

Most Commonly Cited Deficiencies (12/06/02)

At the request of the A2LA Board of Directors, Teresa C. Adams, A2LA Operations Manager, conducted a study to determine the most common deficiencies cited during A2LA assessments. To accomplish this, data from 299 assessment reports, covering all fields and from 81 different assessors were collected and analyzed from March through September 2002. These assessments included solo assessor assignments, assessor team assignments as well as surveillance assignments.

Deficiencies cited during each assessment were collected for ISO/IEC 17025, the A2LA Traceability Policy, the A2LA Advertising Policy, the A2LA Conditions for Accreditation, and the A2LA Requirements for Proficiency Testing Participation, all of which are applicable to all laboratories, across all fields.

There was an indication that several sections of ISO/IEC 17025 pose a problem with regard to a basic understanding of the meaning or intent of the section. In other words, when findings were noted, they were typically noted for the **entire** section, not merely a specific clause or two within the section. These problem areas include:

- (1) Section 4.6 – Purchasing Services and Supplies
- (2) Section 4.10 – Corrective Actions
- (3) Section 4.11 – Preventive Actions
- (4) Section 4.12 – Control of Records
- (5) Section 4.13 – Internal Audits
- (6) Section 4.14 – Management Review
- (7) Section 5.2 – Personnel

The information provided in this report can be extremely useful to laboratories and assessors alike. It points to several key areas where problems, misunderstandings and misinterpretations commonly occur and it can be used as a training tool to ensure a more thorough understanding of the requirements for accreditation. It is understood that many of these problem areas may be attributed to issues that are to be expected with the implementation of a new standard. However, bringing these specific issues to the forefront can only serve to make everyone more aware of areas where further attention should be directed.

Table 1: Summary – Average Number and Type of Deficiencies Cited

	General Criteria	Specific Criteria	Total
Full Assessments	Average 8 Defs	Average 3 Defs	Average 11 Defs
Surveillance Assessments	Average 5 Defs	Average 2 Defs	Average 7 Defs

Table 2: Number of Deficiencies Cited Per Section

<i>Standard/Section</i>	<i>Number Defs Cited</i>
17025 Section 4.1 – Organization	106 Findings
17025 Section 4.2 – Quality System	143 Findings
17025 Section 4.3 – Document Control	194 Findings
17025 Section 4.4 – Review of Requests, Tenders, Contracts	61 Findings
17025 Section 4.5 – Subcontracting	29 Findings
17025 Section 4.6 – Purchasing Services & Supplies	150 Findings
17025 Section 4.7 – Service to the Client	2 Findings
17025 Section 4.8 – Complaints	24 Findings
17025 Section 4.9 – Control of Nonconforming Work	56 Findings
17025 Section 4.10 – Corrective Action	69 Findings
17025 Section 4.11 – Preventive Action	35 Findings
17025 Section 4.12 – Control of Records	123 Findings
17025 Section 4.13 – Internal Audits	100 Findings
17025 Section 4.14 – Management Review	63 Findings
17025 Section 5.1 – General Technical Requirements	18 Findings
17025 Section 5.2 – Personnel	109 Findings
17025 Section 5.3 – Accommodation and Environment	75 Findings
17025 Section 5.4 – Methods and Method Validation	365 Findings
17025 Section 5.5 – Equipment	202 Findings
17025 Section 5.6 – Measurement Traceability	162 Findings
17025 Section 5.7 – Sampling	5 Findings
17025 Section 5.8 – Handling of Test/Calibration Items	22 Findings
17025 Section 5.9 – Assuring the Quality of Results	90 Findings
17025 Section 5.10 – Reporting Results	150 Findings
A2LA Advertising Policy	72 Findings
A2LA Conditions for Accreditation	4 Findings
A2LA Proficiency Testing Requirements	69 Findings
A2LA Traceability Policy	242 Findings

Table 3: Most Commonly Cited Criteria

<i>Criteria</i>	<i>Number of Citations</i>
<i>Cited at least 30% of the time...</i>	
T1 (Traceability Policy) - All calibrations and verifications shall be conducted by accredited calibration laboratories...	147 Citations
17025 Section 5.4.6.2 – Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement...	103 Citations
<i>Cited between 20-30% of the time...</i>	
17025 Section 4.13.1 – The laboratory shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits...	70 Citations
<i>Cited between 15-20% of the time...</i>	
17025 Section 5.9 – The laboratory shall have quality control procedures...The resulting data shall be recorded in such a way that trends are detectable...This monitoring shall be planned and reviewed and may include...	57 Citations
17025 5.4.6.1 – A calibration lab or a testing lab performing its own calibrations shall have and shall apply a procedure to estimate the uncertainty of measurement...	57 Citations

<i>Criteria</i>	<i>Number of Citations</i>
17025 Section 5.4.6.3 – When estimating the uncertainty of measurement, all components which are of importance...shall be taken into account...	52 Citations
Advertising Policy – Section 1.1 – The lab shall have a policy and procedure for controlling the use of the term ‘A2LA’ and the A2LA logo...	50 Citations
17025 Section 4.14.1 - In accordance with a predetermined schedule and procedure, the lab’s executive management shall conduct a review of the lab’s activities...The review shall take account of...	49 Citations
17025 Section 4.6.2 – The lab shall ensure that purchased supplies...are not used until they have been inspected...as complying with standard specifications...	48 Citations
17025 Section 5.2.2 – Management shall formulate the goals with respect to education, training and skills...The lab shall have a policy and procedures for identifying training needs...	44 Citations
<i>Cited between 10-15% of the time...</i>	
17025 Section 5.4.1 – The lab shall use appropriate methods and procedures...The lab shall have instructions on the use and operation of all relevant equipment...	43 Citations
17025 Section 4.6.4 – The lab shall evaluate suppliers of critical consumables...and shall maintain records of these evaluations...	42 Citations

<i>Criteria</i>	<i>Number of Citations</i>
17025 Section 4.3.2.1 – All documents...as part of the quality system shall be reviewed and approved for use...A master list...shall be established...	41 Citations
17025 Section 5.5.2 - ...Calibration programs shall be established...Before being placed into service, equipment shall be calibrated or checked...	40 Citations
17025 Section 5.3.1 – The lab shall ensure that environmental conditions do not invalidate the results...Technical requirements for accommodation and environmental conditions...shall be documented.	35 Citations
17025 Section 4.6.1 – The lab shall have a policy and procedure for the selection and purchasing of services and supplies...Procedures shall exist for...purchase, reception and storage...	34 Citations
17025 Section 5.3.2 – The lab shall monitor, control and record environmental conditions as required...Tests and calibrations shall be stopped when...conditions jeopardize the results...	33 Citations
17025 Section 5.6.3.1 – The lab shall have a program and procedure for the calibration of its reference standards...Reference standards shall be calibrated by a body that can provide traceability...	32 Citations
17025 Section 5.5.10 – When intermediate checks are needed...these checks shall be carried out according to a defined procedure.	31 Citations
17025 Section 4.12.2.1 – The lab shall retain records of original observations...	30 Citations

<i>Criteria</i>	<i>Number of Citations</i>
17025 Section 5.4.2 – The lab shall use methods... which meet the needs of the client... The lab shall ensure that it uses the latest valid edition of a standard... Lab developed methods... may also be used if they are appropriate... and if they are validated...	31 Citations
17025 Section 5.2.5 - ...The lab shall maintain records of the relevant authorizations, competence... qualifications, training, skills and experience...	31 Citations