Accreditation to the ISO/IEC 17025 Standard

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

AAFCO Laboratory Methods and Services
January 2015
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.
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 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

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-uncontroled
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 uncontroled
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
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4.2-Document Control Software

by yhale@saoi.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

Document Control Software

Hello,

In Arizona our IT determined that they wanted us to have an in house system, so we are currently in the last 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

10:29 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 of 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.
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*..., 
  o 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

Training Website

Available Training

ISO/IEC 17025 Available Training: September 2014
Other Available Training: September 2014
References/Documents/Other Resources: September 2014

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)

(Released June 19, 2014)
(Released June 20, 2014)

Ethics and Data Integrity for Environmental Laboratories
(Released September 16, 2014)

Managing Change Rather than Change Managing You, Part 1
(Released October 23, 2014)
Managing Change Rather than Change Managing You, Part 2
(Released October 30, 2014)

ISO/IEC 17025 Section 4.3 Document Control ‘One Lab’s Journey’
(Released November 20, 2014)
Partner Training
http://www.ifpti.org/publications
Partner Training
IFPTI Curriculum Framework project
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

A cooperative agreement work with FDA, the APHL Food Safety Committee’s eLEXNET Work Group* that is attempting to identify and resolve challenges to the timely submission of specimens/isolates (related to foodborne illness) to public health laboratories. This report summarizes the work group’s findings to date including data on communications between clinical and public health laboratories, current challenges to timely submission of specimens, workable solutions to these challenges, and proposed next steps. A key strategy for strengthening the public health laboratory system is to provide food safety testing for use in outbreak surveillance systems such as PulseNet and NARMS help form the food safety 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
Proficiency Test List

Public Resources
- AAFCO Meeting Panel Presentation on Accreditation
- Proficiency Testing – Compliance with the ISO/IEC 17025 Standard
- Why Become an Accredited Laboratory?
- Why Use an Accredited Laboratory?
- Regulatory and Governmental Entities: Benefits of Using an Accredited Laboratory
- Laboratories: Advantages of Accreditation
- List of Proficiency Testing Providers

Related Content
- Center for Veterinary Medicine Animal Food & Feeds
- Center for Veterinary Medicine Guidance for Industry
- of the Food Safety Modernization Act in Ensuring safety of Pet Food
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
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 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
• 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

Thank you!