Proficiency Testing – Compliance with the ISO/IEC 17025 Standard

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State of Wisconsin
Department of Agriculture, Trade and Consumer Protection

ISO 17025 FDA Webinar
February 20, 2014
ISO Core Standards – ANSI/ISO/IEC

AMERICAN NATIONAL STANDARD

General requirements for the competence of testing and calibration laboratories

AMERICAN SOCIETY FOR QUALITY
P.O. BOX 3005
MILWAUKEE, WI 53201-3005
A2LA Documents
# A2LA Requirements Documents

- **R101** - General Requirements: Accreditation of ISO/IEC 17025 Laboratories
- **R102** - Conditions for Accreditation
- **R104** - General Requirements: Accreditation of Field Testing and Field Calibration Laboratories
- **R203** - Specific Requirements: Competition Animal Drug Testing Laboratory Accreditation Program
- **R204** - Specific Requirements: Food & Pharmaceutical Testing Laboratory Accreditation Program
- **R205** - Specific Requirements: Calibration Laboratory Accreditation Program
- **R206** - Specific Requirements: Environmental Testing Laboratory Accreditation Program
- **R207** - Specific Requirements: Environmental Lead Testing Laboratory Accreditation Program
- **R208** - Specific Requirements: Construction Materials Testing Laboratory Accreditation Program
- **R209** - Specific Requirements: Harris County/City of Houston/Port Authority Geotechnical Engineering Testing Laboratory Accreditation Program
- **R210** - Specific Requirements: Kentucky Underground Storage Tank Testing Laboratory Accreditation Program
Section 5.9 Ensuring the Quality of Test and Calibration Results

- There is NO section specifically about PTs
- PTs are NOT required under the core standards
- A2LA accredits to the AOAC guidelines – PTs may be required.

5.9.1 Procedures for monitoring the validity of tests and calibrations. May include but not limited to:

a) Regular use of CRMs and/or internal quality control.
b) Participation in ILC or PT programs.
c) Replicate Tests.
d) Retesting of retained items
e) Correlation of results for different characteristics of an item.
R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories

- Inter Laboratory Comparisons (ILC) – Typically Check Sample Programs- The organization, performance and evaluation of tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

- Proficiency Testing (PT) – The evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

The distinction between ILC and PT does not matter, for the purpose of accreditation an ILC is considered to be proficiency testing.
R103 – Acceptable Proficiency Testing Providers

- Commercial proficiency testing programs.
- Well organized ILCs.

- A2LA strongly recommends participation in PT programs operated by accredited PT providers.
- **Important Note** - There is no such thing as an ISO 17025 accredited PT provider.
- PT providers are accredited to ISO 17043.
- A2LA recommends that ILCs follow ISO 17043, but it is not required.
Within 5.9.1 there is a separate and distinct requirement for all laboratories to participate in relevant and available proficiency testing activities. Where possible, laboratories shall participate in external proficiency schemes.
The standard does not require the use of an external provider.

- AOAC language found in Section 5.9, p33-

“For those test methods not covered by external schemes, or if existing schemes are not suitable or feasible, the laboratory will do it’s best to demonstrate competency and justify it’s actions.”

Additional guidance is found in each accrediting body’s guidance or requirement documents.
If Not Suitable-Why Not

- You decide what suitability means.
- For instance, the provider you have found offers a PT for the product you test but not for the target compound you need. This PT might not be relevant.
- For instance, an accredited provider offers a PT for both the product you test and the target compound. However the PT provider has demonstrated problems delivering a product that is viable.
- We have documented on a Vendor Evaluation form our decision not to use a provider (Section 4.6.4)
## Wisconsin Department of Agriculture, Trade & Consumer Protection
### Bureau of Laboratory Services
#### Vendor Evaluation Form

The following company has been added as an approved vendor for technical supplies for the Bureau of Laboratory Services.

The company is considered acceptable based on their availability of the necessary items, quality of the items, response time for delivery, cost and customer service.

<table>
<thead>
<tr>
<th>Section</th>
<th>Food Chemistry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name</td>
<td>FAPAS</td>
</tr>
<tr>
<td>Type of Supplies</td>
<td>PT Samples</td>
</tr>
</tbody>
</table>

**Date Approved as Acceptable**

<table>
<thead>
<tr>
<th>By</th>
</tr>
</thead>
</table>

If the company is determined to be unacceptable based on the criteria listed above or other described reason, purchasing from the vendor will be discontinued as of this date.

<table>
<thead>
<tr>
<th>Date Removed as Acceptable</th>
<th>Not Approved, 12/7/13 (also a not to use FAPAS as determined in 2013)</th>
</tr>
</thead>
<tbody>
<tr>
<td>By</td>
<td>Steve Sobek - Laboratory Director</td>
</tr>
<tr>
<td>Reason</td>
<td>FAPAS is a PT provider located in Europe. We participated in a FAPAS Zarelonone PT exercise in 2011. FAPAS was unable to transport or track all samples in the exercise. All samples in the exercise were delivered 2-3 weeks past projected delivery dates. The inability to effectively transport and track samples calls into question the PT provider’s ability to deliver a PT sample and maintain integrity.</td>
</tr>
</tbody>
</table>

**BLS-007, E11/5/09**
Alternatives to External PTs

1. Participate in a round robin.
2. Perform an inter-laboratory comparison.
3. Perform a comparison with another method.
4. Or, address the elements found in 5.9.

WI Performs Internal PTs
**Internal PTs-WI Format**

- Overseen by our QA Functionality: assures independence from the operational area
- Single blind – lab knows they are PTs.
- QA functionality issues a report.
- Results are graded in the report, given a Z score if a quantitative method.
Example Internal PT

Food Chemistry Proficiency Sample
Wisconsin Department of Agriculture, Trade and Consumer Protection
Bureau of Laboratory Services

October 2013

Reporting the Results of the Proficiency Sample for Patulin

Sample ID: FCU-PT1-1013
LIMS ID: 13-00198
Date sample prepared: 10/02/13
Amount spiked in the apple cider = 79.9 ug/L
Results reported from the laboratory: 88.2 ug/L
Calculated percent recovery = 72.8%
Assigned value of the study: 79.5% Recovery

Evaluation of the Results: Using the Normalized Relative Standard Deviation of 5.3% based on the current QC limits for Patulin (R/doc master file/TESS/MASTER FORMS/Center Limits QC Limits for FCU, dated 06/21/12) provided a Z score of -1.26 for the reported value of Patulin.

Prepared by:
Fahad Sharieh, Quality Assurance Manager
Technical Services Section
Bureau of Laboratory Services, Division of Management Services
Wisconsin Dept. of Agriculture, Trade and Consumer Protection

M-01-13

R:\Tests\CHECK SAMPLES\FCU PT Sample\10\FCU Internal PT Report - Patulin 100213.doc
The Hierarchy

1. External PTs are required if the samples provided are feasible and suitable and relevant.
2. If suitable and relevant, External PTs must come from an ISO 17043 accredited provider.
3. If no accredited provider is available the external PT must come from a provider that follows ISO 17043
4. You can choose not to use an external PT but you must make the case if you do not use an external PT.
5. If you’ve made the case, you must do alternative as described in Section 5.9.1.
At a minimum laboratories shall participate in at least two proficiency testing activities per year every year. Laboratories with 4 or less sub-disciplines on their scope are required to participate in at least one proficiency testing activity per year, every year.
Activity

- Performing two activities is sometimes incorrectly interpreted to mean you must perform the same PT twice in one year.
- Activity is defined as a test performed on a PT sample.
  - Analyzing an API PT sample for *Salmonella* is one activity.

General Criteria, p. 34 - There is a confusing section under Note. “the proficiency testing activities should cover a minimum of one activity per method/test type and/or technology per year. The laboratory’s entire scope should be covered over a four year period.”

The note speaks to what a PT provider must have available to you. Not the frequency of what is required of you.
Sub-Discipline R103

- Must cover every sub-discipline on their scope over a four year period.
- The word sub-discipline does not refer to method
  - Qualitative Microbiology, ELISA, PCR, Chromatography, etc. are sub-disciplines.
- Chemistry–Food Testing and Biology–Food Testing are disciplines under R103a; an annex to R103.
- For Biology–Food Testing and Chemistry–Food Testing, there are no sub-disciplines.
Section (PT5) –

Laboratories shall have a documented plan of how they intend to cover the applicable program requirements or the major sub-disciplines and materials/matrices/product types (as defined in R103a – Annex –Proficiency Testing for ISO/IEC 17025 Laboratories document) on their scope of accreditation over a four-year period.
R103a Annex

- A2LA requires that the Food Program PT Plan be formulated in spreadsheet format so as to identify and correlate each of the methods listed on the Scope of Accreditation to its corresponding PT event over a rolling 4 year period.
Template

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>SOP #</th>
<th>Reference/Test Method</th>
<th>Program Provider</th>
<th>Jan-14</th>
<th>Feb-14</th>
<th>Mar-14</th>
<th>Apr-14</th>
<th>May-14</th>
<th>Jun-14</th>
<th>Jul-14</th>
<th>Aug</th>
</tr>
</thead>
</table>

Key:
- **Key**
- PT Result is expected
- PT Result was acceptable
- PT Result was not acceptable

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Wisconsin Department of Agriculture, Trade and Consumer Protection
Bureau of Laboratory Services
AZLA Certificate Number 2623.01
Calendar Year:

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## Template in Practice

### Campylobacter: FDA BAM Online, Ch 7

<table>
<thead>
<tr>
<th>Food Microbiology</th>
<th>2091</th>
<th>Salmonella: FDA BAM online Ch 5</th>
<th>American Proficiency Institute (API)</th>
<th>To be Shipped 02-17-14</th>
<th>To be Shipped 06/09/14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Microbiology</td>
<td>2089</td>
<td>Salmonella (BAX): USDA MLG 4C.05, 4.07</td>
<td>American Proficiency Institute (API)</td>
<td>To be Shipped 02-17-14</td>
<td>To be Shipped 06/09/14</td>
</tr>
</tbody>
</table>

BLS-S014, Effective Date: 11/22/13
R:\doc master list\BLS\BLS-S014 Annual PT Plan 2014

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**Wisconsin Department of Agriculture, Trade and Consumer Protection**

**Bureau of Laboratory Services**

A2LA Certificate Number 2623.01

<table>
<thead>
<tr>
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<th>Program Provider</th>
<th>Jan-14</th>
<th>Feb-14</th>
<th>Mar-14</th>
<th>Apr-14</th>
<th>May-14</th>
<th>Jun-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Chemistry</td>
<td>6005</td>
<td>Protein in Meat - Combustion Analysis: USDA CLG, PRO 4.03</td>
<td>USDA-FSIS</td>
<td>To be Shipped first week of Jan.</td>
<td>To be Shipped first week of March</td>
<td>To be Shipped first week of April</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patulin in Apple Juice and Apple cider: AOAC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Multi-Analyte Methods

- The core standard is silent.
- AOAC addresses the issue but does not prescribe an approach - meaning there is no requirement to cover every analyte within a multi-analyte method.
- Can choose to run an analyte per compound class.
- If you choose to perform analysis of multiple analytes in a method there is NO requirement that every analyte pass.
- R103 – When relevant and available, it is necessary to participate in PT only for the test methods for which accreditation is being sought and maintained.

The laboratory decides the approach, and must use a logical criteria for determining the approach.
PT Plan for Food Labs

- A2LA – Laboratories must have a documented plan on how they will cover program requirements for PTs. The plan will be updated and reviewed during management review. The plan will be reviewed by the A2LA assessor during the on-site assessment.
- The lab must cover all the methods on its scope over a four year period, and do a minimum of one method per year.
- The lab should address multi-analyte methods if on the scope of accreditation.
Assessors

- Ultimately your PT plan must pass muster with the assessor; if not a PT or ILC you must have good rationale for what you do.

- Say what you do, do what you say.
In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2010 "AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Foods and Pharmaceuticals"), accreditation is granted to this laboratory to perform the following analyses on food products and water.

<table>
<thead>
<tr>
<th>Pathogens</th>
<th>Internal Method</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>2024</td>
<td>FDA BAM Online, Ch 7</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>2172</td>
<td>USDA MLG, 41.02</td>
</tr>
<tr>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2167</td>
<td>USDA MLG, 5A.03, 5.07</td>
</tr>
<tr>
<td><em>E. coli</em> non-O157 STEC</td>
<td>2174</td>
<td>USDA MLG, Ch 5B.04</td>
</tr>
<tr>
<td><em>E. coli</em> O157:H7 &amp; non-O157 STEC (Smart Cycler)</td>
<td>2125</td>
<td>FDA BAM Online, Ch 4A</td>
</tr>
<tr>
<td>Non-O157 STEC (ABI 7500 Fast)</td>
<td>2181</td>
<td>WDATCP-Bureau of Laboratory Services Method 2181</td>
</tr>
<tr>
<td><em>Listeria</em> (VIDAS)</td>
<td>2030</td>
<td>FDA BAM Online, Ch 10</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>2173</td>
<td>USDA MLG, 8A.05, 8.09</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>2091</td>
<td>FDA BAM Online, Ch 5</td>
</tr>
</tbody>
</table>
## PT Submission

<table>
<thead>
<tr>
<th>PT Program Name</th>
<th>Report Date</th>
<th>Lab ID</th>
<th>Outlying Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA FSIS Interlaboratory Check Sample Program</td>
<td>November 2012</td>
<td>55</td>
<td>X</td>
</tr>
<tr>
<td>American Proficiency Institute - Food Microbiology – Pathogens in Food</td>
<td>12/4/12</td>
<td>55</td>
<td>X</td>
</tr>
<tr>
<td>Wibby Environmental</td>
<td>3/15/12</td>
<td>113122680</td>
<td>X X</td>
</tr>
<tr>
<td>Phenova (formerly Wibby Environmental)</td>
<td>10/11/12</td>
<td>113122680</td>
<td>X</td>
</tr>
<tr>
<td>RTC</td>
<td>4/15/12</td>
<td>RT5319</td>
<td>X</td>
</tr>
<tr>
<td>RTC</td>
<td>11/30/12</td>
<td>RT5319</td>
<td>X</td>
</tr>
<tr>
<td>Thameboxam In-House</td>
<td>1/12/12</td>
<td>12-288</td>
<td>X</td>
</tr>
</tbody>
</table>
Other Items to Consider

- “Applicant laboratories for A2LA accreditation shall demonstrate successful participation in at least one relevant and available proficiency testing activity prior to receiving accreditation.” R103

- AOAC requires demonstration of on-going competency of analysts, Section 5.2.1. Distribution of PTs amongst analysts can satisfy that requirement.

- A list of PT providers and ILCs is found in A2LA document I106 – Available Proficiency Testing Programs.
Steve Sobek - Contact Information

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- (608) 224-4821
Questions?