

Summary of the A2LA Food Assessor Breakout Meeting

(Friday, March 11, 2005)

The 3rd meeting of the A2LA Food Assessor Breakout Meeting was held on Friday, March 11, 2005 at the Sheraton Columbia Hotel in Columbia, MD.

1. Introduction (6:10 pm)

R. Brauning, Recording Secretary, opened the meeting by welcoming everyone.

Review/Approval of 2005 Agenda

R. Brauning opened the floor for comments and concerns from the previous meeting.

P. Royal asked if the Proficiency Testing (PT) plan could capture all methods if there are more than one per matrix. A discussion ensued in which A. Hensley suggested that the laboratory's Scope could be used as a means of capturing the PT plan. There appeared to be a general agreement amongst the group that the Scope would be an appropriate means of obtaining this information if an additional column were added to capture the labs participation in any particular PT event. R. Brauning noted that many times the PT data received by A2LA does not specifically identify the methods for which the lab is accredited and thus the difficulty in determining compliance with the participation requirements of the A2LA food program. A. Hensley noted that the Scope could be printed and attached with any PT that is provided to A2LA so that the information is more easily retrievable.

Approval of Last Meeting Minutes

Minutes of the previous meeting of food assessors were accepted as written.

2. New AOAC Guidelines

AOAC Guidance Revision Schedule

A. Fox indicated that she was not sure when the current guidelines were scheduled to undergo the next revision. However, she thought they were scheduled to begin within the next 2 years.

Assessing to the Requirements

D. Mettler reviewed the new AOAC requirements and led a discussion on common interpretations. Regarding the measures to be taken by the laboratory to prevent cross contamination of samples and controls (section 5.3): The sense of

those in attendance was that so long as these samples and controls are stored separately in a covered container, trash bag etc., that this would be a satisfactory means to prevent the potential cross-contamination when it is necessary to store these materials together with other samples, controls or reagents. A concern was also expressed regarding the applicability of the statement that the related procedures “shall be in compliance with *regulatory* requirements” as it appears to be outside of the purview of an accreditation assessment.

K. Stoub addressed confusion with regard to an apparent contradiction between AOAC’s new 5.4.2 and ISO/IEC 17025. Assessors are under the impression that labs could make minor changes to methods without performing a validation if the changes do not alter the fundamental nature of the method.

It was pointed out that there was no change in the requirements pertaining to MSDS.

Action 1: A. Fox to acquire clarification of Section 5.3 of the new AOAC requirements with regards to the MSDSs. A. Hensley to give R. Brauninger the wording developed during the 2005 Environmental Pb training course for safety (by April 30, 2005).

M. Moore suggested that a clarification to section 5.4.2 would be helpful so that it is clear that bacterial cultures could also be considered a “reference material”. A. Fox noted this was not included in the clause because of their general lack of availability and that use of a “certified culture” is not required.

D. Mettler discussed the apparent inadequacy of the wording for section 5.9 on quality controls. She noted that, as written, this clause would allow the use (and require trending) of negative controls and negative sample duplicates. She also noted that even though the use of sample duplicates was an allowable option, the clause later goes onto *require* duplicates to be trended. A. Fox of AOAC replied that this section appears to mean something other than what the writing committee intended. R. Brauninger told the attendees that the consensus of the AOAC ALACC chairs is that this clause should be interpreted to mean that laboratories are to use a known concentration of something (either as a quality control sample or sample duplicate) to track precision and accuracy. A. Hensley suggested that an interpretative note could be added as an addendum to the AOAC requirements until the actual section can be changed through the proper channels.

Action 2: Although the AOAC ALACC has responded in general to R. Brauninger’s request for interpretation of this clause, K. Stoub and D. Mettler, together with R. Brauninger to craft clarifying language for section 5.9 which will be submitted for consideration by the AOAC ALACC committee chairs (by April 30, 2005).

A discussion of what constitutes a batch took place in the context of the requirements of 5.9. The consensus of the group was that because the wording of this clause includes the term “usually”, this was not an assessable point and therefore the size of a batch is anything that the laboratory defines it to be.

A discussion took place on the meaning of the term “failing assessment date” (section 5.10, Appendix A) relative to the following clause: “All data acquired on instruments which fail a parameter are suspect between the *failing assessment date*, and the last successful calibration/verification date, and the lab shall institute the ‘Control of Nonconforming Work’.” It was decided that a failing assessment date is considered to be the date that the instrument was found to be out of spec.

A discussion took place on the meaning of section 5.10, *Reporting the Results* as it pertains to the electronic signature requirements found in USA Title 21, Code of Federal Regulations Part 11. K. Stoub reminded the group that the interpretation of this clause was discussed during the 2004 assessor breakout meeting and that the consensus was that this clause only covers the electronic reporting requirements, not all electronic records.

Action 3: For clarification purposes, R. Brauningger to add a weblink to USA Title CFR 21 Part 11 to the appendix of the checklist (by April 30, 2005).

Action 4: R. Brauningger to request that the A2LA Communications Manager, D. Valentine add web links on the main A2LA website to the applicable federal regulations referenced in the guidelines (by April 30, 2005).

D. Mettler noted that although freezers, incubators, ovens, autoclaves and water baths were included in Table 1 (the table noting equipment requiring “calibration”) there was an apparent oversight regarding refrigerators, which were left out. Also, M. Moore noted an apparent inconsistency regarding weights; here the use of a single asterisk erroneously implies that weights must be checked on a daily basis. D. Mettler noted that for Table 2, the required recalibration frequency of the reference thermometer should have been updated to show a change from every 2 years to a yearly performance verification. It was also noted that all the asterisks in the tables need to be reviewed and updated to reflect new AOAC guidance.

Action 5: R. Brauningger to seek clarification from the AOAC regarding the omission of refrigerators and amend Table 2 as appropriate (by April 30, 2005).

3. New/ Other Business

No other or new business was raised.

The 3rd meeting of the A2LA Food Assessor Breakout Meeting was adjourned at 8:00 pm.

Minutes prepared by Ada R. Hensley, Senior Laboratory Services Officer.