

Accreditation to the ISO/IEC 17025 Standard

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

Yvonne Salfinger, MS
AAFCO Annual Meeting
Laboratory Methods and Services Committee
August 4, 2015

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

Silver Spring, MD – APHL has been 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



Associations' Interests in the Agreement

- Support APHL, AFDO, and AAFCO Members by providing resources, strategies and tools to achieve accreditation to the ISO/IEC 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 Products

COMMUNICATION

TRAINING

REPORTS

TOOLS

GUIDANCE

DATA EXCHANGE

DIRECT ASSISTANCE

Webpage and Resource Site

- Creation of web pages to support Food/Feed Testing Laboratories seeking Accreditation
- Accessible from www.aphl.org
- 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

Accreditation Resources

For Food and Animal Feed Laboratories Only

SAVED TOPICS: [Accreditation](#), [Food Safety Labs](#), [Member Resources](#)

Member Only SOP

-  [4.11 Root Cause Analysis and Corrective Action](#)
-  [4.14 Internal Audits](#)
-  [4.15 Management Review](#)
-  [4.3 Document Control](#)
-  [4.6 Purchasing Services and Supplies](#)
-  [5.2 Training and Competency](#)
-  [5.4 Validation-Verification](#)
-  [5.4.6 Measurement of Uncertainty](#)
-  [5.5 Equipment](#)
-  [5.6 Traceability](#)
-  [5.9 Control Charting](#)
-  [5.9 Proficiency Testing](#)
-  [FDA ORA Documents](#)
-  [Master Lists](#)
-  [Quality Manuals](#)

Member Only SOP

[4.11 Root Cause Analysis and Corrective Action](#)

- [4.11 APHL Root Cause Corrective Action, April 12, 2013](#)
- [4.11 FL admin 061-7dl-uncontrolled](#)
- [4.11 FL CA 663, March, 24, 2011 QAU](#)
- [4.11 FL CA 674, May 4, 2011 LW](#)
- [4.11 FL CA 681, June 1, 2011 M December 7, 2011](#)
- [4.11 FL CA 692, June 2011 M 9511](#)
- [4.11 FL CA695, July 6, 2011 M](#)
- [4.11 FL CA 698-071111-Mol, August 21, 2011](#)
- [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](#)
- [4.11 NC Nonconformity Report](#)
- [4.11 NC PD-QMS.009 Control of Nonconformities and Corrective Action v4](#)
- [4.11 ORA Laboratory Manual Volume II - Corrective Action Procedure](#)
- [4.11 Root Cause Presentation, A2LA](#)
- [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

[Home](#) | [Create a New Post](#) | [My Stats](#) | [Set Post Alerts](#) | [Set Comment Alerts](#)

-Categories-

All
[Document Control](#)
[Management Review](#)
[Internal Audits](#)
[Measurement Uncertainty](#)
[Traceability](#)
[Available Training](#)
[Training Needs](#)
[Non-conforming Work](#)
[Corrective Actions](#)
[Preventive Actions](#)
[Proficiency Testing](#)
[Equipment](#)
[Media](#)
[Reagents/Kits/Identification](#)

-Posts-

✓	Title	Body	Created By	Published	Category ▼	# Comments with Link
...	APHL Food and Feed Laboratory Accreditation site	Hi! I was wondering if anyone had any suggestions for the APHL Food and Feed Testing Accreditation Resources site? If so, please let Dare (dare.akingbade@aphl.org) and me (yhale@aol.com) know. We would appreciate input to help make this site (and the linking Training and Resources and Information sites) a site you all can go to for information to help become accredited or maintain accreditation. Thanks so much! http://www.aphl.org/aphlprograms/food/laboratory-accreditation/pages/default.aspx		10/14/2013 5:27 PM	APHL Information/products	0 Comment(s)
...	Innovation Grants-Funding Opportunity for APHL member laboratories	Innovation Grants Available - Apply Today APHL's National Center for Public Health Laboratory Leadership (NCPHLL) invites APHL member laboratories to apply for one of three innovation grants, up to a maximum of \$10,000, to fund projects related to workforce and leadership development within their laboratory. Projects must address one of the following topics: (1)		9/19/2013 4:59 PM	APHL Information/products	0 Comment(s)

Discussion Board

etc.) in seeking Accred

Home | Create a New

-Categories-

All

Document Control

Management Review

Internal Audits

Measurement Uncertainty

Traceability

Available Training

Training Needs

Non-conforming Work

Corrective Actions

Preventive Actions

Proficiency Testing

Equipment

Media

Reagents/Kits/Identification

Document control software

PAGE

I was wondering if anyone is using Paradigm 3 software for managing SOPs / equipment records / training records / corrective action reports etc. and would be willing to share any pros and cons of the system. Much appreciated the inputs.

Thanks

Rajesh Parmar

by rajesh.parmar@sdstate.edu at 4:40 PM in [Document Control](#)

Like Comment ***

3 comments

gail.parker@freshfromflorida.com My lab purchased Paradigm 3 in June 2013. We are currently utilizing only the Document Module (but will be using the Training Module within the next year). We have 225 user licenses. We host it in-house on agency servers managed by our agency's IT group. We launched the Document Module for users at the end of March 2014. There can be some network and operating system issues that you'll overcome during installation, checkout, and initial use. Interax (the North American vendor) told us it is not untypical for users to take 8-12 months to get things set up and configured. On the lab-side Interax can only do so much because YOU have to set up work flows for each document. It is very customizable and powerful, which means there is a steep learning curve for the application administrators. Once things are set up, it's pretty sweet. It was a bit overwhelming at first

OneDrive Sites

i:0#.f|aphluserlyhale@aol.com

SHARE FOLLOW

ted to this site. New users are always welcome.

ublished

Category

Comments with Link

/18/2014 4:40 PM

Document Control

3 Comment(s)

/14/2014 9:21 AM

Document Control

2 Comment(s)

Association Training

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



Association Training

- Quality Manual Basics webinar and “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 (AAFCO and MFRPA meetings)
- 2 webinars on Managing change
- Document control webinar-One Lab’s Journey
- Control charts and trend analysis webinar

Association Training planning for 2015-2016

- Basic QMS webinar series / New-hire ISO/IEC 17025 Training
- 2016 Laboratory Accreditation Meeting in conjunction with the Manufactured Food Regulatory Program Alliance (MFRPA)-planned for early February 2016
- New for 2016
 - Addition of Feed Laboratories and additional Food Laboratories under cooperative agreements
 - Federal Quality Managers being engaged as speakers

Partner Training

- Joint Governmental Laboratory Accreditation meeting with MFRPA March 9-12, 2015
 - Laboratory Presentations are available at www.mfrpa.org/presentations-lab.html
- Training on curriculum framework which depicts career-spanning professional development content areas (IFPTI partnership/working primarily with AFDO)
- 3 live webinars (Document Control Software and on Compliance Management Software) to demonstrate commercially available tools of value to laboratories seeking accreditation

DRAFT

Note: Core content areas (common training that everyone at that professional level should take) are denoted by dotted borders.

Partner Activities

- Completing level 2 and 3 competencies for Entry Level Content Areas E1-E18 in the Governmental Food and Feed Laboratory Curriculum Framework; the workgroup is now addressing Level 4 and 5 competencies.

Partner Activities

- IFPTI survey to laboratories regarding competency statements

Food and Drug Officials, Association of Public Health Laboratories, Food and Drug Administration, and other stakeholders, is seeking your help by requesting that you take a survey on competency statements for Entry Level governmental feed and food laboratory professionals.

The competency statements were developed by an Expert Working Group of 15 laboratory professionals from across the US.

The survey should take about twenty minutes to complete, and your input as a laboratory professional is crucial. The survey results will help in the effort to achieve a truly integrated feed and food safety system.

At the beginning of the survey, there is a brief, introductory video presentation covering the national curriculum framework, competency statements, the laboratory curriculum framework, and the purpose of the survey.

Link to the survey: <https://www.surveymonkey.com/r/6Y8LFQQ>

Reports

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

Data Exchange among Food and Feed-Testing Laboratories and FDA's eLEXNET

Discovery
Document



August 2013

Agreement work with FDA, the APHL Food Safety Committee that is attempting to identify and resolve challenges to the (related to foodborne illness) to public health laboratories report summarizes the work group's findings to date including clinical and public health laboratories, current challenges to ns, workable solutions to these challenges, and proposed

th laboratory system is to provide food safety testing for ce systems such as PulseNet and NARMS help form the n. These systems rely on isolates that are almost always

Tools

- Subject Matter Expert (SME) Registry of food and feed laboratory professionals
- List of relevant PT providers for food and feed laboratories
- Accreditation of AAFCO's PT program
- Expansion of AAFCO's PT program

Tools



Expansion of the Scope of the AAFCO CCSP PT

- ☒ Pet Food Program
- ☒ Mycotoxin Contaminants Program
- ☐ Heavy Metal Contaminants Program
- ☐ Veterinary Drug Contaminants Program
- ☐ Drug and Antibiotics Expansion

<http://www.afdo.org/sme/>

[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

[Civil or Criminal Investigations \(10\)](#)
[Dairy \(23\)](#)
[Environmental Health \(50\)](#)
[Epidemiology \(11\)](#)
[Food Laboratory \(56\)](#)
[Food Law & Regulation \(60\)](#)
[Food Processing Technologies \(42\)](#)
[Laboratory Accreditation \(2\)](#)

[Advanced search...](#)

Search: Found: **161** Show:

Name	Contact	Expertise
Ahmed, Mohammed Ohio Department of Agriculture	ahmed@agri.ohio.gov 6147286317	Animal Feed Testing, Food Laboratory

Guidance

- Data Acceptance Workgroup developing guidelines that will facilitate the acceptance of laboratory data by local, state and federal agencies regardless of accreditation status.
- Revising AAFCO Quality Assurance Quality Control Guidelines for State Feed Laboratories
- Finalizing and circulating GOODSamples, written to ensure consistency in the collection and handling of food/feed materials to improve data quality and accuracy

PFP Laboratory Science Workgroup

- Support from APHL staff (Shari Shea)
- Goal: Promote consistency and facilitate information sharing through establishing and utilizing national laboratory best practices.
- *The PFP will support development of a laboratory science system that allows for the sharing of results between strategic partners, recommends processes to leverage laboratory resources to increase information about the food supply chain, and promotes the use of national laboratory best practices. This will encourage partners to utilize each other's results to support aligned decision making and coordinate compliance and enforcement actions in an IFSS.*

PFP Laboratory Science Workgroup Objective

1. Increase the sharing and use of laboratory information among strategic partners
 - Activity: Map current major laboratory initiatives, including information sharing initiatives, to ensure that there is coordination and cooperation among strategic partners
 - Activity: Identify gaps and areas for improvement
 - Activity: Develop best practices to address the identified gaps
 - Activity: Pilot the best

PFP Laboratory Science Workgroup

Objective

2. Optimize initiatives among strategic partners for the use of best practices, specifically the PFP's laboratory best practices manual titled "Food/Feed Testing Laboratories Best Practices Manual (DRAFT)," to prepare human and animal food testing laboratories for accreditation.

- Activity: Review current PFP laboratory best practices manual
- Activity: Establish procedures for maintaining and updating the PFP laboratory best practices manual
- Activity: Identify ways to maximize use of the PFP laboratory best practices manual

The Partnership for Food Protection
Laboratory Task Group

presents



Food/Feed Testing Laboratories

BEST PRACTICES MANUAL

(Draft)

[http://www.fda.gov/downloads/
ForFederalStateandLocalOffici
als/FoodSafetySystem/UCM37
8504.pdf](http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM378504.pdf)

Data Exchange



- Gathering feedback on eLEXNET upgrades National Users Group and through demonstrations provided to APHL's Food and Feed Testing Subcommittee and at the Governmental Food and Feed Laboratories Accreditation Meeting.
- Drafting a plan entitled “eLEXNET Training & Value-Added Services for State Food-Testing Laboratories” to provide individualized on-site eLEXNET training to state laboratories and epidemiologists.

Direct Assistance

- Offering targeted assistance to 16 unfunded laboratories identified by FDA, including on-site visits, conference calls, and review of quality manuals, SOPs, methods, and document control efforts.
 - 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 will require extensive collaboration and coordination among the three Associations, with federal partners, and with a wide range of stakeholders.

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

Thank you!

