TOP 10 ISO/IEC 17025 Deficiencies Found in Electronics Testing Labs

Whether organizations are seeking ISO/IEC 17025 accreditation for the first time, or renewing their accreditation, there are a few frequently overlooked or misunderstood sections of the ISO/IEC 17025 standard to pay close attention to. If you and your team members are aware of these common deficiencies, they can be addressed in internal audits before seeking accreditation from an outside accreditation body.

Here are 10 clauses to consider when seeking accreditation:

Deficiency	Corrective Action
1. 7.2.1: Validation of Methods	This clause has multiple parts, all of which cover the selection, verification, and validation of methods. Laboratories not only have to select methods appropriate for their customer's needs but must also have the appropriate documentation and records to show verification and validation of those methods. Additionally, 7.2.1.5 requires that laboratories verify they are capable of performing a method before introducing it to their scope. Furthermore, when a method is revised by the issuing body, this verification shall be repeated. The depth of this verification is to be determined by the laboratory. However, records must be maintained. This is commonly missed by laboratories adding new methods to their scope or updating standard revisions.
2. 8.8: Internal Auditing	An internal audit needs to confirm the laboratory's management system and activities are in compliance with ISO/IEC 17025. The language in this section is broad to allow laboratories to determine the frequency and depth of the audits, depending on the laboratory's needs and risk tolerance. Once the internal audit plan is decided, records of implementation are required. While ISO/IEC 17025 ultimately leaves it up to the laboratory to determine frequency and depth of internal audits, it is important that laboratories adhere to their own internal procedures and plans. When it comes to internal audits, deficiencies are often cited against the laboratory's own procedure rather than ISO/IEC 17025.

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3. 7.8: Reporting of Results	This section details the requirements for reporting lab results. There are many variables regarding these reports, depending on the customer contract, type of laboratory activities performed, and the methods used. Organizations must take an attentive and individualized approach to applying the requirements of this section. One area commonly missed in this section is 7.8.2.2, which requires the laboratory to identify within the report any data that was supplied by the customer. Additionally, a disclaimer must be made on the report when data is provided by the customer and can impact the validity of results.
4. 7.7: Ensuring the Validity of Results	This section specifies that the laboratory must document procedures that continuously monitor the validity of test results and the required elements the procedure should include. The laboratory must collect and analyze the data from monitoring activities to evaluate and potentially improve their activities. This section also states that laboratories must compare performance and results against other laboratories, which is referred to as proficiency testing. This section frequently uses phrases such as "where appropriate" and "where available." For some laboratories, specific elements of these requirements will not be applicable, but the laboratory should be prepared to account for why that is the case. Regardless of the monitoring activities chosen by the laboratory, it is important that pre-defined criteria are determined, and results are recorded in a way in which trends are detectable. Oftentimes, laboratories overlook these requirements, resulting in a deficiency. These steps are crucial in maintaining confidence and quality in a laboratory's results.
5. 7.5: Technical Records	The focus of this section is the traceability and reproducibility of results. All laboratory activities must have technical records that are detailed enough to reproduce the exact process that initially produced them. This means that many factors will need to be consistently recorded, and both original records and their amendments must be retained. Deficiencies in this area are commonly cited for failing to record relevant environmental conditions such as temperature and humidity or simply omitting who performed the test and when.

Deficiency	Corrective Action
6. 6.6: Externally Provided Products and Services	It is impossible to completely control what goes on outside your lab, but the quality of externally provided products and services is still within your control. This section requires that laboratories determine the suitability of externally provided products and services in a way that supports compliance. It requires that the lab create, document, and maintain procedures, evaluation criteria, and communication methods. Oftentimes, deficiencies are cited because a laboratory does not document or record the appropriate processes and criteria required by 6.6.2 a) through d). Furthermore, it is common for a laboratory to define their requirements for evaluating a supplier but failing to include how the supplier will be re-evaluated and what actions will be taken based on this evaluation.
7. 6.2.5: Personnel Procedures and Records	This clause requires that laboratories have procedures for and retain records of various activities related to the competence, training, and monitoring of personnel. There is a list of specific topics that need to be addressed, either in one procedure or individual procedures. All relevant personnel must adhere to these procedures and records of implementation must be maintained in all cases as objective evidence that they are following all procedures. Similar to section 6.6 discussed above, laboratories oftentimes fail to define the various processes and criteria required by this section. Clause 6.2.5 a) through f) requires that the laboratory maintain procedures and records for determining competence requirements as well as selection, training, supervision, authorization, and monitoring of personnel. It is common for a laboratory to miss one or more of these items in their personnel procedures or records.
8. 6.2.2: Documented Competencies and Supporting Records	The standard states that competencies must be documented and include several elements, including education, training, and experience. Each position category that has an influence on laboratory results must have a documented level of competency. Additionally, it is important to keep in mind that 6.2.5 a), discussed above, requires that the laboratory maintain a procedure for determining competence requirements, an area commonly missed.

Deficiency	Corrective Action
9. 8.9.2: Management Review Inputs	This clause contains a list of 15 items that must be recorded as part of a management review, all of which the laboratory must take care to cover and record. This section may be removed from the list in the next year or so as renewal laboratories get their management review process in order and conduct these reviews with records showing each input. Common deficiencies in this area are often cited against failing to miss one or two of the 15 items required by 8.9.2 a) through o). Similar to internal audits discussed above, it is up to the laboratory to determine the frequency of their management reviews. However, the intervals shall be planned. It is important for the laboratory to follow their own internal procedures here as deficiencies are often cited for not adhering to planned schedules or processes.
10. 6.4.: Equipment	Based on our data, this section of the standard is the one that has most frequently proven challenging to electronics testing laboratories. In the most recent version of the standard, the term "equipment" is used to refer to all types of laboratory resources, including measuring equipment, reference standards, reference materials, reagents, consumables, and more. This section requires procedures for all equipment, including, but not limited to, accessibility, maintenance, storage, calibration, and record-keeping. It lists the specific equipment records that laboratories must maintain for all the equipment in their facility which can influence the activities listed on their scope of accreditation.

The most commonly cited deficiencies in this area are related to equipment calibrations. When sending equipment out for calibration, it is imperative for the laboratory to be aware of specific calibration requirements (procedures, frequency ranges, etc.) outlined in a given test method. Other commonly cited deficiencies in this area include failing to record software and firmware versions in equipment records (6.4.13a), not labelling, coding, or otherwise identifying the calibration status of laboratory equipment so that it is clear to all personnel (6.4.8), and failing to maintain a maintenance plan and maintenance records for relevant equipment (6.4.13g).

Electrical Testing Accreditation Program Information