QMS Quick Learning Activity

Proficiency Testing

ISO/IEC 17025:2017

7.7 Ensuring the validity of results

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Abbreviations and Acronyms

- **AAFCO** – American Association of Feed Control Officials (www.aafco.org)
- **AB** – Accrediting Body
- **ALACC** – AOAC Analytical Laboratory Accreditation Criteria Committee
- **AOAC International–**Organization that provides the ALACC guidelines (www.aoac.org)
- **CRM** – Certified Reference Materials
- **EPA**-Environmental Protection Agency
- **PDP**-Pesticide Data Program
- **ppb**-parts per billion
- **ppm**-parts per million
- **PT**– Proficiency Testing
- **RM** – Reference Material

Abbreviations and Acronyms

Accrediting Bodies (ABs):

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

What ISO/IEC 17025 says

Section 7.7 *Ensuring the Validity Results*

7.7.1 The laboratory shall have *a procedure for monitoring the validity* of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:…

ISO Section 7.7.1 continued

- Use of reference materials or quality control materials
- Participation in interlaboratory comparison *(or proficiency testing programs)*
- Replicate tests or calibrations using the same or different methods
- Retesting or recalibration of retained items
- Correlation of results for different characteristics of an item.

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

ISO/IEC 17025 section 7.7.2

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;
NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b)participation in interlaboratory comparisons other than proficiency testing.

ISO/IEC 17025 section 7.7.3

7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

ISO/IEC 17025 section 8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.
NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

Requirements in addition to ISO/IEC 17025:2017

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- **AAFCO** Quality Assurance Control Guidelines for Feed Laboratories supplement to ISO/IEC 17025:2005, (2014). 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 17025:2017. This document is also known as the **ALACC** Guidelines.

Accrediting Bodies (AB) Requirements

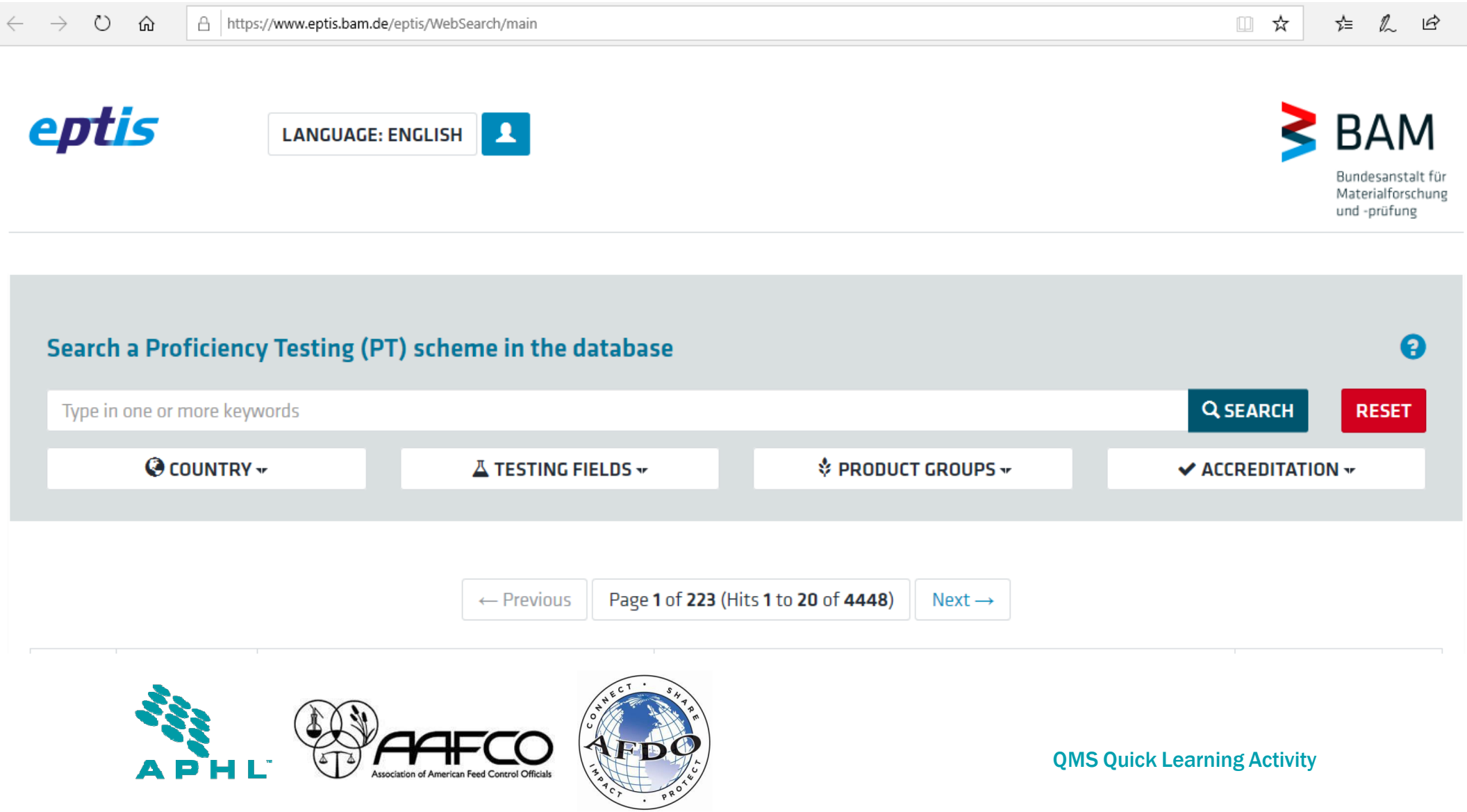
- ABs may have either guidance or policy in place for section 7.7 of the standard.
- Check their websites. They are generally available to download for free.
- ABs for ISO/IEC 17025:2017:
  - A2LA
  - AIHA
  - ANAB
  - PJLA
  - IAS

So what are you supposed to do?

Determine if there is a suitable PT available for:

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

eptis https://www.eptis.bam.de/eptis/WebSearch/main



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So what are you supposed to do?

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

The European Proficiency Testing Information System (EPTIS) database can be used to help located a PT provider and often provides the 3rd party accreditation information. Here is information on the AAFCO PT for Mycotoxins Scheme:

Aims of the PT scheme	
Target group of participants	Animal Feed and Pet Food Laboratories
Linked to specific legislation / standards	
Additional, subsidiary aims	Proficiency Testing for Analytical Laboratories
Number of participants	60
Accredited or otherwise reviewed by a 3rd party	Accredited by ANAB on the basis of ISO/IEC 17043:2010
Operation is commissioned / requested by	no
Fees and frequency	

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 use of a non-accredited program is fine. Just thoroughly document the conversation.

PT Provider's Scope

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

Example of a PT Provider's Scope

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, 2021 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[1]	Quarterly	Matrix: Mashed Potatoes Organisms: Qualitative: Salmonella species, Listeria species, Escherichia coli O157:H7 Quantitative: Coagulase Positive Staphylococcus, Coliform, E. coli, Yeast and Mold, Aerobic Plate Count, B. cereus, Enterobacteriaeae
M02 - Pathogen-Free Microbiology[1]	Quarterly	Matrix: Mashed Potatoes Organisms: Quantitative: Coliform, E. coli, Yeast and Mold, Aerobic Plate Count
M03 - Meat Microbiology 1[2]	Quarterly	Matrix: Ground Meat Organisms: Qualitative: Salmonella species
M04 - Meat Microbiology 2[2]	Quarterly	Matrix: Ground Meat Organisms: Qualitative: E. coli O157:H7
M05 - Meat Microbiology 3[2]	Quarterly	Matrix: Processed Meat Organisms: Qualitative: Listeria monocytogenes

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Remember...

…the standard states in 7.7.1 (a) regular use of reference materials or quality control materials.

Reference material providers can also be accredited to ISO 17034:2016 *General requirements for the competence of reference material producers*

Example: Reference Material Producer's Scope

SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

AMERICAN OIL CHEMISTS' SOCIETY (AOCS)
2710 S. Boulder Drive
Urbana, IL 61802
Dawn Shepard Phone: 217 693 4810

PROFICIENCY TESTING PROVIDER

Valid To: September 30, 2023 Certificate Number: 3438.02

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[1, 2]:

Program Name	Frequency	Sample/Artifact Types
Edible Fat	Quarterly	Q1: Margarine Oil, Vegetable Shortening; Q2: Emulsified Shortening, Emulsified Shortening; Q3: Vegetable Shortening, Vegetable Shortening; Q4 Emulsified Shortening, Vegetable Shortening
Tallow and Grease	Quarterly	Tallow and Grease
Oilseed Meal	Quarterly	Q1: Soybean Meal, Canola Meal; Q2: Peanut Meal, Soybean Meal; Q3: Cottonseed Meal, Soybean Meal; Q4: Safflower Meal, Protein Concentrate
Unground Soybean Meal	Quarterly	Soybean Meal
Cholesterol	Quarterly	Q1: Whole Egg Powder, Egg Yolk Powder; Q2: Mixed Whole Egg and Egg Yolk Powder, Desiccated Cheese Powder; Q3: Desiccated Powdered Turkey, Desiccated Powdered Chicken; Q4: Desiccated Powdered Beef, Desiccated Powdered Seafood

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Program Name	Frequency	Sample/Artifact Types
Gas Chromatography	Quarterly	Q1: Palm Oil, Soybean Oil; Q2: Vegetable Shortening, Cottonseed Oil; Q3: Coconut Oil, Canola Oil; Q4: Sunflower Oil, Olive Oil
Trace Metals in Oil	Quarterly	Soybean Oil
Trans Fatty Acids	Quarterly	Q1, Q3 and Q4: Hydrogenated Soybean Oil; Q2: Non-hydrogenated Soybean Oil, Hydrogenated Soybean Oil

[1] Assigned values and associated uncertainties determined by participant consensus values.

[2] Assigned values and associated uncertainties determined by known values.

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Common Road blocks

- If a 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 may not be in matrix, or may be at the wrong concentration i.e., parts per million (ppm) and parts per billion (ppb) are needed
- PT provider issues – cannot meet needs or not fit-for-purpose

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

Use of Internal Check Samples

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

Internal Checks

1) Use a reference material or quality control material (ISO 17034)

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3) Perform a comparison with another method
4) **Perform an interlaboratory comparison**

Interlaboratory comparison

ISO/IEC 17025:2017
3.3 interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

Internal Checks

1) Use a reference material or quality control material (ISO 17034)
2) Participate in a round robin with other laboratories
3) Perform a comparison with another method
4) Perform an interlaboratory comparison
5) **Test previously analyzed samples**

Internal Checks

1) Use a reference material or quality control material
2) Participate in a round robin with other laboratories
3) Perform a comparison with another method
4) Perform an interlaboratory comparison
5) Test previously analyzed samples
6) **Correlate results for different characteristics of an item**

1) Use a reference material or quality control material
2) Participate in a round robin.
3) Perform a comparison with another method.
4) Perform an interlaboratory comparison.
5) Test previously analyzed samples.
6) Correlate 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 (MN) 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 continued

- The MN laboratory tried a couple commercial PTs but those were quickly deemed unacceptable. The laboratory analyzed for parts per trillion and many of the commercial are ppb/ppm. Additionally, the compound lists did not adequately cover the list of analytes.
- The laboratory went back to Ultra Scientific and had them produce 2 to 3 specialty mixes each year covering each class of compounds. It was expensive but met their customer's 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 Scientific 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 Samples

a) Use as a laboratory control sample.

b) Use for testing competency of analytical staff.

c) Use for verification/validation of methods.

References

- ISO/IEC 17025:2017
  - –https://www.iso.org/standard/66912.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