

Most Common Deficiencies

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Assessment Process Leading To Report Package

- ❖ Agreement on assessor
- ❖ Assessor conducts document review
 - ❖ Quality manual
 - ❖ System and technical procedures
- ❖ Schedules assessment
- ❖ Pre-assessment considerations
- ❖ Conducts assessment
 - ❖ Assessor Report
 - ❖ Deficiency Report

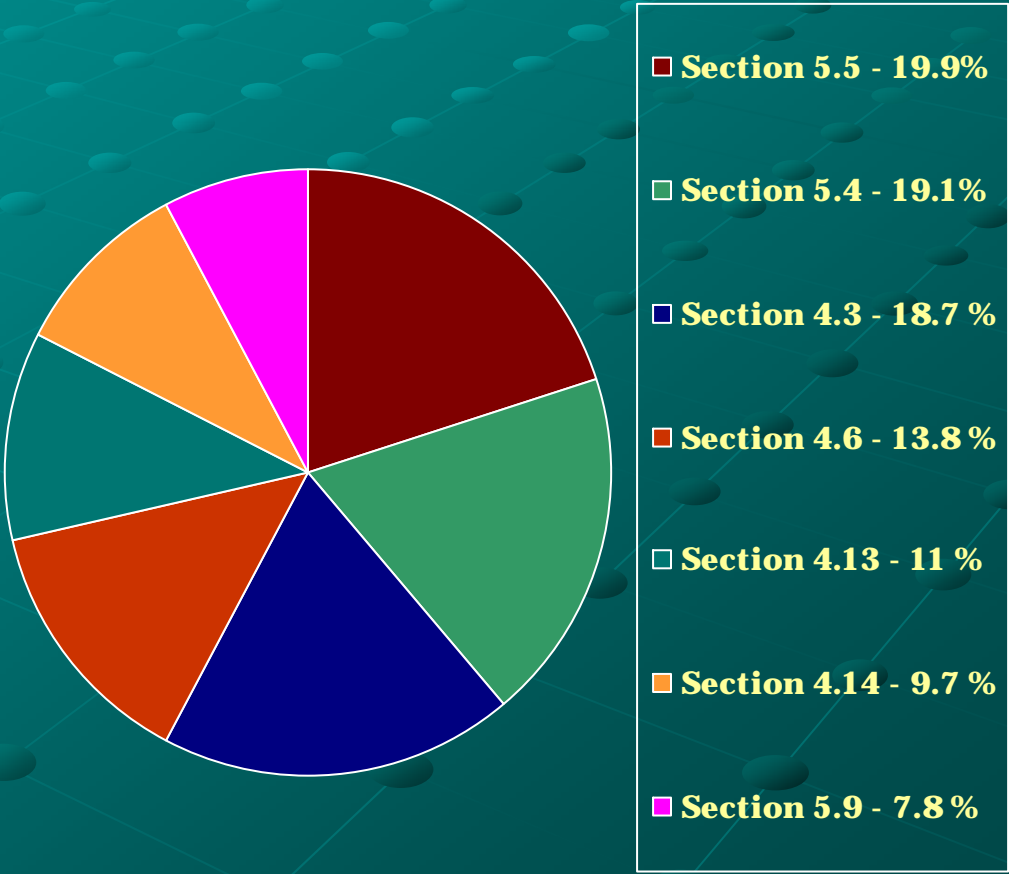
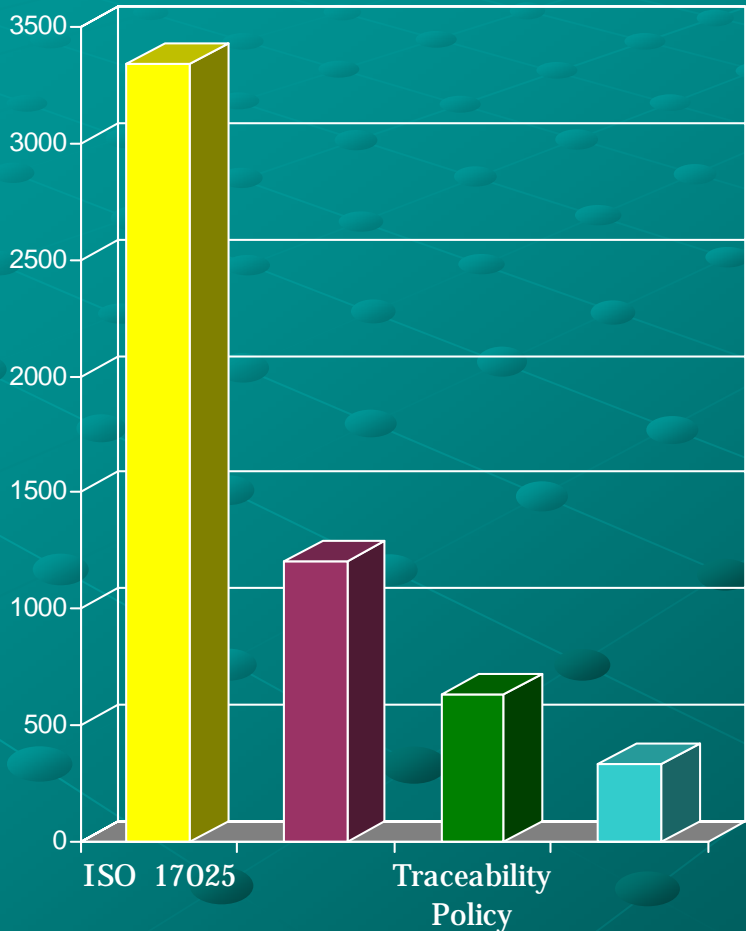
Assessment Criteria

- ❖ ISO/IEC 17025:2005
- ❖ Specific Field/Program Criteria
- ❖ Laboratory's Management System
- ❖ Technical Requirements of Methods
- ❖ A2LA Policies
- ❖ Customer Specifications

Breakdown of Most Common Deficiencies

January 2008 through January 2009

- ISO 17025
- Specific
- Traceability Policy
- PT Policy



NUMBER 10:

ISO 17025 Section 5.9, Assuring the Quality of Test and Calibration Results Deficiency Examples:

- ❖ Data from quality control procedures was not recorded in a way that trends were detectable.
- ❖ Quality control data was found to be outside of pre-defined criteria and no action was taken to correct the problem.
- ❖ The organization was not able to produce a plan for monitoring the validity of tests and calibrations undertaken.

ISO 17025 Section 5.9, Assuring the Quality of Test and Calibration Results: Common Causes of These Deficiencies

- ❖ Organization assumed that their participation in proficiency testing satisfied requirements, which is not always the case.
- ❖ Organization was not aware that a document was required for determining pre-defined criteria.
- ❖ Organization was not aware that they are required to record the planned action taken when quality control data is determined to be outside per-defined criteria.

NUMBER 9:

ISO 17025 Section 4.14, Internal Audits

Deficiency Examples:

- ❖ The organization's internal audit did not verify continued compliance with their calibration/testing activities.
- ❖ The organization was unable to provide objective evidence that the internal auditor was trained and qualified to perform the audit.
- ❖ The area of activity audited was not recorded.

ISO 17025 Section 4.14, Internal Audits

Common Causes of These Deficiencies:

- ❖ The standard requires that the internal audit must cover 3 areas: compliance with ISO 17025; your own management system; and your calibration/testing activities.
- ❖ The internal auditor either had not been trained or there was no record that they had been trained.
- ❖ Organization only retained evidence of findings from internal audit and did not retain records of all areas audited.

NUMBER 8:

A2LA Proficiency Testing for ISO/IEC 17025 Laboratories

Deficiency Examples:

- ❖ The organization's four year plan did not cover all the sub-disciplines on their scope of accreditation.
- ❖ The laboratory did not participate in two proficiency testing events per year.
- ❖ The organization did not submit their proficiency testing results to A2LA.
- ❖ The organization's proficiency testing plan did not include what they would do in lieu of acceptable proficiency testing.

A2LA Proficiency Testing for ISO/IEC 17025 Laboratories

Common Causes of These Deficiencies :

- ❖ Organizations proficiency testing plan was not detailed enough to explain how all the sub-disciplines of their scope would be covered in four years.
- ❖ Proficiency Testing provider may have delayed availability of test and organization did not revise plan to participate in two events per year.
- ❖ Organization assumes that no proficiency testing plan is needed if they offer unique calibrations for which there is not acceptable proficiency testing available.

NUMBER 7:
ISO/IEC 17025 Laboratories Section 4.13,
Control of Records
Deficiency Examples:

- ❖ A technician recorded original data and calculations on his/her worksheet and threw away the worksheet after transferring the final results to the computer.
- ❖ Records were discovered with information made illegible or scratched out and/or alterations to the records where not signed or initialed.
- ❖ The organization had not recorded sufficient data to establish an audit trail.

ISO/IEC 17025 Laboratories Section 4.13, Control of Records

Common Causes of These Deficiencies:

- ❖ Organizations often do not consider their worksheets as records of original observations.
- ❖ Records of data are not always retained when the final report is issued. It is, therefore, not possible to establish an audit trail.
- ❖ General misunderstanding of requirements when making revisions/edits to records.

NUMBER 6:

ISO/IEC 17025 Laboratories Section 4.6, Purchasing Services & Supplies

Deficiency Examples:

- ❖ The organization was unable to produce records to show that actions were taken to ensure that the received services and/or supplies complied with the specified requirements.
- ❖ The organization had utilized a supplier that they had not evaluated.

ISO/IEC 17025 Laboratories Section 4.6, Purchasing Services & Supplies

Common Causes of These Deficiencies :

- ❖ Many times an organization has an appropriate procedure in place to create and maintain the appropriate records. However, sometimes the procedure adopted can become cumbersome and the organization does not end up following the procedure in practice.
- ❖ Organizations do not always keep records of their supplier evaluations or a current list of suppliers that they have approved.

NUMBER 5:
ISO/IEC 17025 Laboratories Section 4.3,
Document Control
Deficiency Examples:

- ❖ The organization's Master List was not up to date.
- ❖ Technician was witnessed using obsolete procedure during calibration/test.
- ❖ Documents in the organization's management system were not uniquely identified and/or did not include the required identification.

ISO/IEC 17025 Laboratories Section 4.3, Document Control

Common Causes of These Deficiencies :

- ❖ Many times clerical errors are made regarding this section. Documents do not get updated appropriately due to human error.
- ❖ Many organization's quality procedures, SOPs, and other controlled documents are available electronically. If people in the organization are able to print these documents it can often cause problems with the use of obsolete documents. Especially if there is not a system to track who has printed what version of a procedure.

NUMBER 4:

A2LA Policy on Measurement Traceability

Deficiency Examples:

- ❖ The organization had not received and acceptable accredited calibration for their XYZ standard. (T1)
- ❖ The organization calibrates its XYZ standard in-house and they do not have and/or apply a procedure for calculating measurement uncertainty. (T9)

A2LA Policy on Measurement Traceability

Common Causes of These Deficiencies :

- ❖ **An organization did not provide enough information in their purchase order to ensure that they would receive an expectable accredited calibration.**
- ❖ **An acceptable accredited provider is not available due to a unique piece of equipment and the organization did not request an exception and provide the appropriate supporting documentation with the request.**

Requesting an Exception to the A2LA Traceability Policy with Form F108/F112

- ❖ Equipment name, model, and identification number
- ❖ Parameter and range of calibration needed
- ❖ Key words used in any website search for an accredited calibration provider
- ❖ List all sources investigated (e.g. specific accreditation body websites, hardcopy directories, state metrology labs, etc.)
- ❖ Reverse traceability study-objective evidence that the measurement being provided by your present calibration provider is traceable to the SI

NUMBER 3:

ISO/IEC 17025 Laboratories Section 5.4, Test and Calibration Methods and Method Validation

Deficiency Examples:

- ❖ The organization's procedure XYZ did not contain Instruction A which could jeopardize the results of tests and/or calibrations.
- ❖ The organization uses internal procedure XYZ which had not been validated prior to use.
- ❖ Not all components which are of importance have been taken into account when the organization estimates the uncertainty of measurement.

ISO/IEC 17025 Laboratories Section 5.4, Test and Calibration Methods and Method Validation

Common Causes of These Deficiencies :

- ❖ Common problems in this area include lack of method validation and improper or incomplete estimates of measurement uncertainty
- ❖ Some documents that can be used for guidance:

P103-Policy on Estimating Measurement Uncertainty for Testing Laboratories

ISO *"Guide to the Expression of Uncertainty in Measurement"*

NUMBER 2:

ISO/IEC 17025 Laboratories Section 5.5, Equipment Deficiency Examples:

- ❖ The organization failed to check it's equipment when it was received after calibration, maintenance, or repair
- ❖ The organization had not calibrated their equipment before placing it into service.
- ❖ The organization did not have the necessary equipment required for the correct performance of the tests and/or calibrations.

ISO/IEC 17025 Laboratories Section 5.5, Equipment

Common Causes of These Deficiencies :

- ❖ Organizations are sometimes not aware that they are to check the equipment when it is received back from calibration.
- ❖ Calibration cycles have been extended and not properly documented.
- ❖ Equipment has been broken, misplaced, or used without being replaced or repaired.

**And The Number One Most Cited
Deficiency Category.....**

“Specific Deficiencies”

- ❖ Deficiencies that fall in this category are those cited for lack of compliance with requirements that fall outside the ISO 17025 standard, such as C205 - A2LA Calibration Program Requirements and P101 – A2LA Advertising Policy.
- ❖ The most common specific deficiencies are those cited against laboratories for not following their own policies & procedures.

Resources

- ❖ [www. A2LA.org](http://www.A2LA.org)
Understanding ISO/IEC 17025
- ❖ Call us at :301-644-3248
and speak with your Accreditation Officer





Questions?

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