

Proficiency Testing – Compliance with the ISO/IEC 17025 Standard

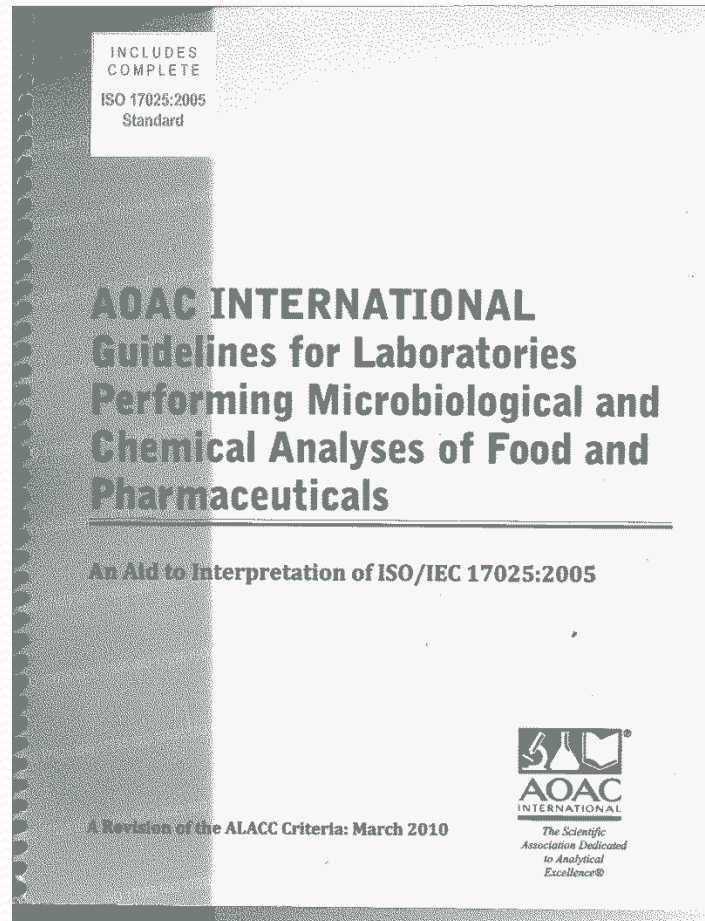
Steve Sobek
State of Wisconsin
Department of Agriculture, Trade and Consumer Protection

ISO 17025 FDA Webinar
February 20, 2014

ISO Core Standards – ANSI/ISO/IEC



ISO Core Standards + Food Testing Requirements – AOAC International



A2LA Documents



The screenshot shows the A2LA website homepage in a web browser. The browser's address bar displays <http://www.a2la.org/index.cfm>. The website features the A2LA logo and the text "American Association for Laboratory Accreditation". A navigation menu includes links for "Home", "Contact Us", and "Login". Below the navigation menu, there is a search bar with the text "Quick Find" and "enter search text: GO!". The main content area is divided into several sections. On the left, there is a large image of a circuit board with the text "Excellence in Accreditation, Commitment to Service". To the right of this image, there are several promotional banners. The first banner is titled "Search for A2LA Accredited Organizations" and includes a link "Click here". The second banner is titled "Gain Recognition. Get Accredited." and includes a link "Apply for A2LA Accreditation". The third banner is titled "A2LA Approved to Accredit FedRAMP 3PAOs" and includes a link "Click here for more information". The fourth banner is titled "A2LA Supporting SGIP Smart Grid Initiatives" and includes a link "Click here for more information". The fifth banner is titled "A2LA & APHL ISO/IEC 17025 Quality Management Series Modules" and includes a link "Click here for more information". The sixth banner is titled "A2LA & WorkPlace Training Webinars" and includes a link "Click here for schedules". Below these banners, there is an "Announcements" section. The first announcement is dated "08/08/2013" and states "2012 A2LA Annual Report now available online!". The second announcement is dated "07/29/2013" and states "A2LA Approved to Accredit FedRAMP". The browser's taskbar at the bottom shows the Windows logo, several application icons, and the system clock displaying "2:36 PM 9/16/2013".

http://www.a2la.org/index.cfm

A2LA - The

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Excellence in Accreditation, Commitment to Service

The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service, membership society. A2LA also offers programs for the accreditation of testing laboratories, calibration laboratories, inspection bodies, proficiency testing providers, medical

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Announcements

08/08/2013 - 2012 A2LA Annual Report now available online!

07/29/2013 - A2LA Approved to Accredit FedRAMP

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" 2 A B C D E F G H I J L M N O P R S T U

R101 - General Requirements: Accreditation of ISO/IEC 17025 Laboratories	12/01/2011
R102 - Conditions for Accreditation	07/31/2013
R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories - 2013 (pdf)	01/01/2013
R103a - Annex: Proficiency Testing for ISO/IEC 17025 Laboratories	06/28/2012
R104 - General Requirements: Accreditation of Field Testing and Field Calibration Laboratories	09/06/2012
R203 - Specific Requirements: Competition Animal Drug Testing Laboratory Accreditation Program	02/07/2013
R204 - Specific Requirements: Food & Pharmaceutical Testing Laboratory Accreditation Program	03/07/2012
R205 - Specific Requirements: Calibration Laboratory Accreditation Program	11/16/2012
R206 - Specific Requirements: Environmental Testing Laboratory Accreditation Program	01/13/2011
R207 - Specific Requirements: Environmental Lead Testing Laboratory Accreditation Program	04/18/2008
R208 - Specific Requirements: Construction Materials Testing Laboratory Accreditation Program	06/22/2012
R209 - Specific Requirements: Harris County/City of Houston/Port Authority Geotechnical Engineering Testing Laboratory Accreditation Program	06/22/2012
R210 - Specific Requirements: Kentucky Underground Storage Tank Testing Laboratory Accreditation Program	09/13/2005

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.

AOAC Guidelines

Section 5.9.1

- 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)

Evaluation Form



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.

Section	Food Chemistry
Company Name	FAPAS
Type of Supplies	PT Samples

Date Approved as Acceptable	
By	

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.

Date Removed as Acceptable	Not Approved, 12/5/13 (also a retroactive record of the decision process not to use FAPAS as determined in 2013).
By	Steve Sobek - Laboratory Director <i>SS</i>
Reason	FAPAS is a PT provider located in Europe. We participated in a FAPAS Zeaxanolone 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.

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
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Reporting the Results of the Proficiency Sample for Patulin

Sample ID: FCU-PT1-1013

LIMS ID#: 13-007995

Date sample prepared: 10/02/13

Amount spiked in the apple cider = 79.9 ug/L

Results reported from the laboratory: 58.2 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 list\TSSMASTER FORMS\Control Limits\QC Limits for FCU, dated 05/21/12) provided a Z score of -1.26 for the reported value of Patulin.



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

11-01-13
Date

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.

PT Frequency Found in R103

- 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.

Frequency-R103

- 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

- AzLA 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

BLS-S014 Annual PT Plan Template - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Acrobat

Clipboard Font Alignment Number Styles Cells Editing

B17

	A	B	C	D	E	F	G	H	I	J	K	L
1	Wisconsin Department of Agriculture, Trade and Consumer Protection											
2	Bureau of Laboratory Services											
3	A2LA Certificate Number 2623.01											
4	Calendar Year:											
5												
6	Descriptor	SOP #	Reference/Test Method	Program Provider	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-
7												
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22			Key		PT Result is expected		X	PT Result was acceptable		CAR-#	PT result was not acceptable	
23												

Ready

Year 1 Year 2 Year 3 Year 4

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Template in Practice

BLS-S014 Annual PT Plan 2014 - Microsoft Excel

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C3 Campylobacter: FDA BAM Online, Ch 7

	A	B	C	D	E	F	G	H	I	J
11	Food Microbiology	2091	Salmonella: FDA BAM on-line Ch 5	American Proficiency Institute (API)		To be Shipped 02-17-14				To be Shipped 06/09/14
12	Food Microbiology	2089	Salmonella (BAX): USDA MLG 4C.05, 4.07	American Proficiency Institute (API)		To be Shipped 02-17-14				To be Shipped 06/09/14

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

Wisconsin Department of Agriculture, Trade and Consumer Protection
Bureau of Laboratory Services
A2LA Certificate Number 2623.01

Descriptor	SOP #	Reference/Test Method	Program Provider	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14
Food Chemistry	6005	Protein in Meat - Combustion Analysis: USDA CLG, PRO 4.03	USDA-FSIS	To be Shipped first week of Jan.		To be Shipped first week of March		To be Shipped first week of April	
		Patulin in Apple Juice and Apple cider: AOAC,							

Year 1 Year 2 Year 3 Year 4

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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.

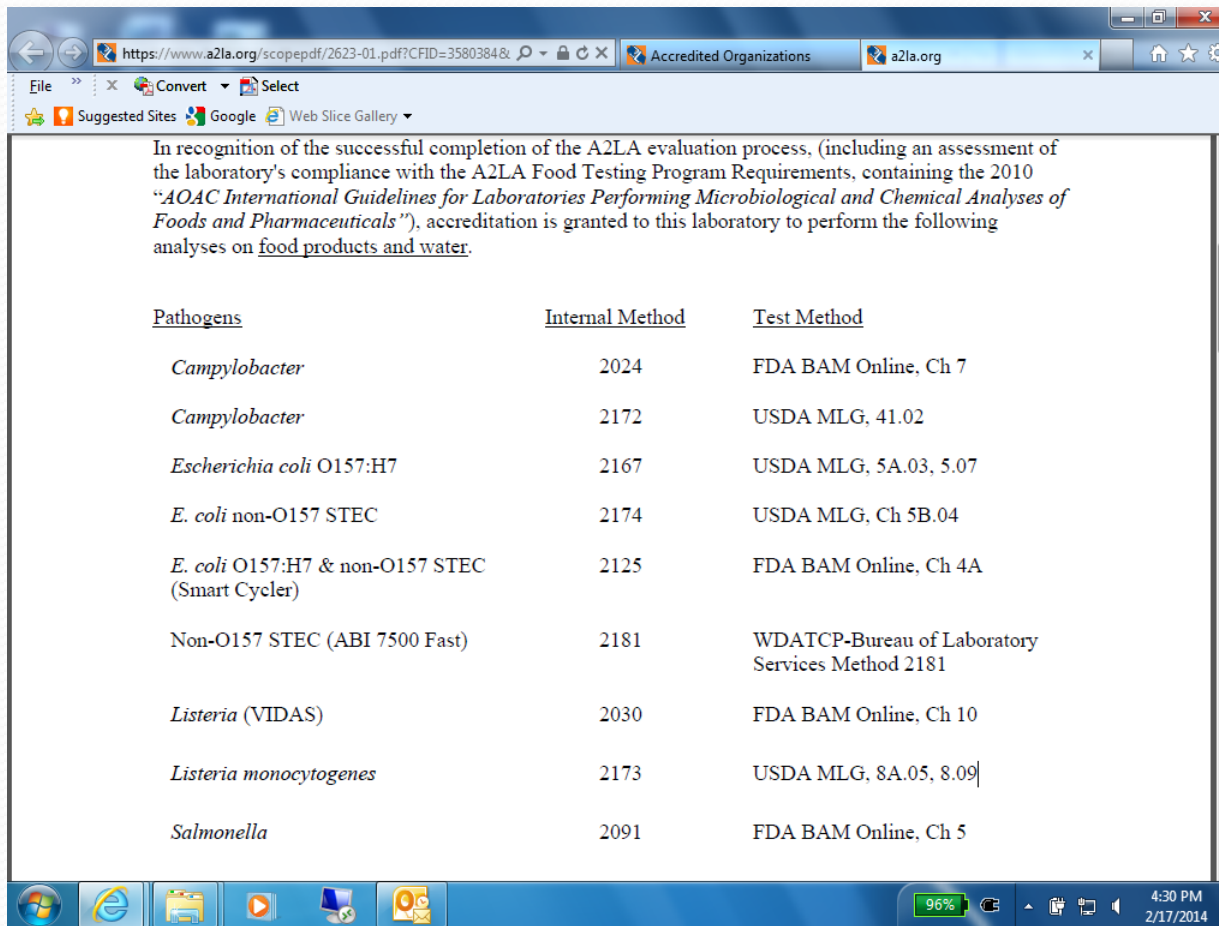
PT Plan for Food Labs

- 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.

WI Scope Example



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.

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

PT Submission

pt_data_submission_form 12.21.12 [Compatibility Mode] - Microsoft Word

Strength of Polyethylene; HN Metrology, Gage Blocks)

Report Date: The date the final report was issued

Lab ID: Number or other identifier assigned to your laboratory's data in the attached report(s)

Outlying Results: Indicate whether any outliers were identified for your laboratory. **If outlying results were identified, documentation of corrective action taken must be attached with this form.**

PT Program Name	Report Date	Lab ID	Outlying Results	
			No	Yes
USDA FSIS Interlaboratory Check Sample Program	November 2012	55	X	
American Proficiency Institute-Food Microbiology - Pathogens in Food	12/4/12	55	X	
Wibby Environmental	3/15/12	113122680	X	X
Phenova (formerly Wibby Environmental)	10/11/12	113122680	X	X
RTC	4/15/12	RT5319	X	
RTC	11/30/12	RT5319	X	
Thiamethoxam In-House	1/12/12	12-288	X	

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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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Questions?