Laboratory Accreditation: The Key Building Block of Nation's Integrated Food/Feed Safety System

ISO 17025: 2005 Accreditation – A State Prospective and Lessons Learned

Maria L. Ishida, PhD

EDUCATE
NETWORK
COLLABORATE

AOAC INTERNATIONAL

128th Annual Meeting & Exposition
September 7-10, 2014
Boca Raton, Florida

Outline

- Bureau of Food Laboratories (Overview)
- How to start the ISO/IEC 17025:2005 accreditation and Lessons Learned
- FDA ISO/IEC 17025:2005 Cooperative Agreement
- Interaction with Associations

EDUCATE
NETWORK
COLLABORATE

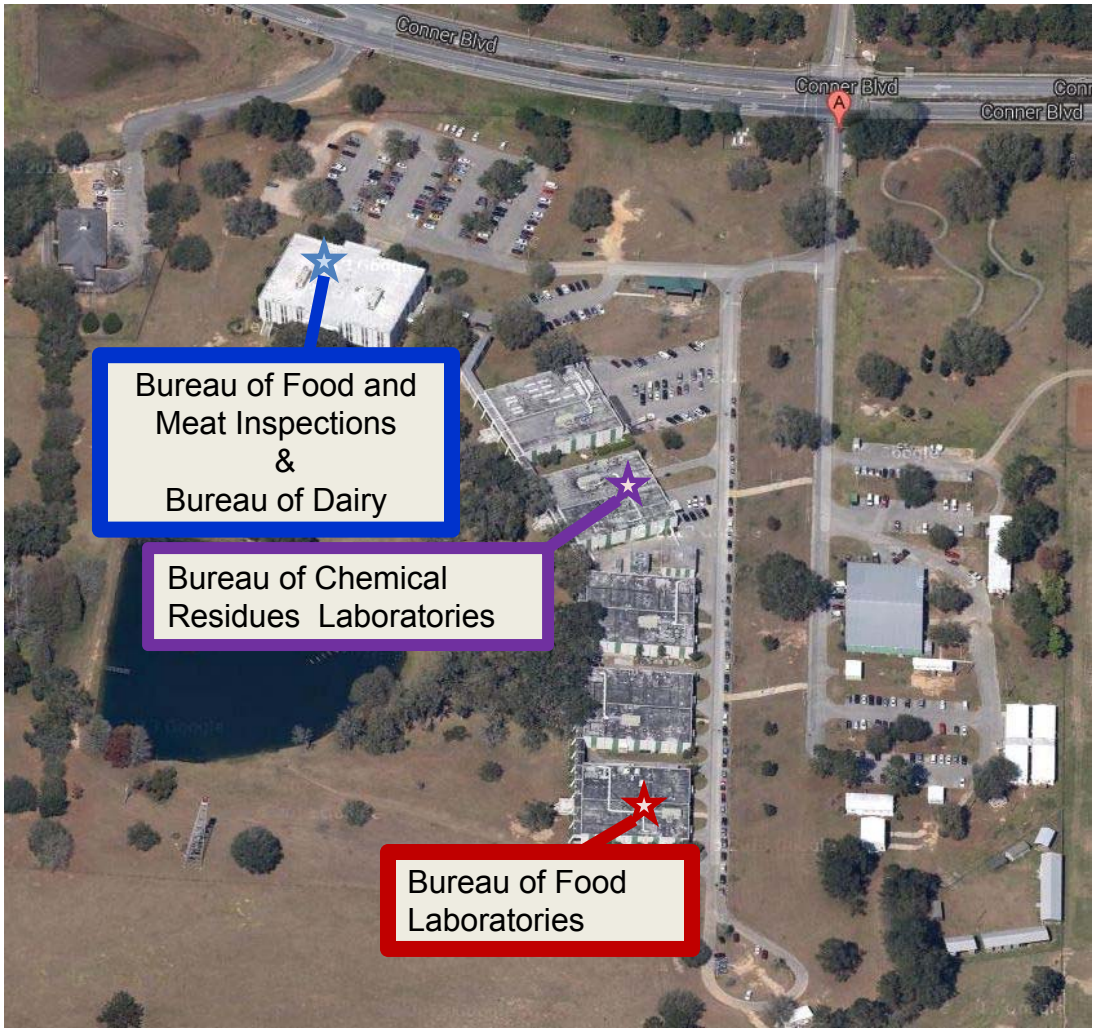
AOAC INTERNATIONAL

Organization

Division of Food Safety

- Bureau of Chemical Residue Laboratories
- Bureau of Food and Meat Inspection
- Bureau of Food Laboratories
- Bureau of Dairy Industry

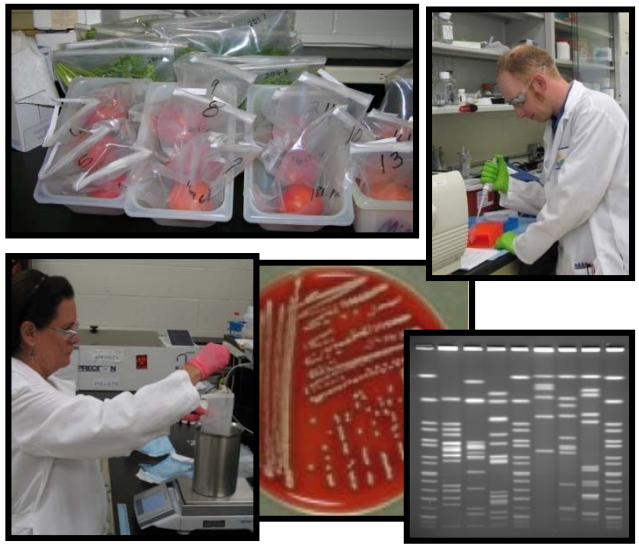
Location – Conner Complex



Bureau of Food Laboratories

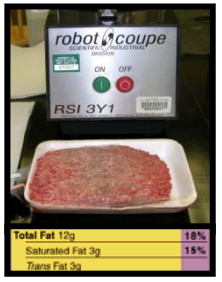
Microbiology Section

Food Safety Testing
Preparedness/Molecular Testing



Chemistry Section

Food Safety Testing
Consumer Protection Testing



Lab Overview

- ✓ Staff of 31 (Chemists, Microbiologists, Biochemists, and Support)
- ✓ Regulatory food testing laboratory
- ✓ Additional Activities:
  - •CDC/PulseNet laboratory
  - • Food Emergency Response Network (FERN) Microbiological Cooperative Agreement laboratory (FDA and USDA)
  - •Non-Tier 1 Select Agent laboratory - Laboratory Response Network (LRN)

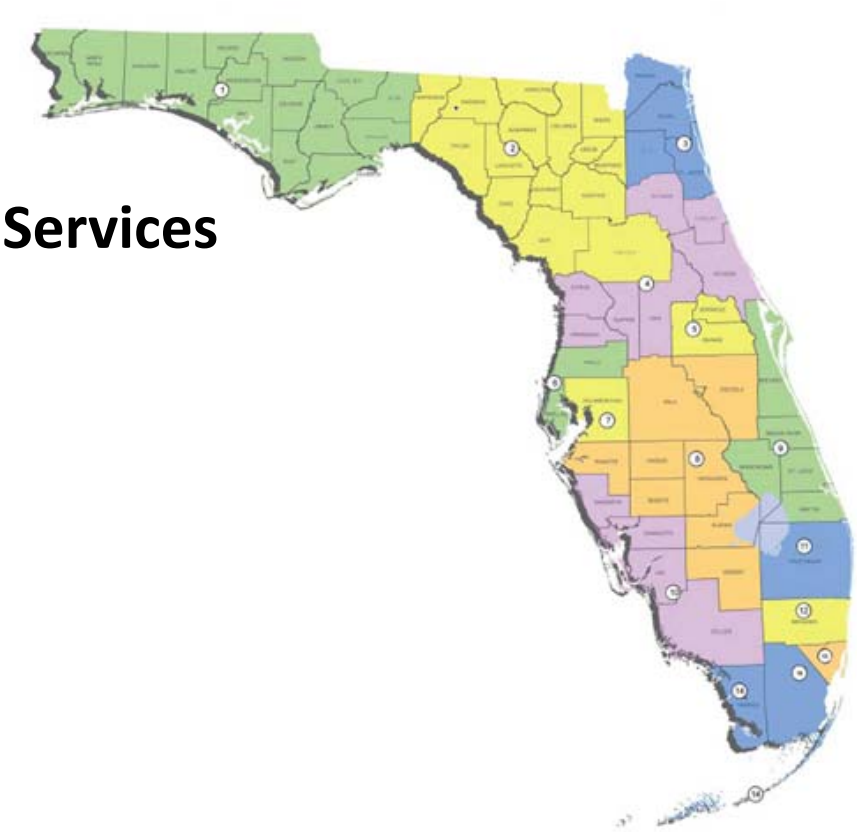
FERN Uniting Federal, State & Local Laboratories for Food Emergency Response

PulseNet USA The National Molecular Subtyping Network for Foodborne Disease Surveillance CDC

LRN Laboratory Response Network

Where Do The Samples Come From?

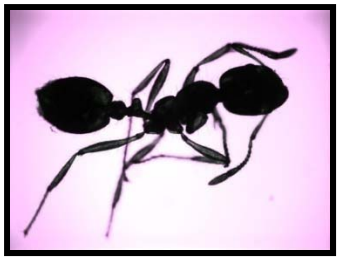
- ✓ **Within FDACS:**
  - – **Division of Food Safety**
  - – **Agriculture Environmental Services**
- ✓ **Within Florida:**
  - – **Department of Health**
  - – **Law Enforcement**
- ✓ **Federal Agencies:**
  - – **FERN: FDA and USDA**
  - – **FDA: contract**



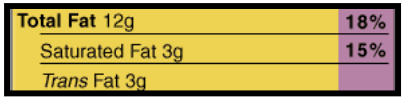
Type of samples

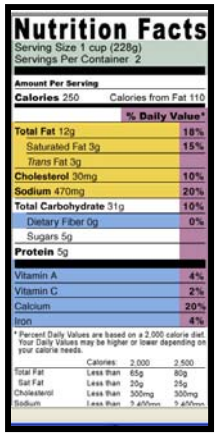
- ✓ Ready-To-Eat Products
- ✓ Environmental Swabs
- ✓ Electronic (pictures)
- ✓ Foodborne Illness

Chemistry Testing



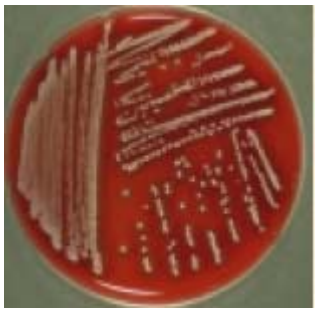
- Decomposition
- Toxins
- Metals (mercury, lead, tin)
- Allergens (egg, milk, soy, wheat, shellfish, fin fish, peanuts, tree nuts)
- Dietary Supplements (ephedrine, caffeine, theopholine)
- Preservatives (sulfites, nitrites, sorbate)
- Authenticity claims (fruit juices, sugars, honey, meat speciation)
- Food Colors
- Vanilla flavoring
- Foreign material
- Nutritional claims
- % Fat content





Microbiology Testing

- Aerobic Plate Count
- *Staphylococcus aureus* and Staph Enterotoxin
- *Bacillus cereus*
- *Escherichia coli*
- *E. coli* O157:H7
- *Salmonella species*
- *Listeria monocytogenes*
- *Vibrio* species
- *Shigella* species
- Yeast and Mold Count
- Coliforms & Fecal Coliforms
- *Campylobacter jejuni* (implementation)



Outline

- Bureau of Food Laboratories (Overview)
- **How to start the ISO/IEC 17025:2005 accreditation and Lessons Learned**
- FDA ISO/IEC 17025:2005 Cooperative Agreement
- Interaction with Associations

EDUCATE
NETWORK
COLLABORATE

AOAC INTERNATIONAL

Laboratory Accreditation

The Bureau of Food Laboratories gained accreditation to ISO 17025, for the specific tests listed in A2LA certificates 2534.01 and 2534.02 on March 31, 2007. Accreditation has been continuously maintained with the current renewal valid to March 31, 2015.

How to Start Process??

- ✓In 2002, on-site training about ISO 17025
- ✓Support by the upper management (Division director)
- ✓Participation in programs such as Pesticide Data Program (PDP) and Microbiological Data Program (MDP)
- ✓Hire a QA officer
- ✓Existing QA system to start

From The Old and Ugly

***E. coli* 0157:H7 ELISA method**

INTRODUCTION

The EHEC-tek test system utilizes Dynabeads that are capable of capturing living *E. coli* cells and an enzyme immunoassay that specifically detects *E. coli* O157:H7 in foods.

MATERIALS

Reagents - components of the EHEC-Tek kit:

- Microelisa strips - 12 wells coated with antibodies specific for *E. coli* 0157:H7.
- Dynabeads anti-*E. coli*
- Negative control vial, reconstituted
- Positive control vial, reconstituted
- Conjugate - monoclonal antibodies to *E. coli* 0157:H7
- Wash concentrate (50X) - diluted (5 ml concentrate with 245 ml distilled water)
- TMB substrate A and B
- Stop Solution
- Adhesive strip covers

Additional materials:

- Strip holder
- Magnetic Particle Concentrator (MPC)
- Wash bottle for reconstituted wash solution
- Reservoir troughs - Four trays labeled for TMB, conjugate, wash, and stop solution.
- Stomacher and sterile stomacher bags
- Incubators (37° & 42°C)
- Microelisa plate reader (filter 2, 450 nm)
- Sterile distilled water
- Microcentrifuge tubes (1.5 ml)
- Microcentrifuge tube racks
- Single channel pipet (100 µl)
- 12 channel pipet (200 µl)
- Pipet tips (200 µl and 2.5 ml)
- Water bath (100° C)
- Terri towels
- Metal beaker for waste wash solution, etc.

Media, Antibiotics, Antisera:

- Modified EC medium with novobiocin (mEC+n)
- Tryptic soy broth with Acriflavine (TSB+a)
- MacConkey-Sorbitol Agar with BCIG (MSA-BCIG)
- EMB agar plates
- TSA slants
- Simmon's Citrate slants
- API 20 E Strips
- *E. coli* antisera 0157 and H7

This is a tentative method only.

Add 100g. Bran Flakes (40%, or 50g. of All-Bran- type products) to 2 or 3 l. beaker and cover with H_2O. Stir well until product seems saturated. Slowly add H_2O with stirring to ca 700-800mls. With T.S.P. adjust pH to 8.0-8.1 and add extract of 10g. pancreatin in 200-250 mls H_2O. Readjust at ca 30 min. and 1 hr. later. Add 2-3 drops formaldehyde and digest overnight in 37-38°C. incubator.

Next morning wet sieve on No.230, decanting off the water before transferring settlings. When sample is transferred and well sieved then detergent wash.

With wash bottle (medium tip) squirt lines of detergent[1] onto product. Wash detergent through product with good flow of H_2O but without forceful heating. (A more thorough rinsing or wash out of the detergent.) This is done 4 times in sequence.

Wet the funnel and side wall of 2 liter trap flask with 60% ETOH.[2] Then using a teaspoon transfer the bulk of sample to trap flask. Complete transfer with wash bottle, finally filling to 800mls. Boil very gently for 30 min. so as to avoid build up of solids at the top of the alcohol. (Best done in a big pan of gently boiling H_2O.) Cool to 25-20°C. before adding 100 mls. of T P V (44.133) and stirring through sample for 1 minute. Immediately add 60 mls. of sp. fl. oil (40 heptane & 60 mineral oil; V:V). Stir magnetically for 7 min. Set aside 5 min. for oil to rise. With wash bottle wet sides of flask with 40% isopropanol. Then fill with 40% isopropanol[2] down rod to bring some oil into neck of flask.

Immediately stir bottom to resuspend settlings in such a way that settlings rise about half way up in flask as a result of steady horizontal rotary motion along the bottom of the flask. Repeat stirring (Suspending step) again after 5 min. and at 10 min. later. Slowly complete filling of flask to bring oil-alcohol interface ca 10-15 mm above the stopper (wafer). Let set 20 min. undisturbed and trap off. Rise neck with 40% isopropanol. Retrap, using 40 mls. of above oil phase.

To the New and Improved!

UNCONTROLLED COPY - NO REVISION NOTICE

SOP No. FL METHOD 480		Page 1 of 16
TITLE: Sugars in Food and Beverages by HPLC		
Revision: 3	Replaces: 11/18/10	Effective: 11/11/2011

1. Purpose

To provide a written standard format for the analysis of monosaccharides (fructose, glucose), disaccharides (sucrose, maltose, and lactose), and sugar alcohols (sorbitol) in foods and beverages. **Note: green highlighting in this document is for emphasis, not to indicate new or altered text.**

2. Scope

This standard operating procedure (SOP) shall be followed in the Bureau of Food Laboratories, Division of Food Safety, Florida Department of Agriculture and Consumer Services.

3. Outline of Procedures

4. References

a. *Official Methods of Analysis* (2005) 18th Ed., AOAC International, Gaithersburg, MD. Official Method 977.20, 'Separation of Sugars in Honey, Liquid Chromatographic Method'. External document FL06756.
b. Thean J and W Funderburk. High Pressure Liquid Chromatographic Determination of Sucrose in Honey. Journal of the AOAC, 1977; 60(4):838-841. External document FL04041.
c. *Official Methods of Analysis* (2005), 18th Ed., AOAC International, Gaithersburg, MD. Official Method 982.14, 'Glucose, Fructose, Sucrose, and Maltose in Presweetened Cereals, Liquid Chromatographic Method'. External document FL06756.

UNCONTROLLED COPY - NO REVISION NOTICE

SOP No. FL METHOD 480		Page 7 of 16
TITLE: Sugars in Food and Beverages by HPLC		
Revision: 3	Replaces: 11/18/10	Effective: 11/11/2011

reattach syringe to sep pak.
6. Place approximately 5-6 ml of sample into syringe.
7. Force sample through sep pak slowly (dropwise). Discard the first 2 ml of the sample.
8. Attach an acrodisc filter to the end of the cartridge, and collect the next portion of the sample in an auto sampler vial. Sample is now ready for HPLC analysis.

6.7 Standard Preparation

Standards must be prepared fresh monthly and should be stored refrigerated.

NOTE: standard preparation and documentation should be performed according to FL LABOP 431, Preparation and Documentation of Chemistry Standards.

a. Tare a weighing boat on the analytical balance.
b. Weigh out the appropriate amount of each component to at least 4 significant figures, according to the Standards table below.
c. Record the exact weight of each component
d. Transfer the mixed standard to a 100 ml volumetric flask.
e. Dilute to volume using HPLC grade water, and mix well.

NOTE: the values listed below are approximate, and the standard does not need to be the exact concentration listed. Standards other than those listed below are permitted, to better match the levels in the sample matrices. For analysis by ion exchange column, do not prepare a mixed standard containing sucrose, maltose and lactose. Since sucrose and maltose will appear as one peak, use only sucrose to quantitate the peak. If lactose is suspected, prepare a separate lactose standard and quantitate lactose using the lactose standard.

Matrix	Fructose	Glucose	Sorbitol	Sucrose	Maltose	Lactos
Orange juice	2 g	2 g	0.5 g	4.5 g	0.5 g	N/A
Grapefruit juice	3.5 g	3.3 g	0.5 g	1.3 g	0.5 g	N/A
Apple juice	6 g	3.5 g	0.4 g	0.7 g	0.5 g	N/A
Grape juice	7 g	7 g	0.5 g	1 g	0.5 g	N/A
Honey	3.9 g	3 g	N/A	0.5 g	0.5 g	N/A
Cane syrup	1 g	1 g	N/A	5 g	0.5 g	N/A
Maple syrup	0.5 g	0.5 g	N/A	6 g	0.5 g	N/A
Sorghum syrup	1.5 g	1.5 g	N/A	3 g	0.5 g	N/A
Corn syrup	0.5 g	2 g	N/A	0.5 g	2.5 g	N/A
Sugar-free products	1 g	1 g	N/A	1 g	1 g	1 g

Table 1. Standards.

UNCONTROLLED COPY - NO REVISION NOTICE

SOP No. FL METHOD 480		Page 15 of 16
TITLE: Sugars in Food and Beverages by HPLC		
Revision: 3	Replaces: 11/18/10	Effective: 11/11/2011

REVISION HISTORY

Original
Date: 06/11/04
Author: Stacie Hammack
Description: New SOP; re-issue of FC METHOD 080 under revised nomenclature

Revision 1
Date: 04/06/07
Author: Stacie Hammack
1. Description: Reformatted per DL ADMIN 050
2. replaced 'form' with 'worksheet' throughout
3. updated reference
4. Section 5.1.a: removed reference to "Fisherbrand centrifuge
5. Section 5.1.g: clarified requirement for versapor filters
6. Section 5.2.i: added control sample
7. Section 5.3 added FL LABOP 431 and FL QA 130
8. Section 6.5 NOTE: changed SYN1 to SYN2, added SUG1 as an acceptable control sample, added maltose to the analytes, and noted that SYN1 is no longer suitable as a control sample.
9. Section 6.5: added a note that a control sample and blank should be analyzed with each set of samples.
10. Section 6.5.b.1: added an allowance for alternate weights and or volumes where necessary due to sample matrix or availability of glassware.
11. Section 6.6: added note that standards are prepared and documented according to FL LABOP 431
12. Section 6.7: added note that alternate standards are permitted to match matrix
13. Section 6.7: deleted section for nutritional samples and added "nutritional samples" to section for "Table syrups"
14. Section 6.8 NOTE: clarified that sorbitol + glucose standard is not required.
15. Section 6.9: clarified that volume should be entered in Empower table
16. Section 6.10: removed reference to "known sample" and the 10% of expected requirement and added evaluation of control sample according to FL QA 130
17. Section 6.10.c: added records per FL LABOP 401
18. Changed reference to "Millennium" software to "Empower" throughout document

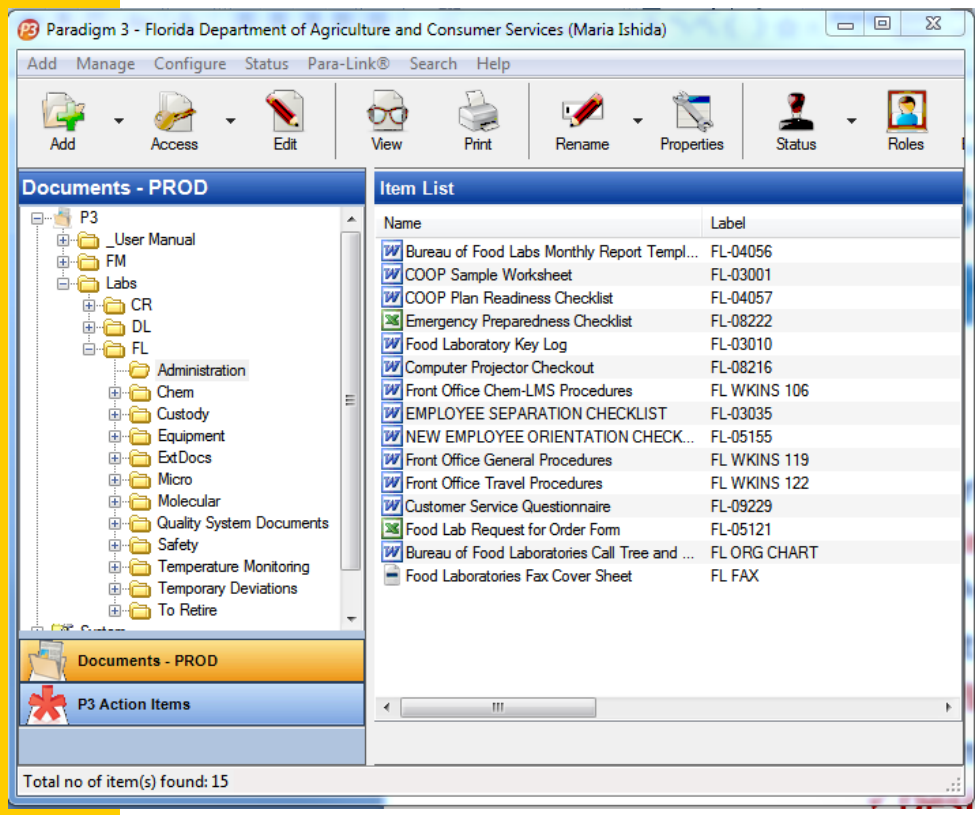
Revision No. 2
Date: 11/18/10
Author: Stacie Hammack
Description:
1. Updated format of revision history table.
2. Revised signature block for new QM.
3. Global revision to incorporate elements of FL METHOD 481 and FL METHOD 482.

Challenges

- ✓Write documents to meet ISO 17025 requirements (SOPs, forms, WKINS, etc).
- ✓Which methods put under ISO umbrella
- ✓Have staff on board

Year	Number of methods	Deficiencies
2007	50 (23 Chem, 25 Micro, 2 MB)	24 non-conformances
2009	48 (21 Chem, 25 Micro, 2 MB)	17 non-conformances
2011	37 (19 Chem, 16 Micro, 2 MB)	7 non-conformances
2013	29 (13 Chem, 14 Micro, 2 MB)	2 non-conformances

Lessons Learned



- ✓SOPs do not need to have everything, adjust your language
- ✓Do internal audits
- ✓Be flexible. Try something new! Be a good listener!
- ✓Do not change what is already working
- ✓Designate a secure place for your documents (restricted user access)

Lessons Learned (cont.)

- ✓Hire consultant before the 1st assessment
- ✓Schedule your assessment visit when everybody is laboratory
- ✓Be prepared and organized
- ✓Work as a team
- ✓Research your assessor
- ✓The assessor is there to help. Ask questions during the visit.
- ✓Answer the questions honestly but don't volunteer additional information.

Accreditation is not substitution for common sense

Outline

- Bureau of Food Laboratories (Overview)
- How to start the ISO/IEC 17025:2005 accreditation and Lessons Learned
- **FDA ISO/IEC 17025:2005 Cooperative Agreement**
- Interaction with Associations

EDUCATE
NETWORK
COLLABORATE

AOAC INTERNATIONAL

FDA ISO Accreditation CAP (2012 – 2017)

✓Participate in Food Emergency Response Network (FERN) activities

✓Support Manufactured Food Regulated Program Standards (MFPS) by providing testing under ISO 17025 requirements (Standard #10)

✓ Help non-accredited funded laboratories (Mentee labs)

- Mississippi State University
- Georgia Department of Agriculture
- South Carolina Department of Heath and Environmental Control

✓ Create Sampling Agreement with Bureau of Food and Meat Inspections

Outline

- Bureau of Food Laboratories (Overview)
- How to start the ISO/IEC 17025:2005 accreditation and Lessons Learned
- FDA ISO/IEC 17025:2005 Cooperative Agreement
- **Interaction with Associations**

EDUCATE
NETWORK
COLLABORATE

AOAC INTERNATIONAL

Sign In | My APHL | Create an Account | LabLog

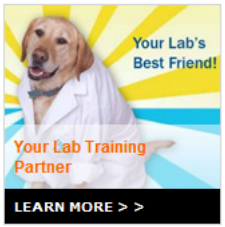
APHL | Association of Public Health Laboratories

Search...

ABOUT APHL | CONFERENCES | EDUCATION | MEMBERSHIP | MY CAREER | POLICY | PROGRAMS | RESOURCE CENTERS

- Environmental Health
- Food Safety
  - Surveillance/Outbreak Testing
  - PulseNet
  - CaliciNet
  - Culture-Independent Diagnostics
  - Food/Feed Lab Accreditation
  - CIFOR
  - Laboratory Resources
- Global Health
- Infectious Diseases
- Informatics
- Laboratory Systems and Standards
- Newborn Screening and Genetics
- Public Health Preparedness and Response
- Research

TEXT SIZE T T T



Food/Feed Lab Accreditation

Training Resources

The Association of Public Health Laboratories (APHL) is collaborating with the Association of Food and Drug Officials (AFDO), Association of American Feed Control Officials (AAFCO) and Food and Drug Administration (FDA) representatives to provide training resources to the laboratories conducting regulatory food and animal feed testing.

SAVED TOPICS: Accreditation, Food Safety Labs, Member Resources

SAVE PRINT SEND ShareThis

The goal of this webpage is to address the educational needs of laboratories seeking initial, or expanding current, ISO accreditation. The ISO/IEC 17025 Accreditation Training Steering Committee identifies training opportunities that may be useful for those seeking ISO accreditation. The trainings listed are not specifically endorsed or recommended by APHL, AFDO, or AAFCO, but we invite you to see the available resources below.

Available Training

Training Opportunities for Laboratories Seeking ISO/IEC 17025:2005 Accreditation - December 2013 version

Webinars

ISO/IEC 17025 Road to Accreditation: Where to Start and What to Consider
(Released August 30, 2013)

ISO/IEC 17025 Road to Accreditation: The Journey Continues…
(Released April 3, 2014)

Key Elements of a Laboratory Quality Manual for US Food and Feed Laboratories
(Released June 12, 2014)

Mentoring Basics – Collaborative Approach to Achieving ISO/ICE 17025:2005 Accreditation, Part 1
(Released June 19, 2014)

CONTACT
JOSH ROWLAND
Senior Specialist, Seminars
240.485.3826
josh.rowland@aphl.org

APHL | Association of Public Health Laboratories

Site Actions | Browse | Page

Food & Feed Testing Accreditation Discussion Board Site ▸ Home

Food & Feed Testing Accreditation Discussion Board Site

Welcome to the Food and Feed Laboratory Accreditation Discussion Board

APHL and its partner Associations, AFDO and AAFCO, thank you for your participation and for your dedication to the work of food and feed safety. We look forward to helping you achieve, maintain, or enha
building an integrated national food/feed laboratory system. Together, we hope to fulfill part of the Associations Cooperative Agreement with FDA to ensure that laboratories have access to the best possible
Accreditation. Any discussion topics you feel are relevant to those involved with laboratory Accreditation may be posted to this site. New users are always welcome.

Home | **Create a New Post** | **My Stats** | **Set Post Alerts** | **Set Comment Alerts**

-Categories-

All

Training Needs Assessment

Available Training

-Posts-

Edit	Title	Created By	Published	Category
	Section 5.5.6 in the ISO17025 STD	jverreth@mt.gov	8/25/2014 9:58 AM	
	A couple of webinars coming up soon	yhale@aol.com	8/15/2014 10:10 AM	Available Training
	Lab Quality Confab October 21-22, 2014 New Orleans, LA	yhale@aol.com	8/7/2014 10:00 PM	Available Training
	Free mentoring resource from ASM	yhale@aol.com	8/4/2014 2:15 PM	
	AAFCO presentation on accreditation	yhale@aol.com	8/4/2014 12:23 PM	Available Training
	PFP website updated with recent newsletter	sharon.shea@aphl.org	7/29/2014 8:46 AM	
	3rd Annual St. Cloud State University Food Microbiology Symposium	sharon.shea@aphl.org	7/23/2014 10:25 AM	Available Training
	Any suggestions for improving the Discussion Board?	yhale@aol.com	7/21/2014 10:52 AM	
	FDA Funding Opportunity Webinars	kathryn.wangsness@azdhs.gov	7/15/2014 7:21 PM	
	Are you happy with your current Document Control System?	sharon.shea@aphl.org	7/14/2014 9:21 AM	
	CDC and full implementation of a QMS-one of steps after Anthrax issue	yhale@aol.com	7/11/2014 9:11 PM	
	Webinar on July 16th: ISO 17025 Accreditatio for Your Lab-Is this necessary	yhale@aol.com	7/11/2014 12:40 PM	Available Training
	ISO 9001	kathryn.wangsness@azdhs.gov	7/11/2014 11:50 AM	
	ISO Strategic Plan Comment Opportunity	kathryn.wangsness@azdhs.gov	7/11/2014 11:47 AM	
	Foodborne Virus Webinar	yhale@aol.com	7/3/2014 11:12 AM	Available Training
	A2LA Answers to some good questions	kristina.mccallum@state.co.us	6/30/2014 5:04 PM	
	ISO 19011 Reference	kathryn.wangsness@azdhs.gov	6/25/2014 9:12 PM	
	Follow up on Quality Manual Workshop	kathryn.wangsness@azdhs.gov	6/24/2014 6:46 PM	
	Pipette Calibration Training Video	kathryn.wangsness@azdhs.gov	6/24/2014 6:23 PM	
	Internal Auditing References	kathryn.wangsness@azdhs.gov	6/24/2014 6:17 PM	
	Pre assessment audits	kathryn.wangsness@azdhs.gov	6/24/2014 6:13 PM	
	Mapping Work Processes-Book recommended by Dr. Martin at the FDA CAP meeting in May	yhale@aol.com	6/18/2014 7:13 PM	

Association of Food and Drug Officials

"Promoting Public Health, Fostering Uniformity, and Establishing Partnerships"

Remember me
Login Forgot password

Home | About | Membership | Conference | News | DDC | Training | Resources | Endowment | Contact

Home > Resources > Subject Matter Experts Registry

Subject Matter Experts Registry (Apply here)

The Manufactured Food Regulatory Program Alliance (MFRPA) has developed a registry of subject matter experts (SMEs). The SMEs database supports the MFRPA's mission of community-building, information exchange, and a national food safety system. This database will continue to grow with contributions from the Association of Food and Drug Officials (AFDO) and the U.S. Food and Drug Administration (FDA).

Search by "Areas of Expertise" or using keywords.

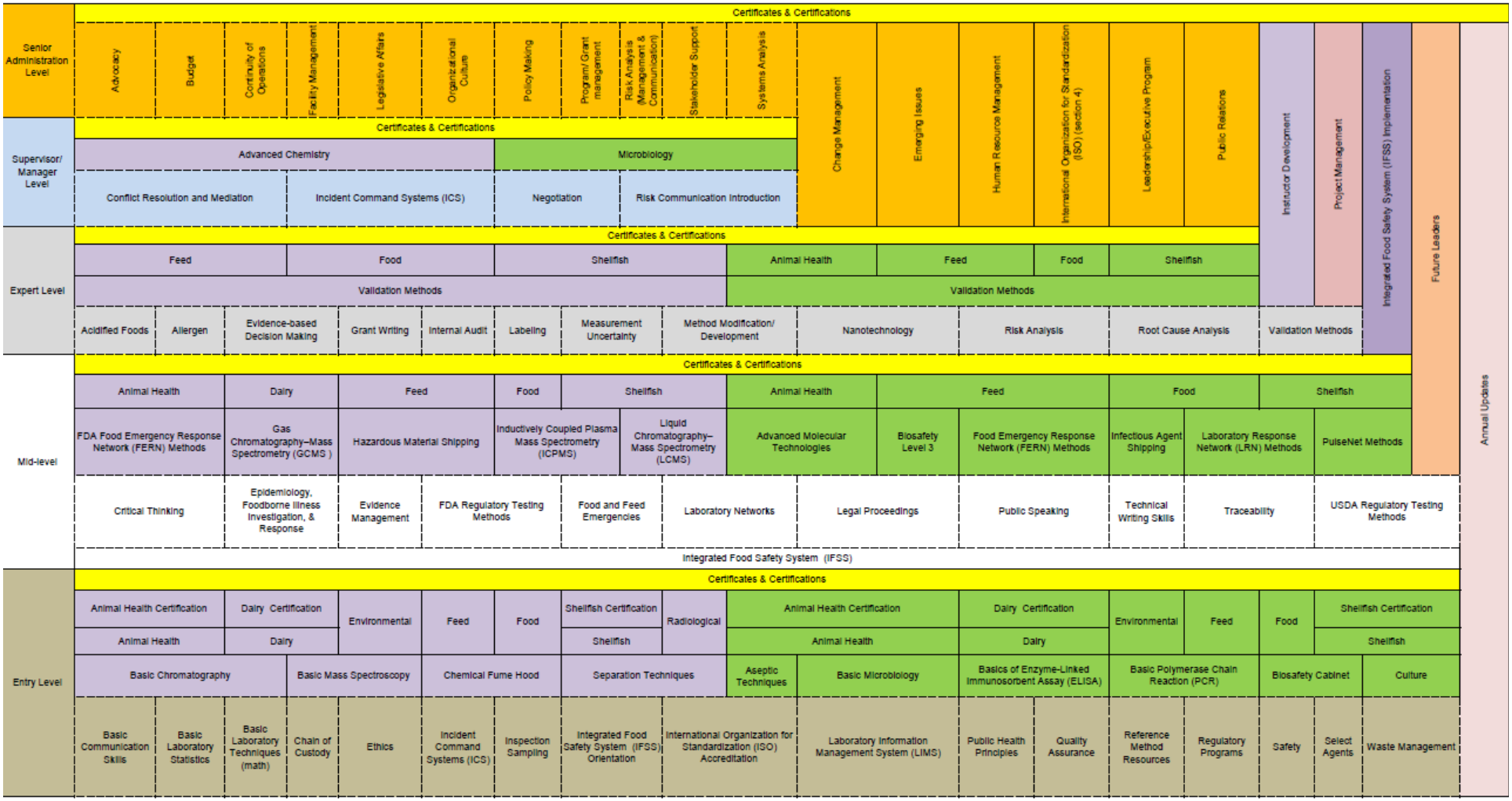
Areas of Expertise

- Dairy (23)
- Environmental Health (49)
- Epidemiology (11)
- Food Laboratory (56)
- Food Law & Regulation (60)
- Food Processing Technologies (42)
- Laboratory Accreditation (2)
- Meat Inspection (23)

Advanced search...

Search: Found: **160** Show: 1-50

Regulatory Food and Feed Laboratory Professionals Curriculum Framework (IFPTI/APHL/AFDO)



Developing a Competency Framework for U.S. State Food and Feed Testing Laboratory Personnel.
Kaml, C.; Weiss, C. C.; Dezendorf, P.; Ishida, M.; Rice, H. D.; Klein, R.; Salfinger, Y.

Journal of AOAC International, Volume 97, Number 3, May-June 2014, pp. 768-772(5)

Acknowledgement

Chemistry:

A. Kirkland
D. Lloyd
G. Parker
E.R. Noche
J. Pelt
M. Engel
M. French *
M. Agharahimi
M. Joseph
S. Patterson*

Custody:

S. Ganey

QA Management:

S. Hammack*
S. Humphries

Microbiology:

A. Dickey
A. Bryant
A. Doughty
C. Franconi
J. Crowe
K. Heddaeus
K. Chung
L. Caulkins
M. Roman
R. Schloss
S. Kim*
P. Hanson*
V. Molleti
M. Sewharack
B. Caudle

Secretary:

V. Martinelli

Contact Information

Maria L. Ishida

Maria.Ishida@FreshFromFlorida.com

EDUCATE
NETWORK
COLLABORATE

AOAC INTERNATIONAL