

## A2LA Medical Refresher Class

**Friday, April 03, 2009  
(8:00 AM– 5:00 PM)**

### **Summary**

#### 1. Welcome and Introductions (8:00)

Ray Minnick gave an update on the A2LA Medical Laboratory Accreditation Program. The application to the Center for Medicaid Services (CMS) for deemed status had been denied. The plan is to strengthen the necessary documentation and resubmit a new application. A2LA is currently offering ISO 15189. There has been interest in ISO 15189 internationally and by some “for profit” laboratories in the United States

#### 2. Using Proficiency Testing Data in the Assessment Process (Attachment #1)

Proficiency testing is used as a “surrogate sample” to assess a laboratory’s ability to accurately perform testing. It is a requirement for accreditation and for regulatory compliance. It is also a self-assessment tool for a laboratory. It was emphasized that assessors can use PT data in a process-oriented approach as they evaluate a lab’s corrective action process, management reviews and other components of the quality management system as well as technical competence.

Currently, proficiency testing in the medical laboratories largely excludes the pre examination phase. A2LA would encourage labs to include this in their proficiency testing programs.

Roxanne Robinson reiterated that A2LA’s PT program needed to be in line with 42 CFR 493 (CLIA). These are regulatory requirements under the auspices of the Center for Medicaid Services (CMS). A2LA will be as prescriptive as the CLIA requirements if not more so. CLIA requires that PT be performed on primary methods only, whereas A2LA specifies that every method on a laboratory’s scope be covered every four years. CLIA does not specify how a primary method is designated. The ISO standard requires that there be comparisons made with secondary methods on the scope. The A2LA PT policy will need to require that a lab describe in their submitted PT plan how they will do comparisons of primary and secondary methods, as well as how they will cover methods for which there is no external proficiency testing available.

It was suggested that the 15189 PT policy require that internal results be submitted to A2LA by the labs for inclusion in the PT database.

CLIA requirements describe what constitutes an unsuccessful performance as described in 42 CFR 493 Subpart H. A2LA will be monitoring results as they come in from the PT providers. These will be summarized and sent to the assessor with the laboratory’s application package.

Cytology PT will be dealt with differently.

### 3. A2LA Assessment Process (Attachment #2)

Ray Minnick gave an overview of the A2LA assessment process as outlined in Attachment #2. A major difference was noted between the CLIA assessment process and A2LA ISO 15189 assessments. It is CMS policy that a lab is only given two week notice before an assessment team comes in, whereas A2LA assessments are scheduled by mutual agreement between a lab and assessment team. A2LA will need to change their policy for the medical laboratory accreditation program that includes the CLIA requirements in order to be in line with CMS requirements.

The two Assessor Report options, narrative and “no report”, were discussed. It was questioned whether the narrative option was practical for the medical program.

**ACTION: Ray Minnick to check with Daren Valentine / Trace McInturff as to whether the narrative report should be an alternative in the medical program. (by May 31, 2009)**

It was pointed out that the individuals who had authority to sign assessment forms were different for CLIA assessments as compared to 15189. The lab director has the ultimate authority in a medical lab, whereas a deputy could be authorized to sign assessment forms during a 15189 audit.

Roxanne Robinson mentioned that CMS was concerned about the training requirements for Accreditation Council members. Consequently A2LA is considering using only A2LA medical assessors as AC members for medical laboratory packages.

R. Robinson suggested that medical laboratories may need two days on site for their surveillance assessments based on her experience conducting the surveillance assessment in the Aruba lab this year.

The CMS “whistleblower” provision and a potential A2LA parallel stipulation were discussed.

### 4. Measurement Uncertainty for Medical Testing Laboratories. (Attachment #3)

Dan Tholen and Lisa Walters presented a review of the guideline for medical labs. Uncertainty in measurement is mandated by ISO 15189 (5.6.2). Guidelines were developed by the Uncertainty in Measurement Task Group, a subset of the MedTAC. Terms associated with uncertainty of measurement were defined as were the processes for estimating uncertainty of measurement. Examinations fall into one of four categories with regard to the necessity of uncertainty of measurement determination. Each category was described.

### 5. 42 CFR 493 Organization (Attachment #4)

Ray Minnick outlined the structure of the CLIA standards. He broke it down by its thirteen subparts and summarized each subpart.

Meeting Adjourned 5:00 PM

## ATTENDEES

A2LA Medical Refresher Class  
3 April 2009

Ewing, E.	A2LA Assessor
Fung, S.,	BIDN Hospital
Gorsky, J.	MEDLAB Consults, Inc
Gumpper, K.	ChemVal Consultants, Inc.
Khoury, N.	Medical Technologist
Maldonado, P.	A2LA Assessor in Training
Miller, D.	A2LA Assessor / Trainer
Minnick, R.	A2LA Accreditation Officer
Murthy, J.	MHRI /Brown University
Riley, G.	AABB/DNACA
Robinson, R.	A2LA VP/COO
Shanklin-Selby, E.	A2LA Accreditation Officer
Tang, Y.	Vanderbilt University Hospital
Tholen, D. (Guest speaker)	A2LA Assessor
Walters, L.	Healthy Solutions Quality Consulting, LLC

*Summary prepared by Elizabeth Shanklin-Selby, A2LA Accreditation Officer.*