

A2LA ASSESSOR CONCLAVE

PLENARY SESSION SUMMARY

Saturday, March 12th, 2005, 8:00 A.M.

1) Welcome

A2LA Vice President, Roxanne Robinson, welcomed all attendees and discussed an overview of the scheduled meeting agenda, particularly the refresher training intended to improve assessor uniformity. It was pointed out that there was a change to the meeting assignments for Sunday, March 13, and a revised schedule and room assignment sheet was available.

2) Refresher Training on the A2LA Accreditation Requirements

A2LA Communications Manager, Daren Valentine, informed attendees that his presentation would discuss interpretations and questions regarding ISO/IEC 17025. The discussion would center on items that A2LA Laboratory Services Officers (LSOs) had submitted to him as common problems they have noted in assessor deliverables with regard to the validity of deficiencies cited. The assessors asked that LSOs discuss any such problems with them first before the lab is informed that a deficiency is to be struck from their record, in the event that further clarification would render the deficiency valid. R. Robinson confirmed that A2LA's internal SOP does require the LSO to communicate with the assessor before a deficiency is struck. It was pointed out that assessors should not take offense at the scrutiny and questions from LSOs, as it is our common goal to increase the consistency of our assessments.

The assessors questioned whether or not the interpretations posted to the A2LA website following the 2004 Conclave are periodically reviewed and updated. D. Valentine confirmed that these interpretations are meant to be kept current, however no new interpretations have been submitted for posting since the 2004 Conclave. The process whereby an interpretation is decided upon and disseminated was discussed, and it was reiterated that LSOs approach their Program Manager, Operations Manager, Communications Manager and/or Vice President to discuss any new interpretations before they are disseminated to labs and assessors.

Action: TMcInturff to formally document how and through whom interpretations are made and provided to assessors (by April 14, 2005).

It was pointed out that assessors are now able to cite observations if a situation is of concern to them but there are no requirements that are being violated. Staff was asked to develop a template form that can be used for documenting observations such that it is clearly explained to the laboratory what the observations mean, what its responsibility may be with regard to responding to them, etc.

Action: R. Robinson to develop a template form for assessors to use to document observations. The form must also include a clear explanation for laboratories on the significance/meaning of observations and what their responsibilities may be with regard to responding to them (by April 14, 2005).

The question was raised as to whether or not having observations documented in a lab's file would adversely affect A2LA during peer evaluations, particularly if some observations appear to be valid deficiencies. R. Robinson reiterated that staff will be reading all observations to ensure that they should not have been cited as deficiencies. It was suggested that assessors be required to document why their observations could not be considered deficiencies (i.e., document what piece of information was missing that would have allowed it to be documented as a deficiency). It was also suggested that labs be given the option of having observations documented by their assessor or not.

Action: R. Robinson to further investigate whether or not labs should be given the option of receiving documented observations from their assessor (by April 14, 2005).

DValentine proceeded with his presentation, discussing sections of ISO/IEC 17025 and how they are to be interpreted (Attachment 1). Various issues raised during the presentation follow.

- A question was raised concerning whether or not the interpretations document contained on the "assessor only" portion of the A2LA website could be provided to laboratories as well. It was clarified that these interpretations provide only a baseline for the absolute minimum necessary to comply with the requirements. Providing this to the laboratories could result in a minimal quality system that does nothing to further and improve quality within an organization and so we encourage labs to develop means appropriate to them for meeting the accreditation requirements, hopefully above and beyond the minimum. It was pointed out, however, that in response to an inquiry from any particular laboratory, A2LA staff will discuss the minimum necessary to meet a requirement and so this information should be available to all laboratories.

ACTION: Staff (lead by DValentine) to discuss whether these interpretations can and should be converted into FAQs that can be posted to the website for general information (by April 14, 2005).

- The question was raised regarding where A2LA has documented their position that laboratory procedures must be documented, since the normative references noted in ISO/IEC 17025 define a procedure as “written or unwritten”. It was clarified that this is specified in the A2LA *Conditions for Accreditation*, which require laboratories to have procedures in a reproducible form, and also within various sections of ISO/IEC 17025 itself.
- Staff was asked if there is a system in place for capturing notices sent to assessors that outline problems with their deliverables such that trends can be detected and appropriate root cause analysis and corrective action performed. R. Robinson confirmed that such problems are being captured in assessor records and corrective actions are taken on trends noted with a single assessor.
- It was asked whether or not labs must own a copy of the normative references noted in ISO/IEC 17025 in addition to all A2LA policy and requirements documents. D. Valentine indicated that a laboratory need not necessarily have these documents on-site if it is able to access/obtain them whenever necessary. It was suggested that P. Unger discuss this matter within ILAC to determine how our international peers are addressing this question.

Action: BMoore to write an article for the April 2005 newsletter regarding whether or not labs are required to own copies of all normative references noted in ISO/IEC 17025 (by April 30, 2005).

It was suggested that the A2LA “assessor only” portion of the website include critical definitions for terms used in ISO/IEC 17025 and also the actual normative references for their use.

Action: Staff (P. Unger and T. Barnett) to devise a means for keeping laboratories and assessors informed of changes and updates to ISO documents and normative references beyond ISO/IEC 17025 and A2LA policies and requirements (by April 30, 2005).

- Discussion took place regarding A2LA’s requirements for participation in proficiency testing vs. ISO/IEC 17025, Section 5.9. It was pointed out that areas of a laboratory’s Scope of Accreditation need never be covered by proficiency testing as long as another area under that particular sub-discipline is covered. P. Unger clarified that ILAC’s current requirements are set up differently from A2LA’s, since it determined that the concept of sub-disciplines is appropriate for calibration laboratories but is not stringent enough for testing laboratories. Therefore, it is possible that A2LA may resort to issuing two separate PT requirements documents, one

for calibration labs, one for testing labs. In the meantime, the technical advisory committees were tasked with reviewing and discussing their current breakdown of sub-disciplines to ensure that they are comprehensive enough to result in thorough coverage of a lab's Scope for proficiency testing purposes.

Action: A2LA staff representatives to technical advisory committees are to ensure that the topic of sub-disciplines is discussed within their committees to ensure they are adequately defined for the purposes of the proficiency testing requirements document (by March 31, 2005).

- It was clarified that A2LA's current interpretation is that, if a laboratory is meeting the A2LA proficiency testing requirements, they are meeting ISO/IEC 17025, Section 5.9 in its entirety. Disagreement with this interpretation was voiced.

Action: A2LA management (R. Robinson, P. Unger, D. Valentine) to revisit the current interpretation of ISO/IEC 17025, Section 5.9 as it relates to compliance with the A2LA proficiency testing requirements (by April 14, 2005).

- The question was raised as to whether or not the asterisk in the *Assessor Checklist* for ISO/IEC 17025, Section 5.9.1 is appropriately placed, since there is some confusion regarding what records an assessor is being asked to review, records that the lab has performed some proficiency testing or records that the lab has reviewed/monitored its own proficiency testing data. R. Robinson clarified that assessors should be examining and verifying records for both.

Action: R. Robinson to review the *Assessor Checklist* to be sure that the asterisks are in the proper place for Section 5.9.1 so that assessors indicate records reviewed for proficiency testing and lab review/monitoring of proficiency testing data and trends (by April 14, 2005).

- A discussion took place regarding the meaning of "opinions and interpretations." It was clarified that most laboratories do not offer opinions and interpretations on their final reports. Rather, they most often simply report results and make a statement of whether it is in or out of tolerance.

A2LA Quality Manager, Teresa Barnett, gave a brief presentation (Attachment 2) on revisions and clarifications to the *A2LA Advertising Policy*.

Action: P. Unger to explore whether or not A2LA must implement an explicit sub-licensing agreement for labs to sign and return to us in order to use the “ILAC MRA – A2LA Accredited” combined symbol (by April 30, 2005).

3) Software Verification

A2LA Assessor, Greg Gogates, offered a presentation on software verification (Attachment 3). It was clarified that this presentation outlined guidance and good lab practice, not requirements that assessors and labs must follow.

Attendees were informed that a Eurolab committee is compiling a document offering interpretations for all clauses of ISO/IEC 17025 that relate to software. The document has undergone comment and has been finalized. Distribution is anticipated later in 2005.

4) Assessment to T9 of the Traceability Policy

A2LA Senior Laboratory Services Officer, Tim Rasinski, delivered a presentation regarding the A2LA *Traceability Policy*. Input was requested from laboratories and assessors regarding the depth to which testing laboratories should be expected to meet T9 for internal calibrations that they perform. It was also clarified that deficiencies should be cited against ISO/IEC 17025, Section 5.4 for testing laboratories that are using inadequate or inappropriate procedures for internal calibrations (rather than against T9 of the *Traceability Policy*).

5) PT Matrix Form and Its Use

A2LA Operations Manager, Trace McInturff, delivered a presentation on the *Proficiency Testing Matrix* and the manner in which it should be used (Attachment 4). Several assessors pointed out that they are not consistently receiving the laboratory's proficiency testing history with their assignment packages.

Action: TMcInturff to investigate why assessors are not consistently receiving proficiency testing history with their assignment packages and ensure that this happens with every assignment processed by staff (by March 31, 2005).

It was also pointed out that assessors are not receiving the database printout of the proficiency testing data that staff receives and monitors. However, staff felt it was too early to begin doing this in any field other than calibration, since the database monitoring system was just implemented for those fields within the past year.

It was again reiterated this year that the proficiency testing participation requirements are unfairly weighted against small labs that only have a few tests/parameters on their

Scope of Accreditation. Attendees were reminded that the twice-per-year participation requirement was established by A2LA and that ILAC and APLAC only require that a lab's full scope be covered over a 4-year period.

Action: TMcInturff to discuss minimum proficiency testing participation requirements at the upcoming APLAC proficiency testing committee meeting, to determine whether or not A2LA can introduce more flexibility into our requirements so that they are more equitable for smaller laboratories (by April 30, 2005).

6) Other Issues

No other issues were raised during the Plenary Session.

Meeting adjourned at 4:05 P.M.

Minutes prepared by Teresa C. Barnett, A2LA QualityManager.