarchy that is suitable for the laboratory, but must
ensure complete compliance with ISO/IEC 17025. The laboratory shall communicate the system to all personnel and ensure that they understand it. The best way to identify that the program has been established and implemented is through training programs for all employees. It would be necessary to document that the training had been completed, and recorded in the employees’ records.

Maintenance of the program is demonstrated through regular review of the QMS documentation, which is recorded in the history of the document. Maintenance is also demonstrated through regular use of the procedures that are established, such as, records of internal audits, management review, and client complaints. Records of calibration and maintenance of equipment are also evidence that the program is being maintained.

E-Clause 4.2.2- Laboratories must have a quality manual that defines its quality system and policies. The laboratories overall objectives need not be included in the quality manual but must be established and reviewed during management review. A quality policy statement describing the purpose of the management system related to quality and the laboratories standard of service shall be made on the authority of a senior executive who has line management responsibility for the laboratory, and who is at the highest level of management on which decisions are made on laboratory policy and resources. All management should commit to these practices. Management is responsible for making sure that the policies are documented and communicated to all personnel. See ISO/IEC 17025 for further instructions for development of a quality policy.

Communication of the quality system and policies, whether through formal training programs or a more casual method, should assure that the personnel understand and implement the program. Generally, this is transmitted to employees through orientation, or other training methods. The fact that the personnel have had this information communicated to them should be documented in some way, generally in their personnel files.

E-Clause 4.2.3— Top management’s commitment to continual improvement of the management system can be shown by, active participation in the development and revisions to the quality manual, through the use of corrective actions and complaints, preventative and corrective actions used to make necessary improvements. Top management must be prepared to provide “evidence” showing the monitoring and improvement of the management system. The management review process may be an appropriate method for looking at the effectiveness of these improvements.

E-Clause 4.2.4— Customer, statutory and regulatory requirements must be communicated to the organization by top management. The use of the quality manuals, memos, videos, posters or other reproducible methods are most
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common. Interviews with laboratory personnel must show that there is sufficient communication regarding this within the management system.

E-Clause 4.2.5— It is a good idea to describe the laboratory’s documentation hierarchy in the quality manual. This usually consists of a documentation pyramid with the Quality Manual at the top, then Operating Procedures and Work Instructions. There are no specific titles required for the hierarchy; you may call these documents anything that is appropriate and works for your organization. You should also refer to the second and third tier documents in the Quality Manual, where it is appropriate to refer to them. For instance, when you are describing your Internal Audit Program in the Quality Manual, it would be appropriate to refer to the Internal Audit Procedure.

E-Clause 4.2.6— When documenting this clause, consider 4.1.5 g), h), and i). The job descriptions of the Technical Management and Quality Manager should describe their responsibility for ensuring compliance with ISO/IEC 17025. In this clause, you are required to briefly describe in the Quality Manual their roles and their responsibilities for ensuring compliance with ISO/IEC 17025. This need not be a lengthy description, but should refer back to the Job Descriptions of these individuals.

E-Clause 4.2.7— Top management must be sure that any major changes or even subtle changes to the management system do not interfere with the goals and objectives established by the laboratory. Management should include all affected parties in the decisions to make changes. For example, when a change has been made to one laboratory policy, have all corresponding changes been made to other areas of the document control system.

Clause 4.3  Document control

4.3.1 General

E-Clause 4.3.1—This clause actually requires little explanation. It contains general information that requires the laboratory to establish a document control system. It also defines some documents that would need to be controlled. What it does seem to miss is that internally generated documents would include the Quality Manual, Policies, Procedures, Work Instructions, Test Methods, and any other documents that form a critical part of the quality system, or have direct bearing on the validity of test data.

4.3.2 Document Approval and Issues

E-Clause 4.3.2.1— The simplest way to show evidence of approval is with a signature on the documents. It is also possible to set up an electronic approval for documents. There must be physical evidence that the documents are
approved. The master list can be an index of the documents, and should indicate the current revision of all documents. All controlled documents should have a list of who gets the document in order to prevent unintentional use of obsolete documents.

E-Clause 4.3.2.2—

a) To assure that the documents are available at all locations, it is necessary to station complete sets of documents in strategic locations throughout the lab. It is also necessary to assure that someone is responsible for keeping these documents sets up-to-date. Another effective way to assure that the documents are available is to have them on a computer network that is available to all necessary personnel. This assures that they are available to everyone, and that the latest revision is available.

b) It is important to assure that controlled documents are periodically reviewed to ensure their continued suitability for use, and their compliance with applicable requirements. Reviews should be done on an annual basis; however, ISO/IEC 17025 does not specifically require this. The object of the review is to determine whether the document continues to be suitable for use and compliant, or whether a revision will be necessary. If the document needs to be revised, see the guidance for clause 4.3.3. The review or revision should be recorded on the document history, and as a quick review aid, you might want to record the review/revision information on the master list of documents.

c) Assigning an individual(s) to make sure that the documents are promptly removed from all areas is essential to this process, whether it is done manually or electronically.

d) To comply with the clause, you should mark all retained documents that are obsolete as such, either with a stamp, written on the document, or in the case of electronically preserved documents, by moving them to a file that indicates that they are obsolete.

E-Clause 4.3.2.3—No further guidance necessary.

4.3.3 Document Changes

E-Clause-4.3.3.1— Review by the same authority does not mean the same person. It does mean that an individual with the same authority and qualifications should review the document. The person should know the background of the document. The quality manual should be up-to-date. There should be evidence in the manual and procedures that these have been looked
at within a reasonable length of time, usually one year. If the evidence appears to indicate that it has not been looked at in five years, there is a good chance that the program has some major problems. Start looking at how the personnel are performing these tasks. I am sure that you will find big differences in the way the task is done now and the way that it is documented. The review should be done to assess the adequacy of the document, whether it remains appropriate for its purpose, and if the document is being used as described. There should be evidence that procedures are reviewed on a periodic basis, even if changes are not made. The Laboratory documentation should define the interval.

E-Clause 4.3.3.2—There are several ways to make altered text. Strike-out is good for text that is removed. You can highlight or italicize the additional text. The next time a revision is needed, the struck-out text and highlights can be removed, and italicized text can be rendered in normal text.

E-Clause 4.3.3.3—It is never a good idea to allow amendments to a document to be made by hand. If it is a practice that the laboratory finds necessary occasionally, a procedure should be written that describes how these changes are done. This procedure should include:

- Who has the authority to make such changes?
- The amendments shall be legible to the users of the document.
- The changes should be initialled and dated, however, we recommend that the method for identifying the individual that made the change be in an identifiable fashion, such as a printed name.
- The method for having the document reissued in the shortest amount of time. Hand changes should be for a single use, and then should be sent for reissue.

E-Clause 4.3.3.4—Several methods to control electronically stored documents are mentioned above.

Clause 4.4 Review of Requests, Tenders and Contracts

E-Clause 4.4.1— How a laboratory reviews requests for quotes or new work can be as varied as the labs themselves. Some laboratories have a very detailed quotation process that includes examination of their ability to do the calibration/test. Other labs do very routine type of work, and the review may be very cursory just to make sure that the client has not required something that they are not capable of doing. Either one of these approaches, or anything in between is OK. The policies and procedures should ensure that:

a) The requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2)
b) The laboratory has the capability and resources to meet the requirements

c) The appropriate test/calibration method is selected and capable of meeting the client’s requirements (see 5.4.2)

d) Contact of the client in the event that the quote and contract are not the same.

See notes in ISO/IEC 17025 under this heading.

E-Clause 4.4.2—All contact with the client and their instructions should be recorded and kept with the job documentation, for use by the people performing the tests/calibrations.

E-Clause 4.4.3— No further information needed

E-Clause 4.4.4—If the laboratory will deviate from the contract, they must notify the client. This should be done prior to commencing the work to prevent trouble should the client disagree with the deviation.

E-Clause 4.4.5—No further information needed

**Clause 4.5 Subcontracting of tests and calibrations**

E-Clause 4.5.1—When you find it necessary to subcontract work, you should always place it with a competent laboratory. The way a laboratory can prove its competence is by accreditation or through your assessment and approval of the laboratory. The only way that one laboratory can approve another laboratory is if the approving laboratory is accredited, or can perform the same test. Therefore, this subcontracting requirement applies only for subcontracting of any part of the tests or calibrations included in your laboratory’s scope of accreditation.

Laboratories should document their policies and procedures for choosing subcontractors. Accredited laboratories using the services of a subcontracting laboratory are responsible for ensuring to their clients that the subcontracted laboratory has a satisfactory quality system and is competent to perform the required calibrations or test. Reliance on ISO/IEC 17025 accredited laboratories is sufficient, as long as the specified test is part of the subcontractor's scope of accreditation. If a laboratory chooses to approve a non-accredited subcontractor laboratory, it should be done using an audit process similar to your own internal audit system, which assures compliance with the requirements of ISO/IEC 17025.

Tests/calibrations are not considered accredited if they are performed by a laboratory that is not accredited or, in the case of a laboratory approved lab, where the test/calibration is not part of the scope of accreditation of the laboratory that did the approval.
This clause out-reaches itself by trying to control all subcontracting, and the accreditation bodies do not have the authority to restrict the use of subcontractors if the client does not need an accredited test. If the client does not need an accredited test, you may use any subcontractor you wish. However, if you include the results of that test in a report that has reference to L-A-B accreditation on it, you must identify those tests as not accredited.

E-Clause 4.5.2—The easiest way to advise the client of your intent to subcontract a test is through the quote. It is not necessary to identify who you will subcontract to, only your intention to do so. Their acceptance of the quote and authorization to perform the work would be the approval to subcontract the work.

In the event that you must subcontract a test after the client has accepted the quote, you need to have a procedure that will assure that the client is notified and approves your intention to subcontract the test. This can be done at the contract review. In the event that subcontracting is in an emergency situation, such as your equipment breaking, you must make sure that there is a procedure for this.

E-Clause 4.5.3—Whenever a laboratory chooses to subcontract a test or calibration, it is responsible to the client for the results of the t/c. When the client specifies the subcontractor, the laboratory is not responsible for the results. The laboratory should make sure that they have kept the evidence that the client specified the subcontractor. The evidence may be in the form of written direction, specified in the t/c method, but should not be accepted on just a verbal. If the client only gives verbal directions, these should be carefully recorded in the records of the test, along with the person giving the directions. (Verbal direction should always be handled as suggested here.)

E-Clause 4.5.4—In this case a register would be called an Approved Subcontractor’s List in the United States. This is not to be confused with an approved supplier’s list. The evidence of approval might be the Scopes of Accreditation, your specific investigation document that shows the subcontractor’s compliance with ISO/IEC 17025, or other evidence. There is no dispensation for using OEM’s for approving a calibration subcontractor. However, if you are seeking compliance with QS 9000, use of an OEM is acceptable under their requirements. If you are seeking accreditation to ISO/IEC 17025, you will need to assure that you are using accredited laboratories. Since the number of accredited laboratories does not include sufficient coverage of all disciplines, most accreditation bodies have made arrangements to ensure that adequate/acceptable calibration can be provided. Ask your accreditation body for its policy.

Clause 4.6 Purchasing Services and Supplies
E-Clause 4.6.1—This clause requires the laboratory to have a formal purchasing policy and procedure. This can be a formal receiving inspection department with dedicated personnel (that may be part of the manufacturing receiving process); in smaller facilities, or where the laboratory feels that it is more qualified to perform the inspection, this may be the function of the specific departments. Whichever method the laboratory chooses to use must be documented. The policies and procedures shall cover the purchase, receiving and storage of reagents and laboratory consumable materials relevant to the test and calibrations. Consumable materials are those items, chemicals, or products that are used once during a test and either are consumed by the test process or rendered unusable for other tests. Some examples are salt for salt spray, special cleaning fluids for gage blocks, and Ph buffers. Special attention must be given to items that have a shelf life in order to assure that these items are not used after their expiration date.

E-Clause 4.6.2—A process for assuring that purchased items are not used prior to verification, and that they comply with the standard specifications or requirements defined by the methods for test/calibration. This may be a formal receiving inspection, or the responsibility for approving the purchased items may be assigned to the authority that originally ordered the item. See clause 4.6.1. Each scenario requires that a formal procedure exists, and that approval of the item is recorded. The records can be a formal inspection record, or simply a stamp of approval, or inspector’s initials on the item or its package. Whichever methods are used, the individuals who approve the items for use must have the appropriate level of competence and training to perform the task. Review of the item’s certification may be satisfactory for this process; however, a formal procedure should include the steps to follow if something is found non-compliant with the requirements. If possible and practical, periodic testing of consumables may be necessary to verify compliance with requirements.

E-Clause 4.6.3—Part of the purchasing procedure must require the laboratory to provide the supplier with the appropriate information to assure the prescribed requirements for the purchased items are met. Purchase documents (purchase orders) for items affecting the quality of tests/calibrations should include a description of the services and supplies ordered, and may include, but are not limited to, the type, class, grade, precise identification, specifications, drawings, inspection instructions, or other technical data, including approval of test results, the quality required and the quality system standard, if necessary, under which they are produced. The application of this clause will have to be evaluated by the laboratory to determine which items are critical to assure that the purchased items and supplies comply with the requirements.

The procedure shall also include the review of the purchase document prior to release. An individual that is familiar with the requirements for the purchased item should do this. Where a formal purchasing department that may not be
familiar with the purchased item issues the purchase document, a formal review is a critical part of the process.

E-Clause 4.6.4—The laboratory must maintain an approved supplier list. The standard does not indicate what type of approval system is necessary to fulfill this requirement, but several methods are available. One method is to use accredited or registered companies, and this is probably the easiest for the laboratory. The second is for the laboratory to conduct a second party audit of the supplier based on ISO 9000 series, QS 9000, or other equivalent, which is probably the most expensive option for the laboratory. The third is to have a process of supplier self-declaration of conformity to a standard (QS 9000, ISO 9000 series, or ISO/IEC 17025), and formal tracking of the supplied items and rating the supplier based on acceptance of supplied items. Or, use any combination of these options. The process that the laboratory chooses to use shall be documented, and records of approvals shall be maintained. See Policy 001 where matters of suppliers of calibration service and traceability.

Clause 4.7 Service to the client

E-Clause 4.7—This clause requires the laboratory to provide the client with all of the information that they need to clarify their request. They must also be afforded the right to monitor the laboratory’s performance of its work, provided it does not cause a conflict or cause a problem with confidentiality. The laboratory must obtain feedback, both negative (client complaints (see 4.8)) and positive and use this information to improve the management system. Feedback can be from client surveys, collected by sales people or through a customer service department. The notes in ISO/IEC 17025 will provide the necessary provisions for a procedure.

Clause 4.8 Complaints

E-Clause 4.8- The laboratory shall have a written procedure to handle complaints. The procedure should include an investigation of the complaint. It is possible that the complaint investigation will indicate that there was no problem. In this case the documentation should indicate that, but it is very important for the laboratory to realize that they still have a client that is upset. It is critical that the laboratory handle all complaints to assure that the client’s concerns are assuaged.

If the investigation indicates that a problem exists, the laboratory must document what actions they have taken to correct the problem. The complaint process should lead into the formal corrective action process as described in clause 4.10, if the investigation indicates that deficiencies exist in the Laboratory Management System as defined in the Quality Manual.
Clause 4.9 Control of non-conforming testing and/or calibration work

E-Clause 4.9.1—The laboratory shall have policies and procedures for handling non-conforming tests/calibrations, or the results of this work do not conform to requirements.

a) Typically the quality manager (however named) or designee would be assigned the authority and responsibility to stop the work and the release of test results, when non-conformances are believed to exist. However, anyone may be given the authority and responsibility for this. The authority and responsibility must be documented. This would be part of the job description of the individual given this authority.

b) Someone must be assigned to evaluate the significance of the non-conforming work. The individual assigned should have the competence to evaluate the significance. This may be anyone within the organization, with the appropriate, demonstrated competence.

c) When the investigation proves that a non-conformance exists, the procedure should lead into the formal corrective action procedure as defined in clause 4.11. The procedure shall also define the process by which the laboratory will process the non-conforming work, whether it is acceptable or the test/calibration will need to be repeated, etc.

d) When the disposition of the non-conforming work requires, the laboratory shall notify the client and recall the work. It is critical to realize that not all non-conformances will require notification of clients. If the investigation indicates that the particular non-conformance does not affect the result that the client has, no notification is necessary.

e) An individual, typically the quality manager (however named) or designee, is responsible for authorizing the resumption of work. The thing to look out for here is that the authority is not assigned to the individual that is directly responsible for the non-conforming activity.

NOTE--Identification of non-conforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Customer complaints, quality control, instrument calibration, checking of consumable materials, receiving inspection, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits are examples.
Clause 4.10 Improvement

E-Clause 4.10—The laboratory must continue to improve the effectiveness of the management system. This may be performed through the use of quality policies, quality objectives, internal audit results, data analysis, corrective and preventive actions and management reviews. Additionally training sessions or other sources of brainstorming with documentation and results may assist in providing evidence for improvement.

Clause 4.11 Corrective action

E-Clause 4.11.1—General—A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of non-conforming work, internal or external audits, management reviews, and feedback from clients or staff observations. When an issue is found against the Quality System, procedure, work instructions, etc. a non-conformance shall be issued for every finding and a corrective action shall be issued with the appropriate evidence for the non-conformance. A policy and procedure shall include the following steps, and records of actions should be kept.

E-Clause 4.11.2—Cause Analysis—Cause analysis is the most important step in the corrective action process. Unless the laboratory understands what truly caused the problem, they will have difficulty defining the corrective actions necessary to prevent the recurrence of the same or similar problems. Often once the root cause is determined the corrective actions are easy to define.

E-Clause 4.11.3—Selection and implementation of corrective actions—The goal of corrective action is to select an action that will prevent the recurrence of the same or similar problems or non-conformances. Any action that the laboratory chooses shall be appropriate to the magnitude and risk associated with the problem or non-conformance.

The required changes shall be documented and implemented. The best way to show evidence of implementation is to record the training of the appropriate personnel. This can be done on the corrective action report, or in the formal training records.

E-Clause 4.11.4—Monitoring of corrective actions—There should be some evidence that a follow-up of the effectiveness of the corrective action has been performed. Several methods exist for doing the follow-up. One method is to verify the effectiveness during internal audits. Another method is a formal process by which each corrective action is reviewed and the effectiveness is evaluated. The effectiveness of the corrective actions should be evaluated within
a reasonable amount of time, to assure that the activity has not slipped back into non-conforming activities. If it is discovered that the corrective actions are not effective, the laboratory should have a process for ensuring that further investigation is performed to determine why the corrective action was not effective. The further investigation should lead to an improved process for correcting the non-conformance, and effective implementation of the corrective action that would prevent the recurrence of the same or similar non-conformances.

E-Clause 4.11.5—Additional audits—No further guidance necessary.

**Clause 4.12 Preventive action**

E-Clause 4.12.1—4.12.2—Preventive action is a pro-active process to identify improvement opportunities, rather than react to the identification of existing problems or complaints. The policies and procedures should reduce the likelihood that a non-conformance will occur. Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses, and proficiency testing results. Once a need to improve has been identified, an action plan should be developed, which includes tasks, assigned responsibility, and timing.

Once the plan is implemented, it should be monitored to verify that the needed improvements have been realized and are effective. There should be some evidence that a follow-up of the effectiveness of the preventive action has been performed. Several methods exist for doing the follow-up. One method is to verify the effectiveness during internal audits. Another method is a formal process by which each preventive action is reviewed and the effectiveness is evaluated. The effectiveness of the actions should be evaluated within a reasonable amount of time to assure that the activity has not slipped into non-conforming activities. If it is discovered that the corrective actions are not effective, the laboratory should have a process for ensuring that further investigation is performed to determine why the actions were not effective.

**Clause 4.13 Control of records**

**Clause 4.13.1 General**

E-Clause 4.13.1.1—A procedure shall be documented that includes identification, indexing, access, collecting (see next paragraph), filing, storage, maintenance and disposal of quality and technical records.

Quality records are those that result from the documentation of actions required by the quality manual, such as, internal audits, corrective and preventive actions, management review, external audits, and others. Collecting, as required above,
can be defined in the procedures developed for each activity; such as, internal audit... The procedure for compliance with this clause need only reference that collection of records is defined by individual procedures.

E-Clause 4.13.1.2— Retention times shall be established that are suitable to the laboratory’s needs. The retentions times should be documented and available for review. Laboratories need to know if their clients or regulatory bodies have specific requirements for retention of records. Assessor, as part of their competence and experience, should be aware of the required retention times for their areas of expertise. Records may be in any media, such as hard copy or electronic media.

E-Clause 4.13.1.3— No further information needed

E-Clause 4.13.1.4— The laboratory shall periodically back up all records that are stored electronically, and there must be a documented procedure. There must be evidence that this is being done. It is recommended that the backup be stored in a place that is separate from where the computer is that stores the records. The laboratory shall have a procedure to prevent unauthorized access to or amendment of these records. A password access system is adequate to fulfill this requirement, however, more elaborate systems may be designed that would further limit the exposure of the laboratory.

Clause 4.13.2  Technical records

E-Clause 4.13.2.1—Records shall include sufficient information to establish an audit trail. This trail should lead back to the original documentation that defines what work is requested. The records shall also contain sufficient information to allow the repetition of the test in as close to the same manner as the original test. If possible, the records should include the identification of the factors affecting the uncertainty. The records should contain:

- Identification of the equipment used
- Original data (it may not always be possible to get these in the case of computer generated data, and there may be other cases)
- Derived data
- Personnel performing the test
- Procedure/method used to perform test
- Test/calibration report
- Sampling plan/method
- Checking the results

E-Clause 4.13.2.2—No further guidance necessary
E-Clause 4.13.2.3—No further guidance necessary.

Note: It is recommended that the laboratory encourage/require the person correcting the mistake to also indicate why the correction was necessary. This is not required by the standard, but is good practice for a laboratory. It will clarify that the data changes were made by the authority responsible for the test/calibration and not altered by unauthorized personnel.

For electronic data, this task is a little more difficult. The most effective way to preserve the original (incorrect) data is to save a copy of the original data, before making the correction. In some instances this may not be possible. Other methods may be available and the assessor shall evaluate the effectiveness of the method.

**Clause 4.14 Internal audits**

E-Clause 4.14.1—The laboratory needs to have a procedure for performing internal audits. Audits may be completed all at once and cover all of the requirements of ISO/IEC 17025, or they may be arranged to focus on different areas or aspects of ISO/IEC 17025 and completed over a period of time. Typically, audits are conducted on an annual basis, however, ISO/IEC 17025 only makes recommendation that it should normally be done once per year. It is possible for a laboratory to choose a different interval, provided it can prove that it is reasonable. L-A-B may at some time make a determination about what they will consider to be an appropriate interval.

Internal auditors should be independent of the process they will audit. In small laboratories this may not always be possible. The auditors should have evidence that they are trained and qualified to perform audits. This should be documented in their records.

E-Clause 4.14.2—Deficiencies noted during audits shall require formal corrective action (see 4.11). If the deficiency casts doubt on the validity of the data, the laboratory shall contact the client to let them know that they have suspect data. This should be a formal procedure.

E-Clause-4.14.3—No further information needed

E-Clause-4.14.4—See comments at clause 4.11.4

**Clause 4.15 Management reviews**

E-Clause 4.15.1—The laboratory shall have a policy and procedures for conducting review of its management system. Typically, reviews are conducted
on an annual basis, but ISO/IEC 17025 only makes the recommendation that it should normally be done once per year. It is possible for a laboratory to choose a different interval, provided they can prove that it is reasonable.

It is recommended that the laboratory establish a standing agenda that includes all of the elements recommended by the standard. The agenda should also include those things that the laboratory has determined are critical for the continued good quality of their laboratory, and essential for the validity of the data.

This activity should include representation from all associated areas. Special attention should be paid to chronic problem areas.

Minutes of the meeting should be kept as evidence of the review.

E-Clause 4.15.2— A plan for implementing actions defined during the review should ensure that the actions are carried out on an agreed timescale. There should be evidence of effective completion of the actions.

See monitoring of implementation in clause 4.11.4.
Clause 5  Technical requirements

Clause 5.1  General

E-Clause 5.1.1— No further information needed

E-Clause 5.1.2— No further information needed

Clause 5.2  Personnel

E-Clause 5.2.1— When the scope of accreditation includes standards or in-house procedures that require the reporting of interpretations of test or calibration results, the accreditation body and laboratory should pay particular attention to ensure that the additional aspects of competence given in NOTE 2 of clause 5.2.1 of ISO/IEC 17025 are met for the areas for which the laboratory provides opinions and interpretations. This should involve establishing that the laboratory has effective procedures to ensure that the relevant expert personnel have sufficient understanding of the relevant subject(s) and a realistic appreciation of the limits of their own knowledge in the context of the opinions and interpretations reported.

E-Clause 5.2.1—All personnel who have a direct effect on the validity of the test results shall be able to demonstrate their competence to perform their specific tasks. The evaluation of competence can be very subjective unless the person is completely inept. Personnel records for education, training, technical knowledge and experience should indicate that the person is likely to be competent. Their records should contain sufficient evidence that they are qualified to perform the tasks as defined in their job descriptions. The laboratory will have to demonstrate that they have an effective training program, and that personnel in training are adequately supervised when performing tests. An effective way to demonstrate an effective training program is to have a training matrix for each position or area within the company, and document the training as it occurs.

The laboratory shall evaluate the competence of all personnel. The evidence that management has determined that the person is competent may be as simple as the person’s supervisor/trainer signing the training records, with the understanding that they are attesting to the fact that the person is qualified to perform the task. Competence may also be demonstrated through outside training courses, or college courses, but evidence must be provided that demonstrates that they are competent. The laboratory shall assure that training is kept up-to-date for all personnel. Personnel records should include relevant qualification, training, skills and experience of the technical personnel. Make sure that these records exist for all personnel that affect the validity of test results.

In some technical areas (e.g. non-destructive testing) it may be required that the
personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the client. Copies of these certifications should be part of the personnel file.

The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications; training, experience and satisfactory knowledge of the testing carried out, also have documentation in their file for:

- Relevant knowledge of the technology used for the manufacturing of the items, materials, and products tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
- Knowledge of the general requirements expressed in the legislation and standards; and
- An understanding of the significance of deviations found with regard to the normal use of the items, materials, and products, etc, concerned.

E-5.2.2—The laboratory will have to produce evidence that they have formulated expectations of the education, training and skill levels necessary for personnel. This should be documented, usually in a job description. The laboratory should have policies and procedures to identify the training needs of personnel and methods to ensure that the personnel are truly qualified. Proficiency testing can serve as a means to evaluate the effectiveness of the training actions taken, along with monitoring the instances of non-conforming work or audit results. There should be documented evidence that the training has been completed. This should become a part of the personnel records for the employee.

The best way to implement this requirement is through a training matrix designed for each position or area. Another effective way to show implementation is by identifying the tests that are performed in the laboratory (similar to a scope of accreditation) and identifying the personnel in the laboratory who have demonstrated the competence necessary to perform the tests. Laboratory management is responsible for assuring that personnel who are listed on the matrix are competent to perform the test.

E-Clause 5.2.3—This clause indicates that all personnel used by the laboratory must be competent, trained and supervised by competent staff to ensure that they work IAW the quality program of the laboratory. It is the responsibility of the laboratory to demonstrate the competence of all staff, whether directly employed or contracted. There must be documented evidence of the training and qualifications for all staff similar to that described above. Subcontracted
employees’ files should be handled in the same manner as staff directly employed by the laboratory.

E-Clause 5.2.4—Job descriptions shall exist for managerial, technical, and key support personnel. These can be done either for specific jobs or specific positions. Job descriptions should include as a minimum, the following:
- Responsibilities with respect to performing tests and/or calibrations;
- Responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
- Responsibilities for reporting opinions and interpretations;
- Responsibilities with respect to method modification and development and validation of new methods;
- Expertise and experience required;
- Qualifications and training programs;
- Managerial duties.

E-Clause 5.2.5—Laboratory management must authorize personnel to perform their tasks. This must be documented. Typically, the records of the staff will show evidence that individuals have demonstrated competence to their supervisor or trainer, and that they are authorized to perform the task. The record shall also include the date on which the authorization and/or competence is confirmed. This can be by signing and dating the records of training/qualification, or other documented evidence. Whatever manner the laboratory chooses to use, the authority must be given and documented by the laboratory. The records of authorization must be available for evaluation.

Clause 5.3   Accommodation and environmental conditions

E-Clause 5.3.1—For each area that requires a controlled environment, the laboratory shall document the conditions that they are controlling. The assessor must evaluate whether the laboratory has documented all of the conditions that might affect the test/calibration.

E-Clause 5.3.2—Parameters that affect the test shall be monitored appropriately. The best way to evaluate the environment is to check the recorders. The laboratory should have records that indicate that they have checked all environmental conditions that may affect their data. Check that all environmental conditions that affect the validity of data are recorded appropriately. The laboratory should have a plan that indicates what actions will be taken when environmental conditions are outside the acceptable range. Some of the conditions that must be monitored are listed in ISO/IEC 17025, but others may be found in test/calibration methods or are known by the technical personnel of the laboratory.

E-Clause 5.3.3—No further information needed
E-Clause 5.3.4—Access to controlled areas shall be identified and controlled to the extent necessary to protect the controlled environment. Access limitations should be posted in a conspicuous spot to prevent unauthorized personnel from entering the controlled area.

E-Clause 5.3.5—You must document any condition within your laboratory that requires a specific type of contamination or housekeeping control. Nonetheless, even if you don’t have specific needs, look behind, under, and on top of equipment, as the laboratory should be clean because the assessors will evaluate the housekeeping.

Clause 5.4 Test and calibration methods and method validation

E-Clause 5.4.1—General—The use of well-documented procedures is needed in order to maintain the consistency of the test/calibration process when they are performed at different times and by different people. The laboratory should have procedures to perform all tests and calibrations. The areas covered should include, as appropriate, sampling, handling, transportation, storage and preparation of items, and where appropriate, an estimation of uncertainty. It is interesting to note that the term “where appropriate” is used when defining inclusion of an estimate of uncertainty with regard to procedures. There are instances in testing where estimating measurement uncertainty is not always a necessary or appropriate part of a test procedure; however, it is always necessary for calibration procedures. These procedures may be ones developed by the laboratory, written by Standards Development Organizations, the manufacturer of the equipment, or other written procedures. The procedures should be specific enough to allow the laboratory to perform tests and calibrations and get valid results. If the lack of a procedure does not compromise the lab’s ability to perform the test, a procedure is not needed. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be part of the document control system.

International, regional or national methods or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method, or additional details.

E-Clause 5.4.2—Selection of Methods—The laboratory must demonstrate that it has the ability to select appropriate test/calibration methods to satisfy their client’s needs, and is appropriate for the activity. Some areas that might be evaluated showing compliance with this requirement are the training records, contract review, and test demonstration. This clause gives sufficiently clear information to understand what is required.
E-Clause 5.4.3—Laboratory-developed Methods—This requirement is simply stated, however, the impact on the laboratory is significant. When the laboratory must develop a procedure for performing a test, it must be a planned activity. You should be able to identify how that activity will progress from start to finish. The plan should be updated as necessary. Some laboratories will begin this process at the quote stage and will continue the process when the quote has been accepted. Other laboratories have previously developed methods that are requested by the client. Some laboratories, particularly in the engineering, durability, and life testing areas, will develop methods specifically to evaluate specific parameters for items. These will be unique for each product, and may be developed at the time the test is being set up. Whatever plan the laboratory uses must be documented. The individual assigned to write the procedure should be competent.

E-Clause 5.4.4—Methods should be developed prior to beginning the test/calibration, and should include the following steps as needed to perform the test, but are not limited to:

- Appropriate identification
- Revision of document
- Scope
- Description of the type of item to be tested/calibrated
- Parameters or quantities and ranges to be determined
- Apparatus and equipment, including technical performance requirements
- Reference standards and reference materials required, if needed
- Environmental conditions required and any stabilization period, if needed
- Description of the procedure, including
  1. Affixing of identification marks, handling, transporting, storing and preparation of items
  2. Checks to be made before work is started
  3. Checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use
  4. Method of recording the observations and results
  5. Explicit instruction on how to perform the test or calibration
  6. Data on repeatability and reproducibility of the method, together with the number of significant figures to be reported for various measurement ranges
  7. Identification of any known limitations of the method, such as applicable concentration ranges, possible interference, and environmental factors
  8. Any safety measures to be observed
- Criteria and/or requirements for approval/rejection
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ISO/IEC 17025:2005

- Data to be recorded and method of analysis and presentation
- The uncertainty or procedure for estimating uncertainty, where needed

Clause 5.4.5 Method Validation

E-Clause 5.4.5.1—Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. This is the definition of validation that appears in ISO 8402.

E-Clause 5.4.5.2—Validation should include procedures for sampling, handling and transportation. The aim of the validation of test methods is to demonstrate that the method is fit for its intended purpose, and that the results have an acceptable uncertainty. The validation should provide information about the method’s ability to produce the results required by the specification, and its repeatability and reproducibility. It should also measure the influence of instrumental, human and environmental factors on the uncertainty of the results. Method validation is required for, but not limited to the following situations:

- New equipment- When a laboratory introduces a new piece of equipment into their laboratory method, validation should be performed to prove that the laboratory is capable of getting a valid result before performing testing for clients.
- The laboratory is attempting a new standard method for the first time.
- Non-standard methods developed by the laboratory.
- Standard methods used outside their normal parameters.

Validation of non-standard and new methods is always a balance between costs, risks and technical possibilities.

The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- Calibration using reference standards or reference materials
- Comparison of results achieved with other methods
- Inter-laboratory comparisons
- Systematic assessment of the factors influencing the results
- Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience

When changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

Clause 5.4.5.3— No further guidance necessary.
Clause 5.4.6  Estimation of uncertainty of measurement

E-Clause 5.4.6.1— Calibration laboratories and testing labs performing their own calibrations must always know and be able to calculate their measurement uncertainty. They must provide the uncertainties of measurements on their calibration certificates unless it can be proved that it is not possible to do so, or the client has indicated that they do not want it on their reports. Evidence must be available for the assessor to review in the case the client does not require the uncertainty of measurement on the certificate. It still must be calculated no matter what the request!

Uncertainty of Measurement—Result of the evaluation aimed at characterizing the range within which the true value of a measurand is estimated to lie, generally with a given likelihood.

General Guidance

Uncertainty of measurement comprises, in general, many components. Some of these components may be estimated on the basis of the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations, and are called Type A evaluation. The Type A can be applied when several independent observations have been made for one of the input quantities under the same conditions of measurement. If there is sufficient resolution in the measurement process, there will be an observable scatter or spread in the values obtained. In this case, the standard uncertainty is the experimental standard deviation of the mean that follows from an averaging procedure or an appropriate regression analysis.

Estimates of other components can only be based on experience or other information, and are called Type B evaluation. Values belonging in this category may be derived from:

- Previous measurement data
- Experience with or general knowledge of the behavior and properties of relevant materials and instruments
- Manufacturer’s specifications
- Data provided in calibration and other certificates
- Uncertainties assigned to reference data taken from handbooks

The measurement uncertainty for a given calibration is the combination of all the type A and type B components of the uncertainty budget.

In Calibration
L-A-B requires that calibration accredited laboratories state on their Scope of Accreditation an expanded uncertainty of measurement $U$, obtained by multiplying the standard uncertainty $u(y)$ of the output estimate by a coverage factor of $k$,

$$U=ku(y)$$

In cases where a normal (Gaussian) distribution can be attributed to the measurand and the standard uncertainty associated with the output estimate has sufficient reliability, the standard coverage factor $k=2$ shall be used. The assigned expanded uncertainty corresponds to a coverage probability of approximately 95%. These conditions are fulfilled in a majority of cases encountered in calibration work.

Preferred Guidance documents, both based on the “Guide to the Expression of Uncertainty in Measurement, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, AND OIML, are downloadable free from the websites:

- EA-4/02-“Expression of the Uncertainty of Measurement in Calibration-EAL-R2”—Available at—http://www.european-accreditation.org/
- NIST Technical Note 1297 “Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results.”—Available at—http://physics.nist.gov/Pubs/guidelines/contents

1) The laboratory shall have and apply a procedure for calculation of best measurement capability/uncertainty.

2) The laboratory shall produce uncertainty budgets for all calibrations that are on the scope of accreditation.

3) The assessor is required to evaluate the uncertainty budgets and calculations.

4) Evaluation of the laboratories understanding of the uncertainty budgets they have produced shall focus on assuring that all components that contribute to the uncertainty are included. This will be done by looking, as a minimum, at the factors that are detailed in Note 1 under 5.4.6.3 of ISO/IEC 17025. They include but are not limited to:
   a. reference standards and materials used
   b. methods
   c. equipment used
   d. environmental conditions
   e. properties and condition of the item under test
   f. operator
g. Known physical characteristics of components such as, coefficient of thermal expansion. These often can be looked up in engineering and scientific handbooks.

5) The laboratory shall maintain the uncertainty budgets and best measurement capabilities/uncertainties up-to-date. The contributions of the calibration of the equipment will change at each calibration. The personnel’s skills may improve with experience or become worse should a long time employee need to be replaced. These factors need to be considered at the time they happen, and a recalculation of the uncertainty would be necessary in order to determine if a change has occurred that affects the best measurement capability/uncertainty.

6) The L-A-B assessor is required to obtain the uncertainty budgets and evaluate the appropriateness of the current calculations. The evaluation will be based on evidence such as the calibration documentation, other contributors that might change over time and current type A studies. See 2 above.

7) For all assessments the lead assessor must include uncertainty budgets and calculation of uncertainty for all parameters on the scope in the Technical Package sent to L-A-B.

E-Clause 5.4.6.2—The complexity involved in estimation of uncertainty of measurement in the case of testing varies considerably from one test field to another and also within one field itself. A less metrologically rigorous process than that which can be followed for calibration can also often be used. Clause 5.4.6.2 of ISO/IEC 17025 allows for these factors. The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- Requirement of the test method
- Requirement of the client
- There are narrow limits on which decisions conformance to a specification are based

If the test method is well recognized (ASTM, ISO) and specifies limits to the values of the major sources of uncertainty of measurement, and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.
In Testing

1) The laboratory shall prepare a needs assessment utilizing the scope of accreditation. This assessment shall be included in the Technical Package sent to L-A-B at each assessment.

2) If the laboratory has tests that fall into categories C, D, or E in the Needs Assessment they shall have a procedure(s) for calculating uncertainty of testing. This is irregardless of whether its clients require the laboratory to report it uncertainty.

3) The laboratory shall demonstrates it’s capability to calculate uncertainties based on their procedure. They should have examples of calculations that cover the scope of accreditation available during the assessment process.

4) The assessor is required to evaluate the calculations of measurement uncertainty.

5) Evaluation of the laboratories understanding of the uncertainty calculations they have produced shall focus on assuring that all components that contribute to the uncertainty are included. This will be done by looking, as a minimum, at the factors that are detailed in Note 1 under 5.4.6.3 of ISO/IEC 17025. They include but are not limited to:
   a. reference standards and materials used
   b. methods
   c. equipment used
   d. environmental conditions
   e. properties and condition of the item under test
   f. operator
   g. Known physical characteristics of components such as, coefficient of thermal expansion. These often can be looked up in engineering and scientific handbooks.

6) The laboratory shall maintain the uncertainty calculation up-to-date. The contributions to uncertainty of the calibration of the equipment will change at each calibration. The personnel’s skills may improve with experience or become worse should a long time employee need to be replaced. These factors need to be considered at the time they happen, and a recalculation of the uncertainty would be necessary in order to determine if a change has occurred that affects the best measurement capability/uncertainty.
7) The L-A-B assessor is required to obtain the uncertainty calculation and evaluate the appropriateness of the current calculations. The evaluation will be based on evidence such as the calibration documentation, other contributors that might change over time, and current type A studies. See 2 above.

8) For all assessments the lead assessor must include uncertainty budgets and calculation of uncertainty for all technologies on the scope in the Technical Package sent to L-A-B.

Further Definition of the Needs Assessment

Prior to accreditation, the laboratory shall do a Needs Assessment for all tests on their proposed Scope of Accreditation. The Needs Assessment shall define what actions will be necessary with regard to the reporting of uncertainty. (Note: the use of the scope of accreditation for the matrix is recommended. This can be done by adding a column to the table of the scope and title it “Needs Assessment. However any method may be chosen.) The Needs Assessment matrix shall group the tests into five categories as defined below.

Definition of Types of Tests for Needs Assessment Matrix

<table>
<thead>
<tr>
<th>Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Qualitative or semi-quantitative tests that require no uncertainty budgets</td>
</tr>
<tr>
<td>B</td>
<td>A test performed to well-recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results. These are defined in ISO/IEC 17025 Clause 5.4.6.2 Note 2</td>
</tr>
<tr>
<td>C</td>
<td>Chemical, environmental, or biological test methods based on published regulatory or consensus methods; such as, FDA, EPA, AOAC, and ASTM, for which uncertainty is not defined in the method. For these types of test, uncertainty can be estimated using the standard deviation of laboratory control samples for more than 50 points. (This does not include laboratory-developed methods that require validation and are covered below).</td>
</tr>
<tr>
<td>D</td>
<td>Test methods that need identification of the major components of uncertainty and a reasonable estimate of the measurement uncertainty.</td>
</tr>
<tr>
<td>E</td>
<td>Test methods that need identification of all components of uncertainty and detailed measurement uncertainty budgets calculated in accordance with published methods that are consistent with the ISO “Guide to the Expression of Uncertainty of Measurements”</td>
</tr>
</tbody>
</table>
Examples of Types of Testing as defined above

Category “A” Testing Defined

Qualitative tests are test for which there are no quantitative results.

For example:

- Go-no go tests.
- Tests where results are a comparison form a reference plaque; such as, Microstructure ASTM A247, Degree of Blistering ASTM A247, Inclusion Content ASTM E45
- Tests where the result is numerically rated by judgment, such as, Tape Adhesion ASTM D3359.
- Tests that are exposure or environmental simulation only; such as, Salt Spray ASTM B117, Xenon Arc SAE J1885 and J1960, Environmental Cycles GM 9505P.

This is a partial list of methods that fall into Category a defined above

<table>
<thead>
<tr>
<th>DESIGNATION</th>
<th>TITLE</th>
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<tbody>
<tr>
<td>ASTM B117</td>
<td>Salt Spray</td>
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<tr>
<td>ASTM D2247</td>
<td>Water Fog Humidity Test</td>
</tr>
<tr>
<td>GM 4456P</td>
<td>Water Fog Humidity Test</td>
</tr>
<tr>
<td>SAE J1885</td>
<td>Xenon Arc Exposure</td>
</tr>
<tr>
<td>SAE J1960</td>
<td>Xenon Arc Exposure</td>
</tr>
<tr>
<td>SAE J400</td>
<td>Chip Resistance-Gravelometer</td>
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<tr>
<td>ASTM D4060</td>
<td>Tabor Abrasion</td>
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<tr>
<td>ASTM D714</td>
<td>Degree of Blistering</td>
</tr>
<tr>
<td>ASTM D661</td>
<td>Degree of Cracking</td>
</tr>
<tr>
<td>ASTM D4214</td>
<td>Degree of Chalking</td>
</tr>
<tr>
<td>ASTM D1308</td>
<td>Effect of Chemicals on Organic Finishes</td>
</tr>
<tr>
<td>AATCC 8</td>
<td>Colorfastness to Crocking</td>
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<tr>
<td>ASTM D1729</td>
<td>Visual Evaluation of Color-Mac Beth</td>
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<tr>
<td>ASTM D3363</td>
<td>Pencil Hardness</td>
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<tr>
<td>ASTM D3359</td>
<td>Tape Adhesion</td>
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<tr>
<td>GM 9071P</td>
<td>Tape Adhesion</td>
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<tr>
<td>ASTM B571</td>
<td>Adhesion of Metallic Coating</td>
</tr>
<tr>
<td>ASTM F788</td>
<td>Surface Discontinuities of Fasteners</td>
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<tr>
<td>ASTM F812</td>
<td>Surface Discontinuities of Fasteners</td>
</tr>
<tr>
<td>ASTM E1268</td>
<td>Degree of Banding or Orientation</td>
</tr>
<tr>
<td>ASTM A247</td>
<td>Microstructure of Graphite</td>
</tr>
<tr>
<td>ASTM E45</td>
<td>Inclusion Content</td>
</tr>
<tr>
<td>ASTM E3</td>
<td>Metallographic Preparation</td>
</tr>
<tr>
<td>ASTM E340</td>
<td>Microetching</td>
</tr>
</tbody>
</table>
Category “B” Tests Defined

In those cases where a well-recognized test methods specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the clause by following the test methods and reporting instructions.

This is a partial list of methods that fall into Category b defined above

### Materials Testing

<table>
<thead>
<tr>
<th>DESIGNATION</th>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM D638</td>
<td>Tensile Properties of Plastics</td>
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<tr>
<td>ASTM D790</td>
<td>Flexural Properties of Plastics</td>
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<tr>
<td>ASTM D256</td>
<td>Izod Impact Strength</td>
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<tr>
<td>ASTM E111</td>
<td>Modulus</td>
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<tr>
<td>ASTM E9</td>
<td>Compression Properties of Metals</td>
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<tr>
<td>ASTM E8</td>
<td>Tension Testing of Metals</td>
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<tr>
<td>ASTM E10</td>
<td>Brinell Hardness</td>
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<td>ASTM E384</td>
<td>Microhardness</td>
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<td>ASTM E92</td>
<td>Vickers Hardness</td>
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<tr>
<td>ASTM E23</td>
<td>Charpy Impact</td>
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<td>ASTM E139</td>
<td>Creep Testing of Metals</td>
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<tr>
<td>ASTM E606</td>
<td>Strain-Controlled Fatigue Testing</td>
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<tr>
<td>ASTM D1238</td>
<td>Melt Flow Rate of Plastics</td>
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<td>ASTM D792</td>
<td>Specific Gravity of Plastics</td>
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<td>ASTM D5024</td>
<td>Gardner Impact</td>
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<td>ASTM D1044</td>
<td>Surface Abrasion of Transparent Plastics</td>
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<td>ASTM D968</td>
<td>Abrasion Resistance by Falling Abrasive</td>
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<td>Ford BO 116-03</td>
<td>Automotive Fogging</td>
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<tr>
<td>SAE J1756</td>
<td>Automotive Fogging</td>
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<tr>
<td>ASTM B487</td>
<td>Coating Thickness</td>
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<tr>
<td>ASTM E517</td>
<td>Strain Ratio and Exponent</td>
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</tbody>
</table>
Category “C”, “D”, “E” Tests

The Category c, d, and e tests require varying degrees of rigor (see above definitions of categories) when estimating the measurement uncertainty. Below is a list, by field of test, of resources that contain specific examples of various uncertainty procedures and budgets. These have been reviewed and found acceptable for use by L-A-B.

General Guidance

NIST Technical Note 1297 - and other guidance can be downloaded free of charge from [http://physics.nist.gov/Pubs/guidelines/contents.html](http://physics.nist.gov/Pubs/guidelines/contents.html)

EA-4/02 Expression of the Uncertainty of Measurement in Calibration-can be downloaded free of charge from [http://www.european-accreditation.org](http://www.european-accreditation.org)


Requirements for Reporting Measurement Uncertainty in Testing Laboratories

There are three times in ISO/IEC 17025 where a testing laboratory would be expected to report measurement uncertainty. They are: 1) When the test method requires it, 2) When the client requires it, 3) When there are narrow limits on which decisions of conformance to a specification are based. L-A-B requires that the laboratory demonstrate its ability to calculate uncertainty of test that fall into the categories of c, d, and e defined above. See L-A-B Policy 001.
E-Clause 5.4.6.3—Uncertainty components/budgets are a combination of many factors that may include, but are not limited to:

- Reference standards
- Reference materials
- T/c methods used
- Equipment used
- Environmental conditions,
- Properties and condition of item being tested
- Calibration of Reference Standards
- Operator
- Known physical characteristics of components such as, coefficient of thermal expansion. These often can be looked up in engineering and scientific handbooks.

**Dimensional Metrology**


**Chemistry**


**Clause 5.4.7 Control of data**

E-Clause-5.4.7.1— This clause is short but special attention should be paid to how the laboratory checks their data. Calculations should randomly be checked to verify that they have been made correctly, and transfers checked to preclude mistakes such as, transposition of numbers. The laboratory should have a system that assures that these checks are being performed. There must be evidence that the checks have been made.

E-Clause-5.4.7.2—This clause does not apply to commercial off-the-shelf items. However, the laboratory should make some checks of software to assure that it is functioning as it should. Some simple calculations, copying, etc., should verify its functionality prior to use for clients’ projects.

When the laboratory does its own programming, the software developed must be documented in sufficient detail and suitably validated to show its fitness for use. There are numerous methods available, and the method chosen should only be as rigorous as necessary to demonstrate fitness for use.
Clause 5.5  Equipment

E-Clause 5.5.1—All equipment, whether owned, rented, leased or borrowed, used to perform the calibrations or tests on your scope of accreditation must be available during the accreditation visit.

If the laboratory is using equipment that is outside its permanent control, it must assure that the requirements of ISO/IEC 17025 are met. This means that the equipment calibration and maintenance should be conducted according to 17025. Equipment that is rented/leased needs to have the same documentation as equipment owned by the laboratory.

E-Clause 5.5.2—The laboratory is responsible for making sure that its equipment meets the calibration/test specifications. This is a critical component of the evaluation of the laboratories competence. The equipment must be capable of giving a valid test result based on the requirements of the specification. This factor must be taken into consideration when purchasing equipment and maintaining older equipment. You must also need to be able to demonstrate that it is capable to perform the test. This can be through manufacturer’s specifications compared to needed range and accuracy, through proof that it meets the requirements stated in the specifications, or other method. Equipment must be calibrated or checked to assure that it meets the specifications prior to use. One good way of providing this evidence to the assessor is to actually sign and date the calibration certificate received after assuring the equipment and/or reference standard meets the required specifications.

E-Clause 5.5.3—Personnel operating equipment should be authorized to do so. The evidence of this authorization should be available for the assessors. The easiest way to do this is through the training/personnel records for each employee.

Up-to-date instructions for equipment operation should be available to the personnel. These can be either manufacturer’s instructions or created by the laboratory. When asked, the individual operating the equipment should know where the instructions are located. The best place to keep the instructions are close to the machines, however, if there is some indication that they may become lost, the laboratory should take steps to ensure that this does not happen. Some laboratories request that two sets of manuals be included with their new equipment; one is kept with the machine and the other is placed in the control of library, quality or other document control system. Typically, there is a minimal charge for the extra set of manuals if ordered at the same time as the equipment.

E-Clause 5.5.4—Unique identification can be a serial number (if available), an asset code assigned by the laboratory, or a code used specifically for equipment control. This only applies to equipment that has a significant impact on t/c.
E-Clause 5.5.5—Records shall contain:

a) No further guidance necessary
b) No further guidance necessary
c) No further guidance necessary
d) No further guidance necessary
e) See 5.5.3 Guidance
f) No further guidance necessary
g) The maintenance plan can be a part of the equipment control system that is designed to assure that calibrations are done at the recommended intervals. The procedures for maintenance should be handled in the same manner as all procedures that are developed by the laboratory. Recommended maintenance intervals, procedures, and necessary equipment are usually found in the operating manuals provided by the manufacturer. These procedures are designed to increase the useful life of the equipment, and are a major factor in maintaining the capability of the equipment.

h) When equipment has been damaged, or malfunctions during a test or during calibration, this must be recorded as part of the history of the equipment. Modifications made by the laboratory must be noted in order to assure that the equipment is used within its specifications, as they exist after modification. It is important for the laboratory to know the repair history, as this may be an indication that the equipment is not suitable for continued use.

E-Clause 5.5.6—There must be a procedure for handling, transport, storage, use and maintenance of equipment that is used for calibration and test. This may be part of the calibration program or completely separate. All elements of this clause may not apply to your laboratory, but the procedure(s) must cover all that do apply.

E-Clause 5.5.7—There should be a procedure for handling equipment that may have been overloaded or mishandled, gives suspect results, or is damaged in some way. Any equipment that is not suitable for use shall be marked as such and, where possible, stored safely until repairs and/or calibration are performed. The laboratory must have a procedure that includes the examination of the effect that the defect had on previous data. Where the examination indicates that the defect had an adverse effect on data that has gone to a client, the laboratory shall follow the procedures for non-conforming work in clause 4.9.

E-Clause 5.5.8—All equipment shall have an indication of its calibration status. There are many methods that are appropriate and include but are not limited to: 1) label that indicates date calibrated, date next calibration is due, and person responsible for calibration, 2) color code, 3) for those items that can not be directly marked (such as weights, thickness gages, etc.) the status can be placed
on the storage container. The idea of the marking is to assure that the equipment is not used past its calibration due date; any method that will assure this is appropriate.

It is important to say something about setting intervals for calibration recall. There is no requirement that all equipment be calibrated within a certain interval. The interval is set based on the usage and performance (as demonstrated by the equipment history) of the device. It is critical that the laboratory understand how the equipment performs over time in order to make a judgment about the calibration interval. There is guidance available on setting intervals through the National Conference of Standards Laboratories (NCSL) [www.ncsli.org](http://www.ncsli.org).

E-Clause 5.5.9—If equipment goes outside of the control of the laboratory, the equipment must be proved suitable for use once it is returned. When this condition exists in a laboratory, there must be a procedure that defines how the steps to assure continued suitability are carried out. Suitability for use may be demonstrated, but is not limited to the following methods:

a) Calibration  
b) Verification  
c) Use of suitable reference materials that verify compliance with requirements.

E-Clause 5.5.10—Equipment may require intermediate checks or verifications between the normal calibrations to maintain confidence in the validity of the results. These checks can help to provide trend and control charts to monitor for unacceptable drift or other problems that may occur. The documented procedure should require a scheduled check or verification, and method for recording the results of the activity.

E-Clause 5.5.11—Where calibrations give rise to correction factors, the procedure must ensure that these are entered correctly into all areas where they are necessary to assure the validity of t/c data. This may be in the software for operation, or adjustment of the controls, or other area. If the correction factors are necessary for the proper use of the equipment, they should accompany the equipment wherever it will be used.

E-Clause 5.5.12—Some calibration and test equipment have adjustment points that when tampered with, can affect the calibration. In this instance, tamper-proof seals must be placed over all adjustment points. When these seals show signs of tampering, it will invalidate the calibration and before the equipment is used for clients work, it must be calibrated again.
Clause 5.6 Measurement Traceability

Guidance on this aspect is to be found in the ILAC document Traceability of Measuring and Test Equipment to National Standards included in the seminar documentation.

E-Clause 5.6—General—Any program of calibrations must be documented, and include the following elements:

- A method to recall items for calibration at regularly established intervals
- Affixing a label or other identification of the calibration status of the item
- Affixing a tamper-proof device on any entrances where adjustments can be made that would adversely affect the calibration
- Performing the calibration to an appropriate and documented procedure
- Reporting the results according to clause 5.10
- Evaluation of the results, especially with regard to out-of-tolerance conditions
- Documenting repairs made to items as part of the equipment history
- It is recommended that a brief history of the equipment’s behavior be created in order to expedite decisions about the equipment, such as interval changes, need to replace, etc.
- Definition of responsibility

Clause 5.6.2 Specific requirements

Clause 5.6.2.1—Calibration

E-Clause 5.6.2.1.1—Definitions

- Calibration-VIM Clause 6.11- Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.
- Notes:
  1. The result of a calibration permits either the assignment of values of measurands to the indications, or the determination of corrections with respect to indications.
  2. A calibration may also determine other metrological properties such as the effect of influence qualities.
  3. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.
• Traceability-VIM Clause 6.10- Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

1. Notes:
   1. The concept is often expressed by the adjective traceable
   2. The unbroken chain of comparisons is called a traceability chain

Elements of Traceability

See L-A-B Policy 001 for further guidance and requirements that are in addition to this document.

• Essential Elements of Traceability
  1. An unbroken chain of comparisons going back to a National Metrology Institute (NMI) natural constant, or standard acceptable to all parties
  2. Measurement uncertainty in each step must be calculated by use of the recommended documents in E-Clause 5.4.6.1, or the GUM
  3. Each step in the chain must be performed to documented and generally acknowledged procedures, and the results must be reported according to Clause 5.10
  4. The laboratories in the chain must be competent by demonstrating that they comply with ISO/IEC 17025. The method to demonstrate compliance is accreditation to ISO/IEC 17025
  5. The appropriate standards must be primary standards for the realization of the SI units
  6. Calibrations must be repeated at regularly scheduled intervals; the length of these intervals depends on the uncertainty needed, frequency and method of use, and stability of the item based on past history

E-Clause 5.6.2.1.2—This clause applies to calibration results that cannot be strictly reported in SI units. A good example of this is Hardness that is reported in RC units, etc. Where a consensus standard is produced by reputable manufacturers, this is acceptable.

This clause also requires calibration laboratories to participate in commercial Inter-laboratory comparisons where they are available. See L-A-B Policy 002.

5.6.2.2 Testing

E-Clause 5.6.2.2.1—No further guidance necessary

E-Clause 5.6.2.2.2—No further guidance necessary
5.6.3 Reference standards and reference materials

E-Clause 5.6.3.1—Reference Standards-VIM 6.6—Standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

Reference standards used by a laboratory must be controlled by a documented calibration program. The calibration must be performed to a documented procedure by a laboratory that can provide traceability in accordance with 5.6.2.1. The procedure can be one developed by the laboratory, one provided by the equipment manufacturer, or one that is developed by a standards writing organization such as ANSI, and must be suitable for its intended use.

See clause 5.4 for guidance on selection of methods and method validation. A good source for calibration procedures in the USA is:

Gidep’s website: www.gidep.org

E-Clause 5.6.3.2—Reference Material-VIM 6.13—Material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. Certified reference material (CRM)-VIM 6.14—Reference materials accompanied by a certificate, one or more of whose proper values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

NOTES:

1. CRMs are generally prepared in batches for which the property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.
2. The certified properties of certified reference materials are sometimes conveniently and reliably realized when the material is incorporated into a specially fabricated device, e.g., a substance of known triple-point into a triple-point cell, a glass of known optical density in a transmission filter, spheres of uniform particle size mounted on a microscope slide. Such devices may be considered as CRMs.
3. All CRMs lie within the definition of “measurement standards” or “etalons” given in the “International Vocabulary of Basic and General Terms in Metrology” VIM.
4. Some RMs and CRMs have properties, which, because they cannot be correlated with an established chemical structure, or for other reasons, cannot be determined by exactly defined physical and chemical
measurement methods. Such materials include certain biological materials such as vaccines to which an International Unit has been assigned by the World Health Organization.

E-Clause 5.6.3.3—Intermediate checks Reference, primary, transfer or working standards and reference materials shall have the necessary checks to maintain confidence in validity of the calibration. These checks shall be carried out according to a procedure and predetermined schedule.

E-Clause 5.6.3.4—Transportation and Storage- No further guidance required

Clause 5.7 Sampling

This clause applies only to laboratories whose work involves the extraction of samples as part of the testing program. There are laboratories that test only the items that are sent to them, and this clause does not apply to them.

ILAC has guidance that is based on ISO/IEC Guide 25, but still is appropriate for use with ISO/IEC 17025.

Clause 5.8 Handling of test and calibration items

E-Clause 5.8.1—The laboratory shall document their procedure for the transportation, receipt, handling, protection, storage, retention and/or disposal of t/c item, that will protect the integrity of the item, and the interests of the laboratory and client.

E-Clause 5.8.2—There are many methods for identifying items, such as marking the item, tagging, bagging, placing in a specifically identified area, or combinations of these and other methods. The major factor is to prevent ascribing results to the wrong samples. It should be noted that any identification method chosen should not interfere with the test/calibration results.

Caution: direct marking may damage some samples. Direct marking may also interfere with testing. In these instances, some other method of unique identification is needed.

It may be difficult to use identifications in some laboratory situations, such as samples in an environmental chamber. In this case the chamber should be marked with the identification of the items in it. This would serve to maintain the identifications of the item.
Guidance for Documenting and Implementing
ISO/IEC 17025:2005

E-Clause 5.8.3—The procedure for handling of items should address the condition of the item when received. Any abnormalities of departures from normal or specified conditions as described in the methods must be recorded. If there is doubt that the item is suitable for t/c, does not conform to the description provided, the procedure should require contact of the client. When the specified method is not sufficiently described the laboratory should consult the client for further instructions before beginning the test.

E-Clause 5.8.4—No further guidance necessary

Clause 5.9 Assuring the quality of test and calibration results

E-Clause 5.9.1—L-A-B requires all accredited laboratories to participate in proficiency testing programs (PT) or Interlaboratory Comparison (ILC) for fields of testing and calibration that apply to their Scope of Accreditation. The laboratory shall participate in one PT/ILC program prior to accreditation. In order to maintain their accreditation laboratories shall participate in one proficiency test per major field for which they have been granted accreditation, and cover its entire scope every four years. The laboratory shall at a minimum complete two PT/ILC’s every year. The PT/ILC shall, where possible, be provided by a commercially available program. The required programs shall comply with ISO/IEC Guide 43. From time to time L-A-B may require the laboratory to participate in other interlaboratory comparisons (ILC). The laboratory shall authorize the Proficiency Testing (PT) provider to supply a copy of their report to L-A-B. L-A-B strongly encourages the use of an “Accredited” PT provider over another, albeit acceptable PT provider simply because Accreditation of the program provides additional confidence to the user of the PT program. The laboratory shall be required to provide L-A-B with the required information to allow monitoring of the laboratory’s performance in the PT program.

The PT providers that are “Accredited” and approved by L-A-B may be found on L-A-B’s web site under “Informational Resources”

The laboratory shall use the other means recommended in ISO/IEC 17025 that are appropriate for their circumstances. Not all methods will apply to all testing/calibrating, and in some instances, it will not be possible to use any of these techniques for certain types of tests/calibrations. The laboratory should be able to prove that the methods are not appropriate.

Where the laboratory has used the methods and can prove that they are of no value, they are considered to have fulfilled this requirement. They should have documented results that prove it is of no value.

E-Clause 5.9.2—Analysis of quality control data must show it to be within “pre defined criteria” documented by the laboratory. When considering out of control
data and action is to be taken, the laboratory may use procedures relating to non-conforming work and initiate the corrective action necessary.

**Clause 5.10 Reporting the results**

E-Clause 5.10.1— no further guidance necessary

E-Clause 5.10.2—

a) -Titles may be other than those examples given.
b) -No further guidance necessary
c) -No further guidance necessary
d) -No further guidance necessary
e) -No further guidance necessary
f) -No further guidance necessary
g) -This is only critical where testing must be completed within a specific time period after sample is obtained, or where time is a critical factor in the testing and calibration.
h) -No further guidance necessary
i) -No further guidance necessary
j) -No further guidance necessary

E-Clause 5.10.3—Test Reports

E-Clause 5.10.3.1

a) -No further guidance necessary
b) -No further guidance necessary
c) -See comments on clause 5.6.2.2.1
d) -No further guidance necessary
e) -No further guidance necessary

E-Clause 5.10.3.2—

g) -No further guidance necessary
h) -No further guidance necessary
i) -No further guidance necessary
j) -No further guidance necessary
k) -No further guidance necessary
l) -No further guidance necessary

E-Clause 5.10.4—Calibration certificates

E-Clause 5.10.4.1—
a) -No further guidance necessary
b) -An identified metrological specification is one that establishes the
   Uncertainty based on a grade, class or other known specification.
   Classes of weight and classes of gage blocks have specified metrological
   Uncertainties associated with the class or grade.
c) -No further guidance necessary

E-Clause 5.10.4.2—See comments at clause 5.6.2.1.1

E-Clause 5.10.4.3—Before and after calibration data are only required for
instruments that have been repaired or are adjusted during calibration.

E-Clause 5.10.4.4—Calibration laboratories shall not place interval
recommendations on labels unless instructed to do so by their client. The end
user of the item is responsible for identifying the appropriate interval between
calibrations. The intervals are determined based on the following factors:

   o Accuracy and permissible limits of errors
   o Purpose and usage
   o Experience with similar items
   o Manufacturer’s recommendations
   o Stability of the item
   o Past history
   o Other characteristics of the item

Intervals can be defined as a period of time, number of uses (a record is
required), before every use, or a combination of all of these. These intervals
should be documented. Intervals may be adjusted (shortened or lengthened)
based on history of item.
E-Clause 5.10.5—Opinions and Interpretations
No further guidance necessary

**Clause 5.10.6  Testing and calibration results obtained from subcontractors**

E-Clause 5.10.6—Clause 4.1.5 of ISO/IEC Guide 58 states that: “The accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.” Therefore, this subcontracting requirement applies only for subcontracting of any tests or parts of the tests or calibrations included in a laboratory’s scope of accreditation.

Laboratories should document their policies and procedures for selecting subcontractors. Accredited laboratories using subcontractors are responsible for ensuring that the subcontractor has a satisfactory quality system and is competent to perform the required t/c. Reliance on ISO/IEC 17025 accredited laboratories is sufficient, as long as the subcontracted t/c is part of the subcontractor’s scope of accreditation. Investigations of non-accredited, subcontracting laboratories should be carried out by competent technical staff of the laboratory, and verify the subcontractor’s compliance with ISO/IEC 17025.

The laboratory must identify the result from a subcontracted lab. The subcontractor does not need to be identified in the report; however, the laboratory must be able to identify which of their subcontractors produced the results. The laboratory must keep a copy of the subcontractor’s report as part of the job records. In no way is a laboratory to imply that subcontracted work is endorsed by L-A-B, unless the subcontractor is accredited by L-A-B.

E-Clause 5.10.7—Electronic transmission of results- No further guidance necessary

E-Clause 5.10.8—Format of reports and certificates- No further guidance necessary

E-Clause 5.10.9—Amendments to test reports and calibration certificates- No further guidance necessary