Background:

- A2LA Accreditation body
- Laboratory has been accredited since 2008
- 5 assessments
- First Deficiency Protest: 2\textsuperscript{nd} audit 2010
How it starts:

• Closing meeting  
  – Auditor will/has to go over how to protest

• Stewing  
  – QAU takes a day or weekend to think

• Internal meeting  
  – Discuss plan of action: corrective action plans and which to protest
Internal Meeting:

Deficiency Report

1. ISO/IEC 17025:2017 requires a list or an equivalent document control procedures identifying the current revision status and distribution of documents in the management system that is established and readily available to provide the use of invalid and/or obsolete documents.

Findings: (SA) The Quality System External Documents is not current as evidenced by the following revisions:
   a. A2LA R101 (Doc. ID: 0042) Revision Status - current revision: 07/20/2021
   b. A2LA P110 (Doc. ID: 0043) Revision Status - current revision: 10/15/2012
   c. A2LA R105 (Proficiency Testing) - current revision: 04/04/2013

Correction: Obtain appropriate revisions.
Corrective Action: QA/QC will sign up for the A2LA RSS feed that sends document updates, and obtain and control current revisions when they are released.

2. ISO/IEC 17025:2017 requires the laboratory to retain records of sufficient information to facilitate identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original.

Findings: (SA) The laboratory does not always capture sufficient information, for example:
   a. Metlab furnace calibration performed on 3/6/12 or 4/25/13 does not include (a) identification of the furnace; (b) name of personnel who performed the calibration.
   b. The lab does not record the identification number of the conductivity meter used for weekly conductive and resistivity testing for the DI water supply.
   c. The laboratory is not able to provide the Certificate of Analysis or lot number of EOTA used for Nitrogen Analysis Sample Number 13252 on 05/22/2011.
   d. Balance, pipet, and equipment used in the testing of the DI water supply for the DI water supply.

This area will require some work and thought.

3. ISO/IEC 17025: Section 4.3.2.1 (AOAC) requires that the person responsible for the preparation of reports be traceable through the information on both the label and in the records.

Findings: (RD) The names of the person preparing TSB and TT broth on 1/29/13 and 4/22/13 respectively were not identified on the reagent bottle labels.

Correction: Revised analyst to record initials on reagent bottle.
Corrective Action: Hold lab wide training on CP-4-11 and policies in 4.3.2.1 AOAC note

4. ISO/IEC 17025: Section 4.3.3.1.1 (AOAC) requires traceability to each analyst performing steps in the testing process.

Findings: (RD) The lab uses form PM-6001, Food Micro Sample Analysis and Media Ready Form to track all media for numbers and samples. Records of review of the forms for completeness or traceability were not available.

Correction: Update forms to ensure this review is recorded.
Corrective Action: Review all scope methods and ensure this is not a systemic problem. Update any forms to include this required information.

Deficiency Report

5. ISO/IEC 17025:5.5.8 requires all equipment requiring calibration to be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

Findings: (SA)
   a. Pipette no. E28751A used for cytokinesis analysis on 5/1/2015 is not labeled with last date of calibration and states only that the due date is 10/26/2015. Correction: Re-label pipette with all required information.
   b. 815-937-705, line 23 status, “After calibration a pipette shall… optionally [reckon] the date the pipette is due for calibration (8 months from calibration date) may be put on the label.”
   c. Timers, such as the VVW CHEM-1 timer, do not have stickers that indicate the date of calibration or the due date for the next calibration. Address this with timer calibration procedures (i.e., update the timer inventory).
   d. Non-CLIA pipettes used for test analyses are calibrated in-house, however, they are not uniquely identified and are not labeled in coded as to those calibration status. No longer use non-class A pipettes.

6. ISO/IEC 17025:5.5.1 and A2LA P113, LST-4 requires the laboratory to have a program and procedure for the calibration of its equipment.

Findings: (SA)
   a. The laboratory was not able to provide a written procedure for the calibration of non-class A pipettes, most recently performed 10/7-4/2011. No longer use non-class A pipettes.
   b. The laboratory was not able to provide a written procedure for the calibration of timers, most recently performed 10/26/2011. Address this with timer calibration procedures.

7. ISO/IEC 17025:5.10.2 requires each test report to include the following information, or to have this information in the laboratory, (a) identification of the method used; (b) name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report.

Findings: (SA) The laboratory did not record the test method(s) used for the analysis of Sample #122002 on the Test Report dated 7/30/2012 nor is it recorded elsewhere in the laboratory records. Additionally, it is not clear who authorized the test report.

Corrective Action: Update Sampling to identify method (i.e. CHEM-MTH-401) with each analysis code for all applicable methods.

8. AOAC Appendix B (I) requires that the organisms required for testing be traceable.

Findings: (RD) Traceability records for the control culture of Salm. typhimurium were not available.
Corrective Action: Obtain an exemption from A2LA for use of MPD fluorescent control (I) may have made this up entirely – or confused this...
Meeting Progress:

Deficiency Report

1. ISO/IEC 17025:2017 (3.2.1) requires a master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system that is established and readily available to preclude the use of invalid and/or obsolete documents. 13-CAR-14

**Finding:** (SA) The Quality System External Documents is not current as evidenced by outdated revisions of:
- a. A10A. E101 (Gen Requirements for Accreditation) - current revision 07/02/2012
- b. A10A. E113 (Initial Traceability for Life Science) - current revision 11/16/2012
- c. A10A. E105 (Proficiency Testing) - current revision 01/01/2013

2. ISO/IEC 17025:2017 (3.2.1) requires the laboratory to retain records of sufficient information to facilitate identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original. This is a repeat deficiency from 2012.

**Finding:** (SA) The laboratory does not always capture sufficient information, for example:
- a. Methane furnace calibration performed on 3/6/12 or 4/28/13 does not include (a) identification of the furnace; (b) name of personnel who performed the calibration. 13-CAR-16
- b. The laboratory does not record the identification number of the conductivity meter used for weekly conductivity and resistivity testing for the DDI water supply. PROTEST
- c. The laboratory is not able to provide the Certificate of Analysis or lot number of EDTA used for Nitrogen Analysis Sample Number 12/2022 on 05/25/2011. 13-CAR-16
- d. Balances, pipettors, and equipment such LC Columns used for each test are not recorded or otherwise linked to sample analysis test reports. PROTEST
- e. The serial number (629100) of the Foss Check Cell used for system suitability of the FOG8 NIR is not recorded as part of daily instrument suitability checks. PROTEST

3. ISO/IEC 17025, Section 4.3.3.1 (AOAC) requires that the person responsible for the preparation of reagents shall be traceable through the information on both the label and in the records. 13-CAR-25

**Finding:** (SA) The names of the persons preparing TSB and TT broth on 3/26/13 and 4/23/13 respectively were not identified on the reagent bottle labels.

9. ISO/IEC 17025, Section 5.5.3 (AOAC) requires the lab to maintain records of calibration and sanitation of equipment. 13-CAR-21

**Finding:** (SA) Labels of work instruction 330 requires the lab to decontaminate Maxwell 16 Equipment *009* on the first Monday of each month. Records of decontamination were not available for 2013. The equipment has not been in use for quite some time but it was not labeled either as being “Out of Service” as required under section 5.5.7 of the standard.

10. ISO/IEC 17025 5.5.4 requires each item of equipment used for testing and calibration and significant to the result shall be uniquely identified. 13-CAR-17

**Finding:** (SA) The laboratory was not able to provide records of the balance or anemometer used to perform in-house calibrations of volumetric non-class A pipettes performed on 10/14/2011.

11. ISO/IEC 17025, Section 5.5.5 requires the lab to maintain records of equipment significant to the tests. This is a repeat deficiency from 2011. 13-CAR-19

**Finding:** (SA) The lab has several incubators in the lab but does not record the incubator number for traceability on the form used to record incubator information for the samples.

12. ISO/IEC 17025 5.5.1, 5.5.5 requires the laboratory to be furnished with all items of measurement and test equipment required for the correct performance of tests, including preparation of test items, processing and analysis of test data (5.5.1). Records shall be maintained on each item of equipment and shall include (a) unique identification; (b) checks that the equipment complies with the specifications; (c) the current location; (d) dates, results, and copies of reports and certificates of adjustments, acceptance criteria, and due date of next calibration; and (e) the maintenance and maintenance carried out to date. This is a repeat deficiency from 2011.

**Finding:** (SA) The laboratory does not always meet these requirements, for example:
- a. CEM MicroPulse microwave digesters in MD9052 or in MD 9900 used for ICP analysis are not on the instrument equipment inventory and have not been calibrated since 2005. 13-CAR-39
- b. Thermo Scientific Legend XT Centrifuge in 61425272 used for ICP sample preparation, is not included on the instrument inventory and there are no records to confirm that it complies with specifications. PROTEST

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Next Steps:

- Writing our protests
  - Simple document
  - Address all parts of deficiency
  - Cite laboratory’s documents or the 17025 Standard

Deficiency 3.

Finding:

1. ISO/IEC 17025 4.13.2.1 states “The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued for a defined period.”

There was no record of the daily check (blanks) being done for the turbidity meter used for Staph testing.

The standard states:

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test, and/or calibration and checking of results.

The turbidity meter is used to determine the turbidity of a tube of positive control culture (relating to the number of organisms in the tube) before it is used to spike the positive control matrix used in the Staphylococcus analysis. The procedures outlined in the controlled documents MICRO-ATH-315 Detection of Staphylococcus spp. in Foods by 3M RapidScreen™ Staph Express Count System and WI-338 Siemens MicroScan Turbidity Meter detail how to use the turbidity meter including how to “blank” the instrument. The reading of the zeroed (blanked) instrument is not recorded by the laboratory much the same way the reading of a zeroed balance is not recorded before sample weigh out begins. While it may be quality critical that the instrument is blanked, as it would be to take a balance before sample weigh out (especially if dilutions are being made), the procedure clearly indicates what to do if the turbidity meter does not “blank” as expected. The absorbance (turbidity meter reading) of the positive control culture tube is being recorded. The laboratory does not see any quality benefit from recording the “blank” reading of the turbidity meter just as it doesn’t see any quality benefit from recording a zeroed balance reading. The laboratory feels that training staff on how to properly use each of those instruments and providing written procedures is adequate to ensure each instrument is being used properly.
- Submitted to Accreditation Council
- Assessor is no longer consulted

- Accreditation Officer collect protests
- Assessor will provide a justification for the deficiency
Protests: Won

Deficiency  #12.  b.

1. ISO/IEC 17025 5.5.1, 5.5.5 b-g requires the laboratory to be furnished with all items of measurement and test equipment required for the correct performance of tests, including preparation of test items, processing and analysis of test data (5.5.1). Records shall be maintained on each item of equipment and shall include (b) unique identification; (c) checks that the equipment complies with the specification; (d) the current location; (f) dates, results and copies of reports and certificates of adjustments, acceptance criteria, and due date of next calibration; (g) the maintenance plan and maintenance carried out to date. This is a repeat deficiency from 2011.

Findings: (SA) The laboratory does not always meet these requirements, for example:

b. Thermo Sorvall Legend XT Centrifuge s/n 41425727 used for PDP sample preparation, is not included on the instrument inventory and there are no records to confirm that it complies with specifications.

A centrifuge is considered to be general service equipment. The recommendations cited in ALACC appendix A, table 3 are followed for centrifuges. The use of a centrifuge in the PDP extractions is not a quality critical step. The sample is centrifuged as a means of aiding the separation of water and solvent phases. The speed of the centrifuge is not critical, approximate values are stated in the method to give the operator some guidance. The critical goal is a phase separation, as long as this is achieved the needs of the centrifugation step have been met.

The lab does have a declaration of conformity from the manufacturer; see attachment 1.

The laboratory feels that no further corrective action is necessary.
Protests: Lost

Deficiency 12

Finding:
Laboratory SOP GP-5-06 (Validation of Methods) 5.7.5 states "All method precision data shall be summarized and submitted to the QAU."

- The results of linearity were not summarized in the information submitted to QAU. Objective evidence: 16-VAL-05, 6-VAL-06.
- The method precision data was not summarized in the information submitted to QAU. Objective evidence: 16-VAL-06.

The standard states:

5.4.5.1 "Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled." ... and "5.5.6 The results of linearity determination shall be summarized and submitted to the QAU."

16-VAL-05 and 16-VAL-06 results of linearity were summarized and submitted to QAU. The summary was in the form of a data packet. The linearity information was not rewritten onto the validation forms but were placed in each data packet. On the top of the data it states LOQ and Linearity established (attachment 1 and 2). The quality assurance team did not find it necessary to re-write the information onto the validation forms.

Deficiency 6

Finding:
Laboratory SOP GP-5-06, 5.4 (Validation of Methods) states "Validation scheme shall be proposed by the method user. The scheme shall be submitted to the Quality Assurance Unit (QAU) for approval when validation work begins" ... and "5.4.3 Select parameters to be run and define the performance requirements and acceptance criteria for the full validation experiment from Sections 5.2 - 5.8."

Validation 16-VAL-07 did not list the validation parameters. It referred to a proficiency test but did not identify any performance requirement and acceptance criteria for validation.

The standard states:

5.4.3 "The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources."

Deficiency 11

Finding:
(JW) Laboratory SOP GP-5-06 (Validation of Methods), 5.2.1 states "The LOD is the lowest quantity of analyte that can be reproducibly detected by the analytical method. For example, when a chromatographic instrument is used the LOD shall be at least three times the instrumental baseline noise."

For validations 16-VAL-05 and 16-VAL-06, the LOQ, not the LOD, was calculated as 3 times the noise. The LOD was not calculated.

The validation packets for 16-VAL-05 and 16-VAL-06 clearly state an LOQ value for both Memensin and Lasalocid. The auditor was shown the LOQ values and GP-5-06 section 5.4.3. GP-5-06 that states:

5.4.3 Methods using Mass Spectroscopy as the quantifying technique may have instances where the LOD equals the LOQ. This shall be subject to the approval of the QAU.

The laboratory’s SOP clearly states that LOD in some instances is equal to LOQ for mass spectroscopy methods.
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