

Summary of the A2LA Medical Technical Advisory Committee (MedTAC) Meeting
Saturday, 4 April 2009
8:00 am to 3:00 pm

- 1) Call to Order (8:00 am): Chairman George Riley opened the meeting and the attendees introduced themselves. See page 5 for the list of attendees.

- 2) **Motion 1 (D Miller/E. Ewing): Approval of minutes from teleconference of December 11, 2008: Approve with addition of Lisa Walters and Deb Koenig as attendees. Passed unanimously.**

- 3) Nomination of Officers: The slate of candidates for 2009 is: George Riley- Chairman; Bill Kavanagh -1st Vice Chair; Deborah Miller - 2nd Vice Chair; Ray Minnick – recording secretary. There were no additional nominations from the floor. The MedTAC members voted to approve those nominees, as balloted.

- 4) Measurement Uncertainty Guidance for Medical Testing Laboratories document was presented by Lisa Walters and a recommendation was made for approval by the MedTAC with the following additional changes to the draft:
 - all references to “of UM” become “*in* UM”
 - “*analytical goal*” changed to “*target uncertainty*”
 - critical value revision to allow some latitude
 - calibrator reagent use *where appropriate*, in addendum
 - paginate
 - clarify use of “CV” in the table and use of “QC coefficient” to determine standard deviation
 - copy category 3, second bullet to category 4
 - category 4 definition revision to refer to “*generate quantitative data*”
 - confidence expression reference added to “Interface with Clinicians...” section

Motion 2 (J. Murthy/Ed Ewing): Recommend approval of the Measurement Uncertainty Guidance for Medical Testing Laboratories document to the Criteria Council once revisions discussed during this meeting are made by Lisa Walters. Unanimously approved.

- 5) Discussion of the A2LA Clinical Laboratory Improvement Amendments (CLIA) Accreditation Program for Medical Laboratories:

R. Minnick reported that the Centers for Medicare & Medicaid Services (CMS) rejected A2LA’s application for deemed status and he briefly summarized the contents of the 10-page March 11, 2009 letter from CMS. There were 3 areas of

concern: 1) lack of confidence in A2LA's handling of proficiency testing (PT) data; 2) Accreditation Council (AC) members aren't trained to the same degree as assessors and 3) unannounced versus announced assessments. There was a general concern about A2LA's lack of timeliness in application responses but R. Minnick indicated that there was a misunderstanding about informal communications that A2LA had with our CMS point of contact. He described the next steps that staff will take in order to re-apply to CMS. This process will start the week following this meeting. It was suggested by the MedTAC members that the assessors submit their yearly training credentials and certificates to A2LA in order to address CMS's concern about continuing education for specialties and sub-specialties. The committee members agreed to be available ad-hoc to A2LA staff to answer questions and resolve impasses while A2LA develops its re-application to CMS. A2LA also needs more cytology assessors in order to alleviate CMS's concerns about how A2LA conducts "for cause" cytology assessments.

- 6) Assessing C312 – Specific Checklist: ISO 15189 Annex B Requirements for Protection of Laboratory Information Systems: There remains a concern that our medical assessors would not be able to technically assess some checklist items, and guidance was needed so that they could. However, the information technology (IT) assessors that have been asked to comment have been unresponsive.

Motion 3 (L. Walters/E. Ewing): Discontinue the MedTAC request to the IT experts for guidance on the checklist items. Approved unanimously.

Discussion ensued about A2LA's ability to include this checklist into our assessments without the IT guidance that is still lacking. The committee members looked again at the checklist items in question.

Motion 4 (D. Miller/E. Ewing): Revise the medical testing application for accreditation to ask probing questions about the LIS systems used by the applicant so that an informed decision can be made by the A2LA Accreditation Officers and team leader about the need for IT expertise on the assessment team, taking into consideration home grown and turn key programs. Unanimously approved.

Action A: Ray Minnick to ask Craig Spooner for assistance in formulating the IT questions to be included in the medical testing application for accreditation (by May 31, 2009).

- 7) Status of PT Task Group Work: The TG has met a couple of times and should have a draft for circulation by mid summer 2009. The intent is a PT requirements document for the ISO 15189 accredited laboratories. It was suggested that the TG look at the APLAC guidance on PT frequency.

8) Old Business: The request for Med TAC members' access to assessor documents on the web was tabled.

9) New Business:

a) Information from Alex Klein, Accreditation Council Chairman: A. Klein talked about AC member responsibilities so that the medical assessors in attendance would feel more comfortable in their potential AC member role. The AC Handbook was reviewed to help answer questions concerning workloads, turnaround times, web site voting, handling appeals, etc. and the AC ballot from the A2LA web site was reviewed.

b) Point of Care testing: The issue was withdrawn while R. Minnick investigates further in order to more narrowly focus A2LA's discussions.

c) Clinical & Laboratory Standards Institute (CLSI) report: CSLI is providing intellectual support and mentorship to developing medical labs in foreign locations. There is a CLSI series of documents that provides an approach to implementing a management system within a laboratory, taking ISO 15189 into account. A2LA is a member of CLSI and the committee members were invited to review any CLSI documents that A2LA received for review.

d) TC 212: A2LA is a member of TC 212. WG 1 continues to draft a new version of ISO 15189. CLSI requested to be removed as secretariat of TC 212. The Association for Advancement of Medical Instrumentation was willing to take it over but also wanted control of all of the CLSI technical committees. TC 212 took a vote and asked CLSI to stay as secretariat for another year while other options were investigated and CSLI agreed. There is concern that leadership on TC 212 could be diminished if CSLI does not maintain its current role.

Post Meeting Note: It was learned later in the Conclave that on April 1, 2009, CLSI reversed their decision to discontinue as Secretariat of TC 212 but must operate on a "revenue neutral" basis. There is one possible change that would result in the British Standards Institute taking over secretariat duties for WG 1 of TC 212.

e) Traceability of measurements for medical testing laboratories: A suggestion was made to form a task group to consider traceability in the medical testing area, using A2LA's life sciences guidance on traceability document as a beginning point. There was considerable discussion about putting new requirements upon medical testing laboratories that could impact the business prospects of A2LA's medical testing accreditation program, for example, fully meeting the requirement for traceability to the SI as required by ISO and CFR 493.

- f) Internal proficiency testing schemes: When suitable external PT programs are not available, A2LA can consider the federal register guidelines found in 493, Appendix C, subpart K, 1236 (a) (c)1 and 1236 (c) 2 to address this issue in the draft PT requirements for medical laboratories. See item 7 above.
- g) CMS validation survey: Dr. E. Ewing's experience with the CMS validation survey process was described. Dr. Ewing explained that the American Osteopathic Association (AOA) inspected his hospital laboratory and CMS followed up with an inspection survey to see if the laboratory had addressed the deficiencies cited by AOA and to see if AOA had performed a thorough inspection. CMS sent a letter to announce their visit and conducted the survey a couple weeks after that. They used 3 inspectors for 3 days. CMS compared their results with those of AOA.
- h) ISO 15189 and CLIA: A2LA's current position to accredit for a combined ISO 15189/CLIA program was debated because some committee members think ISO 15189 compliance is onerous and will not be marketable to much of the medical laboratory community to the degree that CLIA alone is marketable because CLIA is the regulated program. It was suggested that the laboratories interested only in meeting the CLIA requirements could be assessed to ISO 15189 and CLIA in one assessment but could treat the 15189 assessment as a gap analysis and delay accreditation of the ISO 15189 requirements for a period of time (6 months was suggested). The laboratory would have to comply with CLIA requirements without delay.

Action B: The MedTAC asked that A2LA management consider this proposal for a ISO 15189 gap assessment option and possibly consider a market survey to determine its viability and the interest of the medical laboratory community in ISO 15189 in addition to CLIA (May 31, 2009).

- 10. Next meeting: August or early September 2009 by teleconference.
- 11. **Motion 5 (J. Gorsky/E. Ewing): Adjourn the meeting at 3:20 pm. Unanimously approved.**

Summary prepared by Roxanne Robinson, VP and COO

ATTENDEES

Meeting of the A2LA Medical Technical Advisory Committee
4 April 2009

Edward Ewing	A2LA Assessor
Siu Lin Fung	BIDN Hospital
Jay Gorsky	MEDLAB Consults, Inc.
Kathryn Gumpper	ChemVal Consultants, Inc.
Bill Kavanagh	A2LA Member
Deborah Miller	A2LA Assessor/Trainer
Ray Minnick	A2LA Accreditation Officer
Jay Murthy	MHRI/Brown University
George Riley	AABB/DNACA
Roxanne Robinson	A2LA VP/COO
Doreen Rumery	Artel
Liz Selby	A2LA Accreditation Officer
Yi-Wei Tang	Vanderbilt University Hospital
Lisa Walters	Healthy Solutions Quality Consulting, LLC

Total number of attendees: 14