



QMS Quick Learning Activity

Proficiency Testing

ISO/IEC 17025:2005

Abbreviations and Acronyms

- **AACC**-American Association of Cereal Chemists
- **AAFCO** – American Association of Feed Control Officials (www.aaftco.org)
- **AB** – Accrediting Body
- **ALACC** – AOAC Analytical Laboratory Accreditation Criteria Committee
- **AOAC International**—Organization that provides the ALACC guidelines (www.aoad.org)
- **AOCS**
- **CRM** – Certified Reference Materials
- **PT**– Proficiency Testing
- **RM** – Reference Material



Abbreviations and Acronyms

- **PDP**-Pesticide Data Program
- **EPA**-Environmental Protection Agency
- **ppb**-parts per billion
- **ppm**-parts per million



Abbreviations and Acronyms

Accrediting Bodies:

- **A2LA**-American Association for Laboratory Accreditation
- **AIHA**-American Industrial Hygiene Association
- **ANAB**-ANSI-ASQ National Accreditation Board
- **PJLA**-Perry Johnson Laboratory Accreditation
- **IAS**-International Accreditation Service



What ISO/IEC 17025 says

Section 5.9 *Ensuring the Quality of Test and Calibration Results*

5.9.1 The laboratory shall have *quality control procedures for monitoring the validity* of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:



ISO/IEC 17025 section 5.9

- This is the **only section** of the standard that mentions proficiency testing (PT) programs.



ISO Section 5.9 continued

- (a) regular use of Certified Reference Materials (CRM) and/or internal quality control using secondary Reference Materials (RM);
- (b) participation in interlaboratory comparison or **proficiency-testing** programmes;
- (c) replicate tests or calibrations using the same or different methods;
- (d) retesting or recalibration of retained items;
- (e) correlation of results for different characteristics of an item.

Note: The selected methods should be appropriate for the type and volume of work undertaken.



Requirements in addition to ISO/IEC 17025:2005



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- **AAFCO** Quality Assurance Control Guidelines for Feed Laboratories supplement to ISO/IEC 17025:2005, b2014 edition. This includes accreditation requirements added by AAFCO.



- **AOAC** International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals, An aid to interpretation of ISO/IEC 17025:2005. This document is also known as the **ALACC** guidelines.



Accrediting Bodies (AB) Requirements

- ABs may have either guidance or policy in place defining this section of the standard.
- Check their websites. They are generally available to download for free.
- ABs
 - A2LA
 - AIHA
 - ANAB
 - PJLA
 - IAS



So what are you supposed to do?

Determine if there is a suitable PT available for:

- ✓ ***Analyte of Interest***
- ✓ ***Matrix***
- ✓ ***Fit-for-Purpose***



Proficiency Testing Providers for Food & Feed Testing Laboratories

Can't Find What You're Looking For? Get Help Here: Link to Accredited PT Providers by A2LA <https://www.a2la.org/dirsearchnew/ptprovider>
Link to EPTIS PT provider search database <https://www.eptis.bam.de/en/index.htm>

Accredited ISO/IEC17043	Accrediting Body	Accreditation Certificate Number	Valid To Date	Name of Provider	Frequency	Matrices	Analytes
Yes (Animal Feed and Pet Food)	ANAB	AP-2139	3/28/2019	AAFCO Animal Feed Program	Monthly	Animal feed, feed ingredients, etc.	Chemistry Proximates, metals, veterinary drugs, minerals, vitamins, and
				AAFCO Pet Food Program	Quarterly	Pet food or pet food ingredient	Chemistry Proximates, metals, minerals, vitamins, etc.
				AAFCO Mycotoxin Contaminants Program	Quarterly	Animal feed or pet food	Chemistry Mycotoxins
				AAFCO Metal Contaminants Program	Quarterly	Animal feed, pet food, or food/feed ingredient	Chemistry Al, As, B, Cd, Cr, Co, F, I, Pb, Hg, Mo, Ni, V, Se, Cu, S, etc.
Yes	A2LA	1782.01	7/31/2017	AOAC	Quarterly	Potatoes, Mashed	Microbiology Qualitative Quantitative
					Quarterly	Meat, ground	Microbiology Qualitative
					Quarterly	Meat Ground/Processed	Microbiology Qualitative
					Quarterly	Meat, Ground	Chemistry Nutritional Labeling
					Quarterly	Cheese, Processed	Chemistry Nutritional Labeling
					3/year	Fruits/vegetables	Chemistry Pesticide Residue
					2/year	Eggs, Liquid	Microbiology Qualitative
					Quarterly	Infant Formula	Chemistry vitamins, nucleotides, fatty acids and ultra-trace minerals

Found on AAFCO.ORG\Laboratory – Resources for ISO 17025:2005 Accreditation

So what are you supposed to do?

After you have located a PT provider, determine if the provider is accredited to ISO/IEC 17043:2010 Conformity assessment - General requirements for proficiency testing

Source of providers

:

APHL

https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx

AAFCO

<http://www.aafco.org/Laboratory>



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Additional thoughts...

- If there is an accredited provider, the AB may strongly encourage the use of the provider.
- However, you and your customer may jointly agree that a CRM or non-accredited program is fine. Just make sure the conversation is well documented.



PT Provider's Scope

- If the provider is accredited, review their scope.
- A provider may be accredited for a limited number of analytes/compounds.
- Their literature should indicate if the PT or CRM is covered by their scope of accreditation.



Example of a PT Provider's Scope



American Association for Laboratory Accreditation

SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

AOAC INTERNATIONAL
2275 Research Blvd, Suite 300
Rockville, MD 20850-3250
Arlene Fox Phone: 301 924 7077 x143

PROFICIENCY TESTING PROVIDER

Valid To: July 31, 2017

Certificate Number: 1782.01

In recognition of the successful completion of the A2LA evaluation process, this proficiency testing provider has been found to meet the ISO/IEC 17043:2010, "Conformity assessment-General Requirements for Proficiency testing". Therefore, in recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this organization to provide proficiency testing samples in the following analyte/matrix combinations:

Program Name	Frequency	Sample/Artifact Types
M01 - Standard Microbiology	Quarterly:	Matrix: Mashed Potatoes Organisms: Qualitative: Salmonella Species, Listeria Species, E. coli O157:H7; Quantitative: Coagulase Positive Staphylococcus, Coliform, E. coli, Yeast and Mold, Aerobic Plate Count, B. cereus, Enterobacteriaceae
M02 - Pathogen-Free Microbiology	Quarterly:	Matrix: Mashed Potatoes Organisms: Quantitative: Coliform, E. coli, Yeast and Mold, Aerobic Plate Count
M03 - Meat Microbiology 1	Quarterly:	Matrix: Ground Meat Organisms: Qualitative: Salmonella Species
M04 - Meat Microbiology 2	Quarterly:	Matrix: Ground Meat Organisms: Qualitative: E. coli O157:H7
M05 - Meat Microbiology 3	Quarterly:	Matrix: Processed Meat Organisms: Qualitative: Listeria monocytogenes



Association of American Feed Control Officials

(A2LA Cert. No. 1782.01) Revised 08/05/2014

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Example: Reference Material Producer's Scope



American Association for Laboratory Accreditation

SCOPE OF ACCREDITATION TO ISO/IEC GUIDE 34:2009

AOCS
2710 S. Boulder Drive
Urbana, IL 61802-7190
Dr. Richard Cantrill Phone: 217 693 4830

REFERENCE MATERIALS PRODUCER

Valid To: May 31, 2015

Certificate Number: 3438.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this Reference Material Producer for the production of certified reference materials and reference materials of the following categories:

Category of Reference Material Certified Reference Material A.4.4 Plant Materials	Test Analysis Measurement	Measurement Technique
Seed Non-Modified Canola GT73/RT73 Canola Powder Non-Modified Cotton MON1445 Cotton MON531 Cotton MON15985-7 Cotton MON88913 Cotton Non-Modified Maize MON88017 Maize MON87460 Maize MON89034 Maize GA21 Maize MIR604 Maize MIR162 Maize Non-Modified Potato EH92-527-1 Potato Non-Modified Soybean BPS-CV127-9 Soybean MON89788 Soybean MON87701 Soybean MON87705 Soybean Non-Modified Sugarbeet H7-1 Sugarbeet	Purity	Real-time PCR



Association of American Feed Control Officials

(A2LA Cert. No. 3438.01) 06/05/2013

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Remember...

...the standard states in 5.9.1 (a) regular use of CRM and/or internal quality control using secondary RM;



Common Road blocks

- ❖ If PT has to be shipped from outside the country, there may be restrictions for importing the sample matrix
- ❖ The analyte of interest may be found, but it is not in matrix, or at the wrong concentration i.e., parts per million (ppm) and parts per billion (ppb) are needed
- ❖ Issues with PT provider – cannot meet needs or not fit-for-purpose



**ALWAYS DOCUMENT the
ISSUES if a suitable PT
cannot be located .**

*Remember! 4.6 Purchasing
Services and Supplies and approved
supplier list*



Use of Internal Check Samples

Internal check samples may be an acceptable alternative when external PT / check samples are not commercially available or are determined to be unacceptable for your customers analytical requirements.



Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM



Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin with other laboratories**



Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin with other laboratories
- 3) Perform a comparison with another method**



Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin with other laboratories
- 3) Perform a comparison with another method
- 4) Perform an inter-laboratory comparison**



Inter-laboratory comparison

The organization, performance and evaluation of calibration/test results for the same or similar item by two or more laboratories in accordance with pre-determined conditions.*

*ANAB Guidance of Proficiency Testing/Inter-Laboratory Comparisons, June 17, 2015



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Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin with other laboratories
- 3) Perform a comparison with another method
- 4) Perform an inter-laboratory comparison
- 5) Test previously run samples**



Internal Checks

- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin with other laboratories
- 3) Perform a comparison with another method
- 4) Perform an inter-laboratory comparison
- 5) Test previously run samples
- 6) Correlation of results for different characteristics of an item**



- 1) Use a CRM and/or internal quality control using secondary RM
- 2) Participate in a round robin.
- 3) Perform a comparison with another method.
- 4) Perform an inter-laboratory comparison.
- 5) Test previously run samples.
- 6) Correlation of results for different characteristics of an item.

7) Internal Check Samples



Pesticide Data Program (PDP) example

- As part of the USDA Pesticide Data Program (PDP), Colorado, New York and Montana analyzed groundwater and surface water samples. These laboratories were required to become accredited.
- In addition, Minnesota has an extensive ground water and surface water program for monitoring pesticides. Over 2,000 ground water and surface water samples were analyzed in Fiscal Year 2014. The list is unique to this state.



PDP example continued

- The pesticides list is not the “common” EPA list for drinking water or wastewater; there were no commercial PTs that adequately covered the MN list.
- PDP provided the water laboratories in their program two specialty PTs made for them by Ultra Scientific.
- PDP experienced large budget cuts and discontinued the water analysis for its programs. The PTs ended but the MN laboratory’s accreditation did not.



PDP example continues

- The laboratory tried a couple commercial PTs but those were quickly deemed unacceptable. We look at parts per trillion and many of the commercial are ppb/ppm. Additionally the compound lists did not adequately cover our lists.
- The laboratory went back to Ultra and now have 2 to 3 specialty mixes made each year covering each class of compounds. (expensive but meets their customers needs). They cannot cover all of the analytes in the mixes. Their AB accepts using class of compound.
- The laboratory also reviews internal matrix spike recovery data especially for compounds that Ultra is not able to add to a mix because of stability issues.



Internal Check Sample

- Here are some examples of approaches that can be taken:
 - Find a matrix with the analyte
 - Develop in-house using CRM/RM
 - Work with a CRM/RM company
 - Have another laboratory make it
 - Use a previously analyzed sample
 - Compare results for different characteristics of the sample



Re-Purpose PT/Check Samples

- a) Use as a laboratory control sample (LCS).
- b) Use for testing competency of analytical staff.
- c) Use for verification/validation of methods.



References

- ISO/IEC 17025:2005
 - <https://www.iso.org/standard/39883.html>
- AB websites for their policies on proficiency testing
- Eurachem: “The Fitness for Purpose of Analytical Methods, A Laboratory Guide to Method Validation and Related Topics”
 - <https://www.eurachem.org/index.php/publications/guides/mv>
- AOAC: “How to Meet ISO 17025 Requirements for Method Verification”
 - http://aoac.org/aoac_prod_imis/AOAC_Docs/LPTP/alacc_guide_2008.pdf

