

Summary of the A2LA Life Sciences Advisory Committee Meeting

(Sunday, March 13, 2005)

The 34th meeting of the A2LA Life Science Advisory Committee (LSAC) was held on Sunday, March 13, 2005 at the Sheraton Columbia Hotel in Columbia, MD.

1. Introduction (8:30 am)

Approval of Last Meeting's Summary and Agenda

Motion 1: A. Liabastre: Approve the summary of the 33rd meeting of the LSAC with no amendments. (Motion passed).

2. **DISCUSSION – Environmental Program**

Stack Testing Accreditation – A2LA's Involvement

M. Miller and F. Jarke led a discussion on the topic “Should A2LA Accredit Stack Testing per ASTM D7036?”

If A2LA should accredit these laboratories, should the accreditations be conducted under our current environmental or chemical programs? M. Miller stated that the addition of the NELAC requirements created a larger burden on the laboratories than necessary. The interested laboratories requested to be assessed only to ISO/IEC 17025 without any additional requirements.

Should the Site-Testing Requirements be used? F. Jarke informed us that 1/3 of the states assess his laboratory. M. Miller said that when only a home-based audit is performed, then not all tests could be performed due to the type of testing. There is a lot of rental equipment within the Stack Testing Community. M. Miller suggested that we look at the competency of the laboratory staff due to equipment rentals. M. Moore has completed an intense audit through reports and then went out in the field to observe the laboratory staff. A. Liabastre asked if this is an activity that A2LA really wants to be involved with. F. Jarke has never used the On-Site Testing checklist from A2LA, however, the State of Pennsylvania has an appropriate checklist with technical components. A. Liabastre pointed out that a checklist is needed that is devoted explicitly to Stack Testing. M. Moore and F. Jarke agreed. M. Moore stated that the current 17025 checklist in addition to an ASTM checklist would be sufficient. The point was made that assessors must be in good physical shape in order to conduct these assessments.

A vote was requested to determine if any one thought that NELAC should be involved. None of the attendees were of the opinion that A2LA should pursue this route. The discussion then considered 17025 vs. ASTM. M. Miller presented a comparison between 17025 and the ASTM method. A major difference was that ASTM (5.2) requires that the analyst perform 10 tests, possess 1 year of air experience, and take/pass an exam, however

it is not a performance test. Another big difference is that the auditor has to meet the same criteria as the personnel: 1 year experience, pass exam, and completed 10 stack tests.

G. Rodrigues asked what the benefit would be, how many laboratories are out there, and can we assess them competently. S. Lerman stated that, to please the industry, A2LA will have to assess to the ASTM method, but that the Board should specify that 17025 is also to be used. M. Miller asked a bi-partisan individual that runs a stack lab and he said that he wants 17025 instead of the ASTM, because he feels that it does more for him internationally. It was thought that, without the states requiring the accreditation, the stack testing companies will not want to become accredited. K. Stoub indicated that the Criteria Council would want to see that 17025, the ASTM guidance, and the On-Site testing requirements are used for these laboratories. B. Kavanagh also suggested that A2LA needs to take into account the liability that would be incurred by A2LA.

Motion 2: Through a show of hands, the committee recommended that the requirements of ISO/IEC 17025 should be used instead of ASTM D7036 or NELAC (3 abstains).

Motion 3: If additional Stack testing program requirements are developed, they should incorporate the requirements specified in the A2LA On-Site Testing checklist as well as combining the requirements specified in ASTM D7036, those from the EPA, and from the states of Louisiana and Pennsylvania. The creation of new program requirements will be started if the BOD approves the addition of this new business.

3. Results of the 2004 LSAC Officer Balloting

R. Brauninger provided results from the balloting for officers of the LSAC for the January 1, 2005 to December 31, 2006 term. Based upon the outcome of the balloting the A2LA Board of Directors approved the following individuals during their Fall 2004 meeting:

Chairman:	Mitzi Miller
1 st Vice Chairman:	Dan Tholen
2 nd Vice Chairman:	George Rodrigues
Recording Secretary:	Roger Brauninger

4. Calibration vs. Verification

S. Lerman led a discussion on the concepts and meaning of the terms *calibration*, *verification*, and *standardization*. S. Lerman developed definitions as a proposal for common usage. D. Tholen stated that the VIM definitions were not used and expressed concern with the reasoning behind the definitions presented. S. Lerman clarified that he was looking to propose a concept not a definition.

M. Moore reminded all attendees that ISO/IEC 17011 is the new document that we are currently working under. A calibration can be completed with a single point according to M. Moore. M. Moore informed attendees that the international community is coming together with definitions and we need to begin moving towards agreement within the community as a whole. A year ago the LSAC had decided to call everything (verification, standardization, calibration) a calibration.

M. Moore read the definitions for calibration from the other standards. J. Scott informed attendees that ISO 9000 is moving toward a management standard and they take the VIM vocabulary and create a behavioral standard. A. Liabastre informed attendees that the new standard is now a management system standard and is incorporating all of the VIM definitions. K. Stoub read A2LA's Traceability Policy (T1 and T9).

It was suggested that a task group be set up to consider recommending removal of the term *verification* from T9 since this is not a term used anywhere within ISO 17025. K. Stoub noted that the term *intermediate check* should be used instead as this is the term used in 17025.

Motion 4: K. Stoub recommended that a task group be formed to develop common terms that are going to be used (hierarchy of documents).

Motion 5: M. Miller recommended that the LSAC form a task group to provide guidance on how the terms: Calibration, Calibration Laboratory, Verification, Reference Materials/Reference Standards, Intermediate Check or Checks, Standardization, Method Validation and Measurand are to be understood as they relate to specific equipment, including: Analytical balances, Thermometers, pH meters, Incubators, Ovens, Centrifuges, Mechanical pipettes, Class A pipettes, Reference weights, Optical micrometers, Ultra low temperature freezers, and Analytical measuring equipment (ICP/MS, GC/MS, LC, Spectrophotometers).

Motion 6: K. Stoub recommended that the same task group review the A2LA Traceability Policy particularly with respect to clauses T1 and T9.

Action Item 1: K. Stoub to request the Criteria Council (CC) to identify the hierarchy of normative documents to be used as the basis for identifying the appropriate terminology (by March 13, 2005).

Action Item 2: A task group was set up consisting of: Marlene Moore (leader), Dave Evanson, and George Rodrigues (for definitions), Linda Crumpler, Pat Royal, Dawn Latham, Dawn Mettler, and Dave Evanson (for equipment examples). The group, upon completion, will submit the material to the LSAC for review and comments (by September 30, 2005).

Action Item 3: The task group (with the addition of Roger Brauninger and Ada Hensley) will also be responsible for the review of T1 and T9 of the Traceability Policy. Upon completion, submit draft to the LSAC for review and comments (by September 30, 2005).

5. T1 – Its Relationship to Reference Materials and Reference Material Producers

S. Lerman then led a discussion on reference materials and standards with respect to T1 of A2LA's Traceability Policy and ISO Guide 34: 2000 "General Requirements for the Competence of Reference Material Producers". G. Rodrigues sought clarification regarding the applicability of this policy with respect to Reference Material Producers (RMPs) as they are not required to be accredited to ISO 17025 (Guide 34 only). R. Brauninger noted that *currently* this is, in effect, a moot point since all of the RMPs accredited by A2LA are also accredited to ISO 17025.

6. **Calibration of pH/ Conductivity Meters**

T. Smith presented the requirement that pH meters must be calibrated and that accredited laboratories are providing a service for a traceable solution. A. Liabastre asked if their certificate had been scrutinized to see if they described the calibration method on their cert. K. Stoub asked if there is any reason not to accept the slope that is established by the pH manufacturer. M. Moore asked which pH meters are falling under this requirement. Also, the pH solution that is used states what the requirements are for the pH (for example, pH 7.0 @ 25°C). If this is wrong, then the assessor must look into this further. M. Miller informed us that the Standard Methods already allow for this. A. Liabastre asked if there is any information regarding conductivity meters. T. Smith said that the OEMs give specific information on what is expected.

M. Miller asked why the laboratories have to complete this extra step if they are completing and passing the appropriate PTs. M. Moore said that there is now traceability with the solutions.

Motion 4: A. Liabastre requested that the A2LA staff provide advice to the laboratory to know what to look for on the calibration certificate and how it refers to traceability. M. Miller said that Action Item #2 is involved with this and should give insight to the laboratories.

Motion 5: M. Miller and K. Stoub to speak to the CC and keep the practice the same regarding the accredited traceable buffers and the Traceability Policy until the LSAC has finished their review as mentioned before. In the meantime, buffer/conductivity supplies and millivolts calibration will not be required to be accredited until the LSAC task group has formulated their recommendations and submitted them to the CC.

K. Stoub stated that a laboratory he assessed purchased the approved calibration standards and that, when used, the lab could not stabilize the pH meter. This laboratory had to go back to Fisher in order to get the pH meter to stabilize.

7. **Review of A2LA Policies/Interpretations**

Life Science MU Annex

R. Brauningner provided the LSAC with an overview of the Measurement Uncertainty (MU) annex. The LSAC annex is used specifically for life sciences laboratories instead of across the board at A2LA. In April 2004, this annex came out for use.

Motion 6: R. Brauningner to submit the annex to the CC. B. Kavanagh stated that it should go through the CC process before being placed into use. There is an inconsistency with the annex and the memo sent by T. Barnett on 1/9/2005. The annex stated that it is a “guidance” document, where the memo states that the new policy includes the annex. Does that automatically make the annex a policy?

Action Item 4: R. Brauningner to obtain a clarifying interpretation on whether the document is considered *guidance* or a *policy* due to its association with the Uncertainty of Measurement policy document (by April 30, 2005).

D. Tholen reviewed the highlights of the annex: Type I – no estimate is necessary, Type II – micro kits, etc. where the estimate is included within the specifications of the method, Type III – all other well characterized methods (AOAC, EPA, etc) where the estimates have been determined.

A discussion ensued on what was the appropriate frequency, or rule of thumb for recalculating these estimates? M. Miller noted that this estimate was often used to identify precision of the analysis and sought an opinion from the group. R. Brauningner noted that there is no wording in ISO 17025 that addresses this issue thus the interpretation should be that it is up to the laboratory to determine when and whether or not an uncertainty estimate needs to be recalculated.

D. Tholen stated that the point behind this requirement is that the laboratories should know their method. The LCS can be used piecemeal for most of the method components with other contributors separately identified (or as representing the contributors in their totality). Sampling can become a major component of the measurement uncertainty.

Motion 7: Regarding the LSAC MU Annex, G. Rodrigues requested that a paragraph break be placed on page 4 first paragraph at “The components of uncertainty...”.

Action Item 5: R. Brauningner to edit the LSAC MU Annex to reflect the needed changes. D. Tholen to review the revised document for consistency (by April 30, 2005).

P. Royal noted that there are often “swing shift” and night shift personnel performing testing activities that may not be as closely supervised as the day shift personnel. She then asked the group whether individual analyst variability should be considered when looking into the measurement uncertainty estimates and contributors. The group discussion resulted in agreement that the impact of differences between individual analysts may need to be considered. It was suggested that the analyst variability is probably one of the largest sources of error and thus, when applicable, should be considered by the assessor when evaluating the laboratory’s estimates.

M. Moore informed the group that Mr. Bill Engersoll has developed an uncertainty of measurement calculator. It is a free tool that can be used by the laboratories. It has been validated and the data acquired can be requested. The approach has been written up in a scientific paper and has been peer reviewed. The name of the paper is “*Environmental Analytical Measurement Uncertainty Estimation Nested Hierarchical Approach*”. Links to the excel spreadsheets (as well as other useful documents) can also be located in the “documents” window at the www.navylabs.navy.mil web page.

M. Miller brought up a question on the amount of data points (for the category III labs) that is required for method validation (for example: there are laboratories performing forensic tests (e.g. Homeland Security) where they may receive vastly different test items at various times – i.e. shoes, etc). M. Moore noted that she did not believe that the LSAC is the proper group to make this decision and that it should be up to the actual laboratories and their stakeholders. M. Miller indicated that the decision should be applied consistently and thus it should be discussed with the laboratory, but that a policy may not be necessary as the assessors should not dictate to the laboratory what is necessary.

Action Item 6: R. Brauning obtain interpretation on whether there is a minimum number of data points necessary in order to meet the method validation requirements of ISO 17025 and A2LA's internal policies (by April 30, 2005).

G. Rodriguez, as a member of the NCSL committee 174, noted that the group should be aware that they are looking for a greater number of examples of methods to be added to the back of the GUM.

8. Environmental Scope of Accreditation and Selection List Update

A. Hensley led a discussion on the course that A2LA staff has been developing for an alternative to the current environmental selection list. What has been put together is a listing of all of the possible relevant methods and analytes in a format that will allow the lab to cut and paste the respective components together to form their scope of accreditation. She indicated that, when complete, this would be posted to the A2LA web site. M. Miller indicated that, when providing instruction to the laboratory in completing generation of their scope, that A2LA should explain that additional methods/analytes beyond what are listed is an option open to the laboratories and that they may be added as desired. A. Hensley then went on to describe the need to create similar alternatives for other current environmental scope formats (e.g. the Kentucky and Wyoming leaking underground storage tank programs as well as for the environmental lead program). K. Stoub suggested that perhaps electronic submission be required. There was general agreement to this suggestion but no motions were entertained.

Action Item 7: A. Hensley to produce similar alternatives for other current environmental scope formats and selection lists (e.g. the Kentucky and Wyoming leaking underground storage tank programs as well as for the environmental lead program) and have all posted to the A2LA web site upon completion of review by the LSAC for omissions or needed corrections (by September 30, 2005).

9. Environmental Assessment Issues

- M. Miller suggested that, in order to make it easier for assessors to plan their assessment schedule that A2LA add a check off box on the ISO 17025 assessor's checklist to note whether the laboratory is at a fixed address or if it is or includes a site location.
- A. Liabastre noted that occasionally the lab is not completely ready to provide a copy of the scope at the time of the onsite assessment. M. Miller noted that too many times the lab has not adequately reviewed the scope document for content. M. Miller noted anecdotally that representatives from the State of Georgia told her that they would not have approved A2LA again if a vertical Scope (listing the elements / analytes in a columnar format) had not been previously implemented.
- M. Moore noted that there needs to be a review of 8260B /5035 documentation. M. Moore then requested that the group consider the placement of stand-alone sample preparatory methods on the laboratory's Scope of accreditation if this is so requested by the laboratory. A proposal was put forth indicating that it may be appropriate to place sample preparation methods on the checklist as an aid to the assessor but that they need not be placed on the laboratory's Scope. R. Brauning reminded the group that, were these activities to be placed on a Scope, then the laboratory would be obligated to demonstrate their proficiency with this activity

per the A2LA PT policy and ISO 17025 section 5.9. M. Miller indicated that in her experience that most environmental labs do not really wish for sampling and preparatory methods to be so listed.

Action Item 8: A. Hensley to poll all of the A2LA accredited environmental laboratories to determine their interest level in placing Sampling and/or Prep Methods onto their Scope (making certain to explain to the laboratories that in doing so that the laboratory must fulfill 5.9 of the standard) (by May 31, 2005).

Action Item 9: A. Hensley to investigate the placement of a check off box on the ISO 17025 assessor's checklist to note whether the laboratory is at a fixed address or if it is or includes a site location (by April 30, 2005).

M. Miller then went on to review some specific issues and offered her suggestions (bolded) as related to the need for a consensus interpretation by the LSAC assessors for when they are performing environmental laboratory assessments:

- Is the re-use of methylene chloride captured during K-D concentrations of extracted samples an acceptable practice? **The laboratory is required to capture whether it is volatile or not. Look for no peaks.**
- NPDES ICP Method requires a 5% acceptance window for the CCV. **This is only informally accepted. Therefore, it remains 5%.**
- Is solid or aqueous required for LCS preparations for soil samples? **The accrediting authorities are going to solid preparations.**
- Are solid matrix method blanks required by NELAC or are reagent blanks considered as acceptable MBs for soil samples? **NELAC is recommending solid preparation/method blanks.**
- If a solid matrix MB is required, what is recommended for metals and organics? **It depends upon the methods. The assessor needs to know the methods in order to determine. Typically, clean sand for organics, however for metals, water is the only option as sand contains metals.**
- Is sonicator tuning required each day of use by SW3550B? What frequency is recommended? **While the labs have generally been defining it themselves, the method states: "calibrate the device per the manufacturer's instructions".**
- Is drying to constant weight always required for the NPDES samples for solids and HEM or can extended drying times be used for solids? **NPDES – methods are determined state by state. However, some regions have there own requirements. Emails or phone calls are often needed to determine which regions and states require what method. Method 1664A has very specific requirements. Some states allow the laboratory to do a small study to show that repeated drying for their typical client samples is not required. States have specific requirements.**

- Is it permissible to eliminate the DDT breakdown check from 8270C if pesticides are not being determined? **If the laboratory has other ways to check breakdown, column degradation ratio or injection port active sites, then one could substitute that for breakdown check. For regulatory testing no substitution is allowed. Appropriate injection and column maintenance and added resolution checks may fulfill the requirement but that depends on the use of the data.**

10. New/Other Business

Proficiency Testing Requirements and Sub-disciplines

A. Hensley led a brief discussion on the subdisciplines and technologies that are listed in A2LA's Proficiency testing policy document for biological and chemical laboratories, raising the question as to whether the numbers of areas listed are adequate. A. Hensley noted that in her opinion all laboratories should perform *some* activity (per the requirements of ISO 17025 section 5.9) for every test on their scope every year.

R. Brauningger pointed out that life science laboratories are already doing this when they perform QC with their tests and that proficiency testing requirements should be kept to the baseline required by ILAC. He also pointed out that the Chemical section in the PT policy refers to *all* accredited analytical chemistry laboratories (not just life science laboratories) and thus review of this possible interpretation should be accomplished jointly with the MAC. K. Stoub indicated that it would be useful to find out specifically what ILAC's requirements are. G. Rodrigues requested that consideration be given to allowing the laboratory to meet the A2LA PT policy by simply meeting the requirements of section 5.9 of ISO 17025.

Motion 8: A motion was put forward to form a task group to review: 1) A2LA's present proficiency testing policy with respect to tightening the current A2LA requirement for Biological and Life Science Chemical laboratories (currently there is a minimum of 2 PT activities per year for as many tests/matrices/ technologies as possible, covering the entire scope in a period of 4 years). 2) Whether it is necessary to add additional sub-disciplines for PT activities and 3) Determine the need to have all methods on the laboratory's Scope covered with specific PT activities. 4) Re-writing of the policy and review the PT requirements for the Life Science laboratories as currently written.

Action Item 10: A task group consisting of: M. Miller, A. Hensley, D. Tholen, L. Crumpler, F. Anderson, D. Evanson, C. Pixley, and V. Cook was formed to address the issues raised in Motion 8 as well as to seek a definition for the term "sub-discipline". This information is to be completed in time for review by the LSAC and then presented to the A2LA BOD at their June meeting (by September 30, 2005).

COI for New Members

R. Brauningger handed out conflict of Interest documents for signature by all those who had not previously provided one.

Motion 9: Adjourn the 34th meeting of the A2LA Life Sciences Advisory Committee. (Motion passed). The meeting was adjourned at 4:00 pm.

The 34th meeting of the A2LA Life Sciences Advisory Committee was adjourned at 4:00 pm.

Minutes prepared by A. Hensley, Senior Laboratory Services Officer, and R. Brauning, LSAC recording Secretary.