Accreditation to the ISO/IEC 17025 Standard

Resources, strategies and tools from APHL, AFDO, and AAFCO

AAFCO Laboratory Methods and Services January 2015



2012-APHL Awarded Multi-Million Dollar Cooperative Agreement to Build an Integrated Food and Animal Feed Laboratory System

Silver Spring, MD – APHL was awarded a five-year cooperative agreement of up to \$7.5 million by the FDA to further the goals of the Food Safety Modernization Act. APHL will work collaboratively with the Association of Food and Drug Officials and the Association of American Feed Control Officials to strengthen and integrate food and feed testing laboratories for the advancement of public health









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#### Associations' Interests in the Agreement

- Support APHL, AFDO, and AAFCO Members by providing resources, strategies and tools to achieve accreditation to the ISO 17025 standard
- Contribute to the development of an Integrated Food Safety System
- Build relationships among the Associations that support food laboratories





## FDA's Interest in this Partnership

- FSMA Mandates on building state and local capacity
- Agency commitment to building an integrated food safety system

APHL, AAFCO, and AFDO are in a unique position to help implement these agency priorities

## Why Build an Integrated Food/Feed Laboratory System?

- \*A common national laboratory accreditation standard will be implemented
- Gather expert opinion, develop consensus statements, assess current practices against standards, communicate with a trusted voice, carry ideas and issues to decision makers, and convey the importance of our members' work
- Educate and train our members and put forth practice guidelines that define the field
- Collaborate on and disseminate regulatory compliance strategies
- Allow leveraging of resources and harmonization of efforts





# Member Involvement SUBCOMMITTEES AND WORKGROUPS



# Available ProductsCOMMUNICATIONTRAININGREPORTSTOOLSGUIDANCEDATA EXCHANGEDIRECT ASSISTANCE

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#### Webpage and Resource Site

- Creation of web pages to support Food/Feed Testing Laboratories seeking Accreditation
- Accessible from <u>www.aphl.org</u>
- Housed on our Food Safety Program pages
- Repository of ISO/IEC 17025 resources
- Open to anyone in the governmental food and feed testing community (password protected)



#### Resources

#### Food and Animal Feed Laboratory Accreditation

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	Member Only SOP							
Accreditation Resources	4.11 Root Cause Analysis and Corrective Action							
For Food and Animal Feed Laboratories Only	4.11 APHL Root Cause Corrective Action, April 12, 2013							
SAVED TOPICS: Accreditation, Food Safety Labs, Member Resources	4.11 FL admin 061-7dl-uncontrolled							
SAVED TO TES. ACTEMIZION, TOOD Safety Labs, Member Resources	4.11 FL CA 663, March, 24, 2011 QAU							
	4.11 FL CA 674, May 4, 2011 LW							
Member Only SOP	4.11 FL CA 681, June 1, 2011 M December 7, 2011							
4.11 Root Cause Analysis and Corrective Action     4.14 Internal Audits	4.11 FL CA 692, June 2011 M 9511							
	4.11 FL CA695, July 6, 2011 M							
🖽 4.3 Document Control	4.11 FL CA 698-071111-Mol, August 21, 2011							
4.6 Purchasing Services and Supplies	4.11 FL s03011 9dl uncontrolled							
	4.11 ORA Laboratory Manual Volume II, Corrective Action Procedure							
	4.11 MT PDP QC 2R v5, Corrective Action							
± 5.5 Equipment	4.11 NC Nonconformity Report							
∃ 5.6 Traceability	4 11 NC PD-QMS 009 Control of Nonconformities and Corrective Action v4							
E 5.9 Control Charting	4.11 ORA Laboratory Manual Volume II - Corrective Action Procedure							
5.9 Proficiency Testing     FDA ORA Documents	4.11 Root Cause Presentation, A2LA							
Master Lists								
	4.11 TX M0036 Improvement and Preventative Action Procedure							
	4.11 Revised FL CA Log							

Food/Feed Laboratory Accreditation Discussion Board

- An on-line forum for the exchange of information related to becoming accredited to the ISO/IEC 17025 standard
- Must request a link to sign up for access
- Accessible through MyAPHL
- Open to state and local food and feed testing personnel

#### **Discussion Board**

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Management Review		AAFCO Check Sample Program Announcement for 2015		1/6/2015 5:31 PM	Proficiency Testing	0
Internal Audits		Training opportunities are at APHL's website-see link!		1/6/2015 12:11 PM	Available Training	0
Measurement Uncertainty	1	ISO/IEC 17025 Internal Auditor Training & Measurement Uncertainty Workshop		1/6/2015 12:09 PM	Available Training ; Internal Audits; Measurement Uncertainty	0
Traceability		Free workshops on Mentoring at ASM meeting in May		12/17/2014 11:21 AM	Available Training	0
Available Training		New Eurachem Guide-The Fitness for Purpose of Analytical Methods		12/16/2014 9:09 AM	Other	0
Training Needs Non-conforming Work		APHL Seeks Nominees for FDA's Food Advisory Committee		12/11/2014 2:50 PM	Other	0
Corrective Actions	<b></b>	White Paper: Understanding What is Needed to Produce Quality Data	sharon.shea@aphl.org	12/11/2014 1:18 PM	General information (White papers, Newsletters, etc.)	0
Preventive Actions		Free webinar-Most Common 17025 Nonconformities in a Food Testing Laboratory		12/2/2014 7:32 PM	Available Training	0
Proficiency Testing	I.	Question for input to PacNW AOAC meeting		12/1/2014 6:46 PM	Traning Needs	0
Equipment		Free Webinar-Dec 3 on Vet Drug Residues in Food Animal Tissue		11/27/2014 7:50 PM	Available Training	0
Media		Benefits of Accreditation to ISO/IEC 17025		11/25/2014 9:52 AM	Other	1
Reagents/Kits/Identification Sy	/stems 🛛 🤯	Free Pre-recorded webinar Document Control One Lab's Journey		11/21/2014 11:24 AM	Available Training	0
General information (White pa Newsletters, etc.)	pers, 🧊	Free recorded webinar: How sample mass and particle size affects the uncertainty of your analytical measurements		11/14/2014 10:43 AM	Available Training	0
LIMS/Data exchange		Change management webinars now on the Training Resource Page		11/4/2014 2:04 PM	Available Training	0
Partnership for Food Protectior information/products	n (PFP) 🛛 🕞	John Kotter's Leading Change-\$1.95 for audiobook		10/30/2014 4:34 PM	Available Training	0
APHL Information/ products		Webinar-Moving Laboratory Research on Pathogen Detection into Commercial Practice		10/29/2014 3:20 PM	Available Training	0
Quality Manual		Webinar: Food Safety Magazine: Improved identification of pesticides using APCG-MS		10/29/2014 11:32 AM	Available Training	0
Other		ACS Lunch and Learn-Lunch and Learn Webinar Series with "How Sample Mass and Particle Size Affects the Uncertainty of Your Analytical Measurements"		10/29/2014 11:12 AM	Available Training	0
	1	Vacancy-Laboratory Quality Systems Manager-Alaska		10/22/2014 11:02 PM	Other	0
		Suggestion to share training resources		10/20/2014 12:28 PM	Other	0
		Free Change Management-2 part APHL Training Webinar starts October 23		10/17/2014 11:18 AM	Available Training	1
		Internal Auditor and MU Training in December 2014		10/11/2014 12:39 PM	Available Training	0

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#### **Discussion Board**

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



#### 4.2-Document Control Software

by yhale@aol.com on 10/9/2013 10:19 AM

If you have purchased a Document Control software, what are you using? Could you share some of the pros and cons? If you have not purchased software, how are you handling document control in your laboratory? Thanks for any feedback-this is one of the most frequently asked questions!



#### Comments

Hello,

In Arizona our IT determined that they wanted us to have an in house system, so we are currently in the test phase of a Share point Document Control system. So far the test seems to be working well, they are still developing the "control" access for the system, but so far it looks good.

Kathryn

i:0#.f|aphluser|kathryn.wangsness@azdhs.gov on 10/9/2013 11:29 AM

#### Free Webinar on Document Control by iPassport on 11/25/13

Genial Genetics, a Silver Level Sustaining Member of APHL, is hosting a free introductory webinar to iPassport, specifically tailored for APHL member laboratories, entitled "iPassport, a PHL Success." The webinar, organized in conjunction with APHL's Quality Systems Program, will be held on Monday, November 25, 2013 at 2 pm Eastern time. iPassport is a complete quality management system including comprehensive document control and compliance management tools. To date, the product has 1,250 users in 15 public health laboratories and is being utilized across a collective total more than 300 departments. Besides document control and general compliance management, the system has tools to deal with standards management, auditing, task management, equipment maintenance cycles, staff competency, complaint management, inventory control and staff training documentation. In order to participate in the webinar, APHL members must register for this free event at http://www.genialgenetics.com/aphl-webinar. For more information on iPassport, visit http://www.genialgenetics.com.

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## **Association Training**

- Prioritized list of training topics
- Spreadsheet of currently available ISO/IEC 17025:2005 training
- 3 Pre-recorded webinars ISO/IEC 17025
   Road to Accreditation:
  - o Where to Start and What to Consider,
  - o The Journey Continues...,

ISO/IEC 17025 Section 4.3 Document Control
 'One Lab's Journey'



## **Association Training**

- 2 pre-recorded webinars on Document Management and Quality Manual Basics
- "Build your own QM" workshop
- "Let's Go! ISO! How your colleagues began their path to ISO accreditation" workshop
- Mentoring: 2 webinars and 1 workshop
- Sampling Awareness Building Seminars



#### **Training Website**



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## Partner Training http://www.ifpti.org/publications

#### DEVELOPING A COMPETENCY FRAMEWORK FOR U.S. STATE FOOD AND FEED TESTING LABORATORY PERSONNEL

THE RANGERT ALL DESIGNAL OF AGAIN DISTRIBUTIONAL VOL. 17, No. 3, 2014

#### AGRICULTURAL MATERIALS

#### Developing a Competency Framework for U.S. State Food and Feed Testing Laboratory Personnel

CRUEI KANE

Samandard Yand Namitin Tanaima Janima Camindam, Barla Cani, Mi Cahada Dan Yuang Samang Samang

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## Partner Training IFPTI Curriculum Framework project

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#### Reports

http://www.aphl.org/aphlprograms/food/laboratoryaccrediation/Documents/2013Aug20\_DataExchange\_FDA%20Discovery%20Document.pdf

Rapid and Thorough Submission of Clinical Specimens/ Isolates to Public Health Laboratories



operative Agreement work with FDA, the APHL Food Safety Committee Group\* that is attempting to identify and resolve challenges to the ens/isolates (related to foodborne illness) to public health laboratories t. This report summarizes the work group's findings to date including etween clinical and public health laboratories, current challenges to or specimens, workable solutions to these challenges, and proposed

public health laboratory system is to provide food safety testing for surveillance systems such as PulseNet and NARMS help form the ety system. These systems rely on isolates that are almost always



## Tools

- Subject Matter Expert (SME) Registry of food and feed laboratory professionals http://www.afdo.org/sme/
- List of relevant PT providers for food and feed laboratories
- Accreditation of AAFCO's PT program
- Expansion of AAFCO's PT program



#### Tools

Service to participants on a regular schedule to be tested for analytes of interest by each laboratory. All materials requiring preparation are pre-ground. Results for individual analytes are

reported using specified AAFCO method codes and units to allow for analysis of the performance of individual methods or method types. Laboratory data are reported using the AAFCO Data Reporting Website. Reported results are analyzed statistically and participants receive for each analyte and method reported.

> Report cards and consensus reports are downloaded from the Data Reporting Website. New for 2015, we are offering four related programs that target different testing needs. Extra materials from each testing round are offered for purchase as Quality Reference Materials (QRMs) or "past samples."

#### Mycotoxin Contaminants Program

The Mycotoxin Contaminants Program consists of quarterly shipments of animal feed or pet food that has been contaminated with naturally incurred mycotoxins. Mycotoxins that may be present include aflatoxins, funonisins, decoxynivalenol, zearalenone, och-

ratoxin A and T-2 toxin. Subscription to the Mycotoxin Contaminants Program is limited to laboratories in the U.S. and Canada for 2015.

#### **Minerals Program**



The Minerals Program consists of quarterly animal feed, pet food, and food samples with both naturally occurring and spiked minerals at concentrations of health (toxicologi-

cal significance. Minerals present may include administration arsenic, boron, cadmium, chromium, cobalt, copper, fluorine, iodine, lead, mercury, molydenum, nickel, selenium, sulfur and vanadium. The Minerals Program is available worldwide for 2015.



#### lo.org/sme/

Tools Help

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.

Ahmed, Rasheed	Rasheed_Ahmedr@Gmail.com 96508190196	Environmental Health, Food Law & Regulation, Regulatory Inspections - Retail Food
Ahmed, Mohammed Ohio Department of Agriculture	ahmed@agri.ohio.gov 6147286317	Animal Feed Testing, Food Laboratory
Name	Contact	Expertise
Advanced search Search:	Found: 160 Show: Ahme - Godi (1-50)	
Areas of Expertise Animal Feed Testing (10) Civil or Criminal Investigations (10) Dairy (23) Environmental Health (49) Epidemiology (11) Food Laboratory (56) Food Law & Regulation (60) Food Processing Technologies (42)	~	

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## **Proficiency Test List**

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### Guidance

- Revising AAFCO Quality Assurance Quality Control Guidelines for State Feed Laboratories in February
- Developing GOODSamples to ensure consistency in the collection and handling of food/feed materials to improve data quality and accuracy

#### **PFP Laboratory Guidance**

- FDA's Partnership for Food Protection released Best Practice Guidelines for labs performing regulatory testing in Dec 2013
- One goal of these guidelines is to assure acceptance of data from state/local labs
- Review the PFP section on laboratory equivalency, provide guidance on content, and develop a resolution of support and implementation



#### http://www.fda.gov/downloads/ForFederalSt ateandLocalOfficials/FoodSafetySystem/UC M378504.pdf



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#### Data Exchange



- Evaluate documented technical and standards work for food/feed lab data exchange
- Provide feedback on eLEXNET upgrades
- Examine core data elements in order to identify the minimum elements that meet eLEXNET requirements



## **Direct Assistance**

- On-site consultation
- Perform data input to relieve QM of this duty
- Organize and review records or documents
- Provide internal audits
- Search for and provide sources
- Available by phone to provide information and suggestions



# Achieving these objectives requires

Achieving these objectives requires extensive collaboration and coordination among the three Associations, with federal partners, and with a wide range of stakeholders.

## **Import Alerts**

- NY State Food Lab accredited to ISO 17025 standard
- < 12 Import Alerts linked to NYSDAM data prior to 2008
- > 36 Import Alerts since 2008
- > 12 Import alerts this year alone
- Work closely with FDA NY State District office



## **Chinese Chicken Jerky Treats**

- Collaboration with Vet-LIRN members in FDA CVM and Cornell U Vet Diagnostic Lab
- NYSDAM worked closely with FDA NY District office, NY State initiated a recall in 2012 – resulted in a national recall of several brands
- Provided data packets and methods to FDA for review



## Imported Chia seed products

- Timeline from report of analysis to Import Alert < one week - fast</li>
- NY FDA District and NYSDAM participated in CORE Tactics Meetings & Ops Briefings
- Successful collaboration between State and FDA resulted in prevention of future adulterated product from entering U.S. commerce





## Here's to safer food through quality data from accredited laboratories





