MEDICAL TESTING ADVISORY COMMITTEE MEETING  

March 24, 2012  
8 a.m. – 5 p.m.

MedTAC Attendees: Greg Cooper, Marianne Farallo, Siu Lin Fung, Edward Chan, George Rodrigues, Jay Murthy, Yi-Wei Tang, John Choppala, Dan Tholen, Patrick Foley, Charles Ferrer, Doreen Rumery, Patricia Hui-Ng, Bradley Harper, Deborah Miller, Dennis Wegner, Lisa Walters, William Kavanagh, Evan Ntrivalas, Robert Bredt, Chris Sandlin, Sue Styles, Kathryn Gumpper

Staff Attendees: Roxanne Robinson, Larnell Simpson, Amanda McDonald, Nicole Kwarteng

**SUMMARY**

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<td>1) CALL TO ORDER AND INTRODUCTIONS: MedTAC Chairman</td>
<td>Call To Order Made by: Bill Kavanagh</td>
<td>None.</td>
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| 2) APPROVAL OF MINUTES FROM LAST MEDTAC MEETING OF 2 APRIL 2011 :MedTAC Chairman (Attachment 1) | Approval of Minutes from last MedTAC Meeting of April 2, 2011. | Motion: to approve the minutes with no changes  
1st: T. Rand Collins  
2nd: Deborah Miller  
Approved with no objections |
| 3) ELECTION OF OFFICERS: MedTAC Chair | **Election of Officers**  
Chairman Bill Kavanagh  
First Vice Chair Qussay Albakri  
Second Vice Chair Yi-Wei Tang | Motion: to approve the slate of candidates  
1st: Deborah Miller  
2nd: Charles Ferrer  
All approved no objections |
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| 4) DISCUSSION/COMMENTS REGARDING ISO 15189 TRAINING OF ASSESSORS ON 19TH TO 23RD MARCH 2012: All who attended | Assessors who attended the training course were asked to offer positive and negative feedback. **Positive Feedback:**  
- Overall the assessors found the 2nd training session to be much more informative and organized better.  
- The assessors added that they thought there was great improvement in the explanations of Measurement Uncertainty and Measurement Traceability.  
- The assessors also found the course to be much better focused around the standard.  
- There was a discussion on how it would be nice if they could get CE credits for attending the A2LA assessor training course. A2LA took this as an action item.  
**Negative Feedback:**  
- The assessors proposed that, in the future, A2LA administer the exam at a point in the week when the material for the exam has just been covered. This time the exam focused primarily on the ISO 15189 standard so the assessors thought it would have been more helpful to have the exam towards the middle of the week.  
- The assessors found the deficiency-writing | **ACTION:** Amanda McDonald to look into getting approval for CE credits for the ISO 15189 assessor training class (due July 2012). |
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<td>exercises that were performed on the last day to be very informative. The assessors requested more examples of them throughout the week.</td>
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<td>R. Robinson pointed out that normally the exam would cover assessment processes, MT and MU concepts and she accepted the suggestions made.</td>
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<td>OLD BUSINESS:</td>
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<td>a) Review and Discussion of draft A2LA Traceability Policy Annex for Medical Laboratory Testing: Lisa Walters</td>
<td><strong>Measurement Traceability Policy</strong></td>
<td>ACTION: Greg Cooper to add a Measurement Uncertainty calculation example for a lab- modified method (non-FDA approved) with in-depth validation to A2LA policy P603e (due July 2012).</td>
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<td>• Discussions took place on Measurement Traceability and Measurement Uncertainty and how they are new concepts for both A2LA, medical assessors and medical laboratories.</td>
<td>ACTION: Amanda McDonald to add acronym list to A2LA documents to define all the terms so that the reader can easily reference these terms (due July 2012).</td>
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<td>• Clauses were closely reviewed by the members and the recommended changes will be included in the next revision to be reviewed by the MedTAC.</td>
<td>ACTION: Lisa Walters to work on revising the Measurement Traceability Policy to contain further explanation on definitions of traceability, calibration, verification, validation, qualification, standardization, etc. The definition of calibration will be taken from the CFR.</td>
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<td>• Discussion took place on non-FDA approved methods and measurement uncertainty and how it would be beneficial to provide an example in the A2LA Measurement Uncertainty document.</td>
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<td>• Discussion took place on the definitions of traceability, verification, validation and how they can have different meanings, especially in</td>
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the lab setting. The MedTAC suggested that A2LA define these terms in the traceability document.

- The point was raised that the definition of Calibration in the VIM is not exactly the same as the definition given in the CFR. This was followed by a discussion regarding the VIM and CFR definitions.

- The MedTAC agreed to use the CFR definition for calibration and then give an example of the different levels of checks (calibration, validation, verification) with the “Golden” thermometer/working thermometer example.

- It was agreed that a reference thermometer will be an accredited calibration and the working thermometer will only need a verification.
  - Periodically, the working thermometer will have to be “checked” against the reference thermometer. This check is a “verification.”
  - The laboratory will have to have a set schedule and procedure for establishing the verification.

The traceability policy will also be revised to give a “golden” thermometer and working thermometer calibration/verification example (due July 2012).

**ACTION:** Lisa Walters to obtain definition of Medical Device and clarify the language of “FDA approved” in the measurement traceability document (due July 2012).

**ACTION:** Roxanne Robinson and MedTAC chair to ensure that MedTAC has a larger discussion in the future on the analytical equipment that should potentially be added to the Calibration Table in the Measurement Traceability Policy (due January 2013).

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<td>b) Review and Discussion of An Excel spreadsheet-based scope development tool</td>
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<td><strong>ACTION:</strong> Working Group, consisting</td>
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| draft A2LA Medical Test Method Selection List: Greg Cooper was presented. The spreadsheet will aid A2LA staff and medical laboratories in creating the Medical Scopes of Accreditation.  
  - The spreadsheet has selection lists that pre-filters information as a laboratory selects a certain area or alphabetical listing.  
  - The suggestion was made to add further information regarding PT to further clarify which PT program a lab is participating in.  
  - It was indicated that help is needed for Pathology areas. A working group to address Pathology area of Scope selection list was formed. | of Dr. Robert Bredt (WG Chair) and Patrick Foley to provide suggestions for further developing the Pathology selection of the draft medical selection list (due July 2012). |
<p>| c) Review and Discussion of draft R654: Specific Requirements: Accreditation of Medical Testing Laboratories Meeting the ISO 15189 Requirements: Roxanne Robinson | R. Robinson explained that she has been working on this document to add further applications and clarifications for our ISO 15189 program. She received permission from the Accreditation Bodies in India and Australia (NATA), who already have robust medical accreditation programs, to use aspects of their documents. Clauses were closely reviewed by the members and the recommended changes will be included in the next revision to be reviewed by the MedTAC. The last section reviewed was 5.3 Equipment. | <strong>ACTION:</strong> Roxanne Robinson to go through the ISO 15189 standard and look for other areas with “should” that we would want to make “shall” in R654, and ensure that “manufacturers’ instructions for use” and “national, regional and local” are used properly and consistently in the draft R654 (due July 2012). |</p>
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<td>d) Other old business</td>
<td>None.</td>
<td>None.</td>
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<td>5) NEW BUSINESS</td>
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<td>a) Update on Application for CMS Deemed Status: Roxanne</td>
<td>A2LA is still waiting for CMS action.</td>
<td>None.</td>
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<td>b) Date/time for CLIA training of assessors: Roxanne</td>
<td>A2LA is waiting for a response from CMS before scheduling assessor CLIA training. Assessor CLIA training could possibly occur at 2013 Technical Forum.</td>
<td>None.</td>
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| c) News from CLSI: Roxanne, Greg | **CLSI – Greg Cooper**  
- Greg Cooper recently received a copy of the published C51 on Uncertainty of Measurement.  
- CMS had decreed that “Equivalent QC” Procedure (EQC) is going away and replaced with Individualized Quality Control Plan (IQCP). In order to implement Evaluation Protocol-23 (EP-23), the government must explain how to go about doing it. The government has to publish in the interpretive guidelines. Once published, a 2 year implementation period will be imposed.  
- There are going to be changes in industry in regards to the frequency of Quality Control.  
- *C24-A3 Statistical Quality Control for* | None. |
# AGENDA ITEM

## DISCUSSION

**Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline** is up for renewal. They are going to be forming a committee.

- The FDIS version of ISO 15189 may possibly go out for vote in 2nd quarter, 2012.
- ISO 17511 on traceability is up for renewal. This document will be going back to the working group for changes.

### d) Status of revision to ISO 15189: Roxanne

Roxanne noted that ISO 15189 is being revised and there could potentially be a 2012 version so we will most likely need to have training again next year on the deltas between the 2012 version and 2007 version of ISO 15189.

### e) Other new business

None.

### MOTIONS & ACTION ITEMS

**MOTION TO ADJOURN:**

1st Bill Kavanagh 2nd Kathi Gumpper

*Summary prepared by Amanda McDonald, A2LA Accreditation Officer.*
A2LA Medical Technical Advisory Committee (MedTAC) Meeting Summary
The Sheraton Columbia Hotel,
Columbia, MD
Saturday, April 2, 2011

1) Call to Order (Deborah Miller)

Approval of the November 15, 2010 MedTAC Teleconference Minutes - (provided to the committee in advance of this meeting) Those in attendance were not sufficient to constitute a quorum of at least eight, therefore the committee was not able to vote, per the bylaws.

Deborah Miller is served as the Chair of the Committee for this meeting as George Riley, the current chair, is unable to do so due to his new position with the US Government.

Election of Officers – Deborah Miller requested volunteers from those in attendance.

Discussions occurred as to what is involved in being Chair. It was pointed out that the Chair is also involved on the Criteria Council which entails monthly meetings that usually last one hour and requires around one hour of preparation to review the documents. R. Robinson described the roles of the Criteria Council members and the types of documents they review including program requirements and policies that the CC is responsible for. A question was asked as to how one becomes a CC member and staff responded that anyone interested should submit their resume to A2LA staff for review. CC members may be removed due to inactivity on the committee.

Currently, the officers of the MedTAC include a Chair, 1st Vice Chair and 2nd Vice Chair. Qussay Albakri expressed interest in being an officer. A2LA Staff will send out requests for volunteers to serve as officers and will follow with elections.

Old Business:

CMS Application Process - R. Robinson updated the group on the A2LA application to CMS and the challenges we have had with the previous application submittals. She provided some examples of differences in practices that are completely acceptable and expected practices under ILAC that are not accepted by CMS such as pre-assessments. She also described the extent of detail required for crosswalks. CLIA requirements allow 180 days for their review of our application. A2LA provided the application package to CMS on January 31, 2011. They provided us with positive feedback on our application this week stating that it was complete and well organized (which is the first time A2LA received this feedback) and so the next step is for CMS to review our application against the requirements. A2LA had to separate the ISO/IEC 15189 requirements from the CLIA requirements because it was causing issues.
with CMS. A2LA will still offer assessments to both sets of requirements concurrently if the laboratory so desires but we will not package it as such to CMS.

Deborah Miller stated that, although CMS is a proponent of quality, the law allows them to enforce only what is contained within the regulations- which do not include management system elements. This is likely what drives their stand for not wanting to see ISO/IEC 15189 in our application package.

It was stated that the assessment report is a legal document that can be used in the court of law and so it is likely that CMS would not want any discussion on ISO/IEC 15189.

A member expressed that A2LA’s legal representative should determine if A2LA is adequately covered. R. Robinson said that if our documents are subpoenaed we would have to provide those documents.

A follow up question was raised regarding the individual insurance coverage provided for assessors and whether A2LA should look closer at the extent of coverage to protect A2LA and our assessors. R. Robinson said that A2LA insurance covers A2LA and its committees and that was one reason for the creation of an assessor committee. The coverage is 2 million per each event and it does cover our medical program.

**A2LA Traceability Policy for Medical Laboratory Testing** – R. Robinson described the document hierarchy of A2LA policies. R. Robinson stated that she was expecting to see a listing of equipment that is used in a medical laboratory so that assessors could refer to it as guidance to determine the traceability requirements that would be needed per piece of equipment so that we can ensure consistency from assessment to assessment. The policy is good but it should be supported by a table that serves as guidance for both laboratories and assessors to reference. R. Robinson says that the VIM version is outdated. A2LA staff will provide this document to the group electronically.

**Action Item #1:** A2LA Staff (R. Robinson) will insert the LS equipment calibration and verification table into the traceability document and provide it to the MedTAC for comment by April 15, 2011.

**Action Item #2:** MedTAC members will review and provide comments on the traceability document and minimum requirements for the equipment calibration and verification table by May 31, 2011.

R. Robinson also expressed issues with the timing of this document in relation to the new ISO/IEC 15189 and said that we may want to wait to see the FDIS version of 15189 before finalizing this version.

R. Robinson presented the equipment calibration and verification table that Life Sciences uses and stated that a similar table could be used for the medical accreditation program.

One member emphasized input from medical experts was needed in reviewing this table to remove equipment that may not be relevant and add equipment that is of relevance.

Another member stated that, under the frequency category, he did not see any comments about manufacturer’s recommendations for frequency of calibrations.

A member noted that there should be notes or references included on the source of the requirements.
Applications - R. Robinson provided an update on an action item to write applications on ISO/IEC 15189. It is encouraged by the ISO committees to write applications, or additional requirements for specific disciplines in the medical field. This is intended for laboratory’s applying to ISO/IEC 15189 program. CLIA requirements will supersede these requirements. R. Robinson relied on applications established by the NATA and NABL medical accreditation programs. These include explanations for clarification or additional requirements. These will ultimately be placed in the checklists so that laboratory and assessors are aware.

One member asked for a definition of a collection site. Some receive samples from thousands of collection sites but only a select few operate under their control. We will only assess those collection sites that are under their control. The member said that they will provide comments on this issue.

A member noted that the document contains a section on safety. He said that, due to our liability insurance, we must be careful that we are clear that we are not safety experts and that we will not be citing findings to safety. We cannot say what is safe and what is not safe but we as assessors could state that the laboratory is not following its own procedures for a given safety issue.

A2LA will provide additional details on what we can do as far as assessing for safety and also provide a section on this in the assessor training.

The group reviewed ISO/IEC 15189 to determine when safety is discussed in the standard (Accommodation & Environment).

**Action Item #3:** A2LA Staff (R. Robinson) will provide the MedTAC committee members with A2LA R654 Specific Requirements for Medical Testing Laboratories document for review and comment to be received by May 31, 2011.

**Action Item #4:** A2LA Staff (R. Robinson) will purchase ISO/IEC 15190 Safety for Medical Laboratories by April 30, 2011.

An additional member arrived resulting in a quorum.

**Motion 1:** Approve minutes of the prior MedTAC teleconference.

Minutes were approved.

**Motion 2:** Staff to issue an email notification seeking volunteers to serve as officers.

Motion approved.

**Action Item #5:** Staff (R. Robinson) will solicit (via email) volunteers to serve as officers for the MedTAC by April 30, 2011.

**OLD Business (continued): CLSI GP 26** R. Robinson and D. Tholen explained that CLSI GP 26 is a broader based document encompassing GLP/ GMP, ISO/IEC 15189, CAP etc. It is too broad and our focus should be remain strictly with ISO/IEC 15189. CLSI GP 26 is not going to be used for accreditation purposes.
CLSI is in direct conflict with CASCO on this issue since CLSI is the US standards representative and secretary of the TAG yet they are promoting the GP26 document.

**Discussion of the Partnership with Institute for Quality Management in Healthcare (IQMH) in Toronto and A2LA** – A2LA established a contract with them on Decoding 15189, a web-based, on demand training program. Phil Smith explained the different modules that are being provided. Currently IQMH is offering a free trial to promote this further. Our role in this arrangement is to promote the training and staff will take the training and create test questions that IQMH will use for gaining PACE credits.

**Medical Scope Task Group Report** - R. Robinson showed the Medical application Scope of Accreditation and explained the degree of detail. This is due to the requirements of monitoring and PT activities.

**Action Item # 6:** A2LA Staff (R. Robinson) will provide this document to the full MedTAC committee for review and comments due by May 31, 2011.

**New Business – DIS ISO 15189** – A2LA submitted comments to TC 212. The committee will consider the comments and issue the FDIS ISO 15189.

**Action Item # 7:** A2LA Staff (R. Robinson) will provide the results of the comments we provided on the DIS ISO 15189 to the MedTAC committee once we receive it from the TC 212 committee.

**CLSI Report – R. Robinson attended the CLSI Conference this week. They met in Atlanta and many people were there from CDC. She did not see anyone from CMS. The other medical accreditation bodies (ABs) were in attendance including COLA, CAP and the Joint Commission.**

TC 212 met and reported on the status of their review of all the standards that they are currently working on.

CLSI is writing an internal audit guidance procedure for a very broad based group of laboratories including food, veterinary, medical etc.

R. Robinson met an attendee that has numerous collection sites that are CAP accredited. They just went through the assessment process and provided R. Robinson on the details of what is wrong with unannounced visits. The negative aspects far outweigh any positive items.

**TAG 212 Met** – All the comments received will be reviewed by October 2011 and they will know whether it will go FDIS ISO/IEC 15189.

R. Robinson felt that, based on her experience this week, A2LA should continue to attend and participate at CLSI.

P. Smith described the A2LA workshop in Erie, PA in which there were two speakers Lisa Walters and Greg Cooper. We were able to arrange for PACE credits for this and the session was attended by 15 people. P. Smith stated that we will adopt PACE for all of our training programs.
NEXT MEETING: It was determined that the likely timeframe for the next meeting will be July 2011.

Meeting Adjourned 12:00PM

Summary prepared by Amanda McDonald, A2LA Accreditation Officer.

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<td>Qussay Albakri</td>
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<td>Bill Kavanagh</td>
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<td>Roxanne Robinson</td>
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