



Accreditation

Impact of ISO Accreditation

on State Food Testing Laboratories

and the

Role of Data Acceptance Criteria

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Laboratory accreditation supports food safety by ensuring the:

- Validation
- Traceability
- Accountability



of food testing data for rapid response



Benefits of ISO/IEC 17025 Accreditation

Compliance to a recognized standard, operational consistency and efficiency, and customer confidence.

- Consistency
 - Tasks are done the same way every time
 - Ensures ongoing product (result) quality
 - Documents institutional memory
- Efficiency / Effectiveness
 - Clear expectations for completing tasks
 - Clear, well-organized information
- Customer Confidence
 - Demonstration of competence





Additional Reasons

- Supports international growth strategies
 - International acceptance of data
- Customer driven
- Alignment with FDA, USDA, customers, competitors
- Data defensibility
- Promotes continuous improvement efforts
- A positive cultural upgrade
 - Issues are truly resolved
 - and learnings are captured





An increase in the number of accredited laboratories benefits human and animal food regulatory agencies with:

- Increased testing capacity and capabilities for regulated products leading to a safer food supply in the US
- High quality, defensible data leading to a more fully integrated food safety system





- In 2012, <25 accredited governmental food testing laboratories, including state, local and federal laboratories in US (PDP, MDP, FDA, FSIS labs)
- In 2012, FDA provided 5-year cooperative agreements to 31 state laboratories that perform testing for the (MFRPS) to achieve (23 laboratories) or enhance (eight laboratories) ISO/IEC 17025 laboratory accreditation.





- In 2015, an additional 6 food testing and 20 animal food testing laboratories (AFRPS) were awarded 5-year cooperative agreements to advance their efforts towards accreditation
- In 2016, one more animal food laboratory was funded
- In 2017, 2 more animal food laboratories were funded

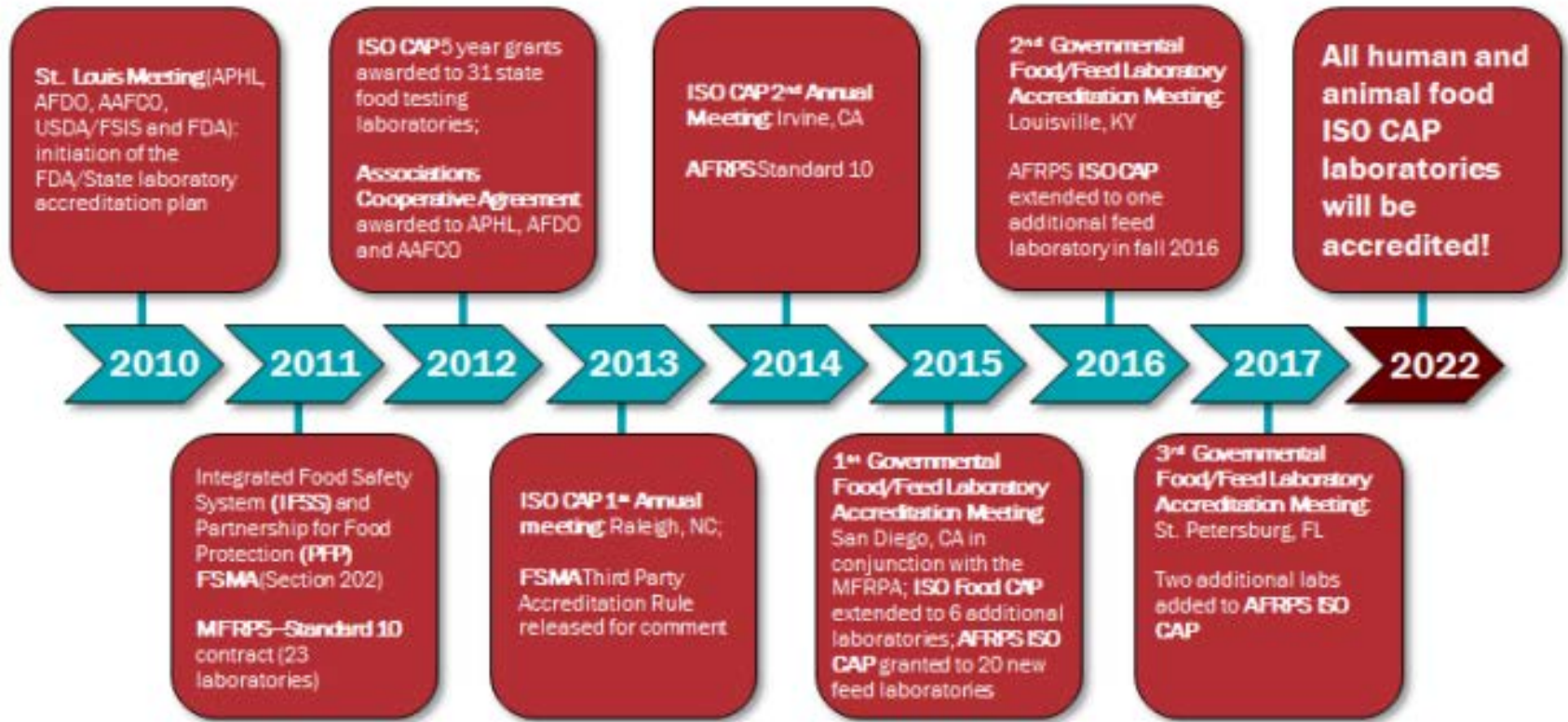
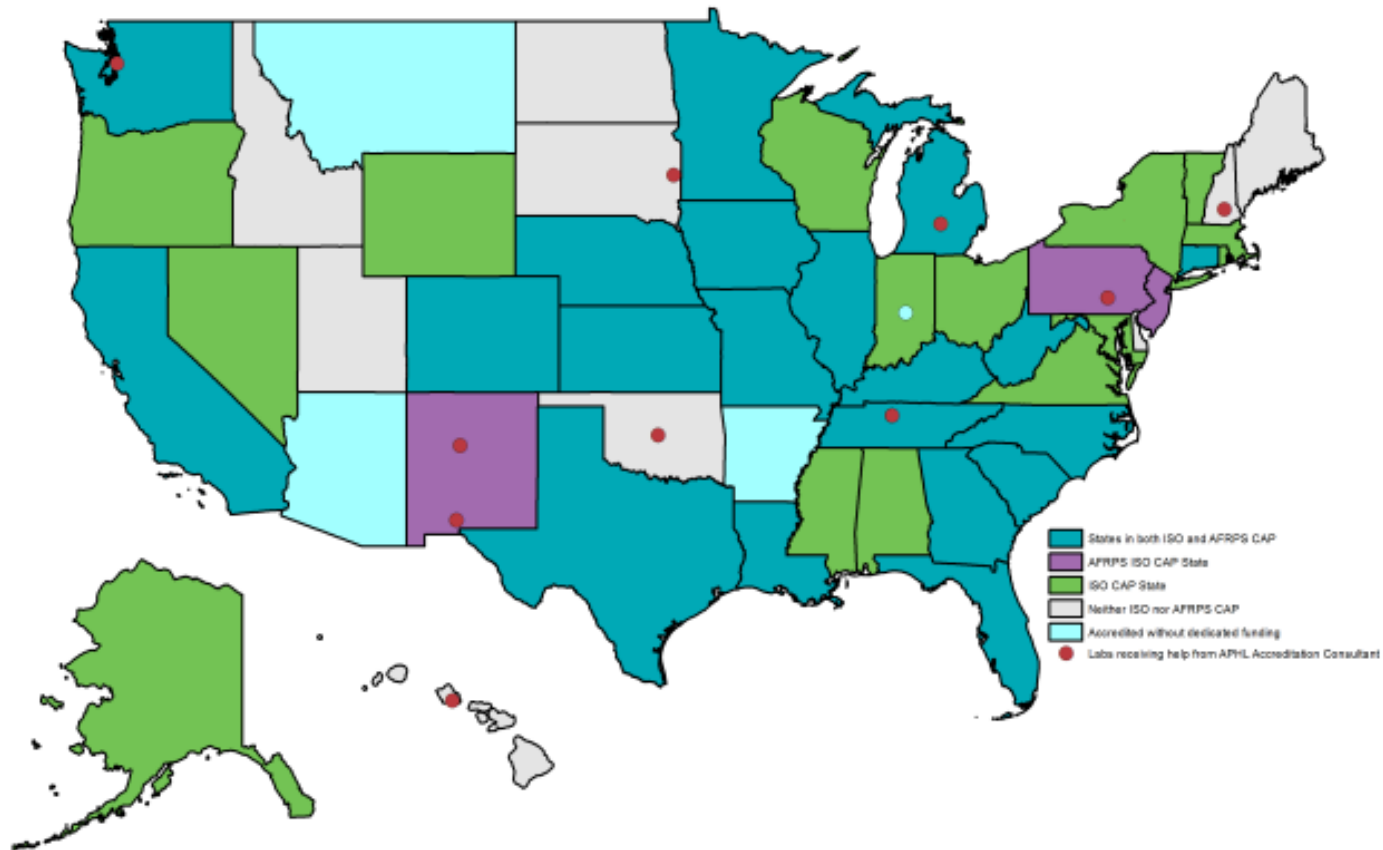




Figure 2. Laboratories working towards achieving or expanding scope of accreditation (as of August 2017)





Several laboratories were able to achieve accreditation without dedicated funding from FDA, using APHL consultant/hired consultant, other grants, or other means but were not part of the current accreditation cooperative agreement:

- Arizona Department of Health Services (2015)
 - Nebraska Department of Agriculture(2015)
 - Montana Department of Agriculture
 - Arkansas Department of Health Laboratory
 - Office of the Texas State Chemist Laboratory
 - Colorado Department of Agriculture
 - Marion County Health Department (Indiana)
 - Michigan Department of Health (2017)
 - Hawaii Department of Health (2018)
- All laboratories can use resources provided by the Associations cooperative agreement to expand the scope of their accreditation. www.aphl.org
 - Others are working towards accreditation also!





https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx

Accreditation Resources

ISO/IEC 17025 Accreditation
Training Resources

Electronic Laboratory
Exchange Network
(eLEXNET)

Quality Management
Training Series

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) to provide documents, best practice guidance, and accreditation strategies and resources to laboratories conducting regulatory food and animal feed testing.

The goal of this webpage is to address the needs of food and feed regulatory laboratories seeking initial, or expanding current, scope of accreditation in order to improve quality management systems and optimize testing capabilities. Please see a list of available resources below:

Public Resources (click to expand)

- + Success from the Field
- + Updating to the ISO/IEC 17025:2017 Standard
- + Why Accreditation
- + Proficiency Testing
- + Method Validation/Verification
- + Quality Improvement Resources & Tools
- + Sampling
- + Internal Audits
- + Partnership for Food Protection (PFP)
- + Laboratory Curriculum Framework
- + APHL Annual Meeting-The Road to ISO/IEC Accreditation: The Race to Improve Quality is On: How Do We Fuel Up for the Future and Drive Towards Integration?

Resources

Public Health Associate
Institutional
Membership
Application

Accreditation
Resources Flyer

Data Acceptance White
Paper

ISO 17025
Accreditation Costs
Survey Report





ISO/IEC 17025 Accreditation Training Resources

Accreditation Resources

**ISO/IEC 17025 Accreditation
Training Resources**

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Quality Management
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The following resources have been collected by the ISO/IEC 17025 Accreditation Training Steering Committee for food and feed testing laboratories seeking initial or expanded ISO accreditation. These resources are neither endorsed nor recommended by APHL or its partners at FDA, AFDO or AAFCO.

Resources

Quality Management Training Series

- + Training Documents
- + Webinars
- + Recorded Presentations from the Governmental Food and Feed Laboratories Accreditation Meeting, St. Petersburg, FL, January 23-26, 2017
- + Recorded Presentations from Joint Laboratories Accreditation & Manufactured Food Regulatory Program Alliance MFRPA 2016 Meeting, Louisville, KY, February 2016
- + Recorded Presentations from the Governmental Food and Feed Laboratories Accreditation Meeting, San Diego, CA, March 2015
- + "Let's Go ISO" 2014 APHL Annual Meeting Pre-Conference Workshop Materials

An [AFDO SME registry](#) is available and gets updated every 6 months.

A [Directory of State and Local Officials \(DSLO\)](#) is also available and has the updated contact information for every state and territory and some locals—anyone who deals with human and animal food testing or regulation.





Additional Cooperative Agreement Program Benefits

- Strong collaboration for an IFSS
- Associations working to support laboratory community.
- Quality managers and technical staff working across the country are helping one another resolve daily challenges.
- Personnel from both ISO/IEC 17025 accredited and non-accredited laboratories are learning from common challenges and sharing best practices.
- FDA laboratory personnel are working more closely with state laboratory staff
- Regulatory food program staff are operating in an atmosphere of collegiality with their laboratory counterparts regarding sampling plans, operating procedures and other common issues.





Examples of collaborative efforts with the associations on supporting

ISO accreditation- FDA funded three associations: APHL, AFDO, AAFCO

- Co-Ag steering committee (APHL, AFDO, AAFCO and FDA)
- Collaborative training efforts (FDA, APHL)
- Training, Food/Feed Subcommittee, Lab Managers Steering Committee
- Web-based repository resource center and Community Listserv (APHL)
- Ad Hoc Laboratory assistance (APHL, FDA)
- Data Acceptance working group (APHL, FDA)
- Sampling working group – GOODSamples document (AAFCO)
- **Laboratory sampling work group- GOOD Test Portions (AAFCO)**
-will be published soon, maybe this week!!
- Proficiency Testing Program (AAFCO)
- QA/QC guidelines (AAFCO)
- Development of a competency based career spanning training curriculum framework (AFDO, and starting 2017-APHL as lead)



Desired Program Outcomes:

- Increased number of accredited regulatory human and animal food testing laboratories
- Increased regulatory testing capacity by accredited laboratories
- Harmonized laboratory standards throughout the country
- Increased data sharing and data acceptance for regulatory action
- Enhanced federal-state partnerships in building the nation's integrated food safety system
- Increased collaboration among the community of regulatory laboratories testing human and animal food
- Improved sampling methods implemented in the human and animal food regulatory field (*GOODSamples*, *GOOD Test Portions*)
- Harmonized career-spanning educational opportunities for regulatory human and animal food laboratory professionals (Curriculum Framework)
- **Increased public health protection**



What is the driver for all this?

An Integrated Food Safety System where data is accepted seamlessly for more rapid action to protect the safety of the food supply

Laboratory accreditation has been identified as a critical element for ensuring the integrity and validity of human and animal food testing to support mutual reliance, or the interdependence and *trust* shared between parties



Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories





Data Acceptance White Paper

<https://www.aphl.org/aboutAPHL/publications/Documents/FS-2017Jun-Best-Practices-Food-Feed-Data.pdf>

- primarily designed to advise such non-accredited governmental laboratories which may have a QMS in place that demonstrates their ability to provide reliable data, but it is not based on ISO/IEC 17025.
- describes the phases of testing included in an ISO-based QMS, which can instill confidence in laboratory data submitted to regulatory agencies.
- does not take the place of regulatory requirements.
- intended to be a tool to assist laboratories and end users in data review and acceptability.

Best Practices for
Submission of Actionable
Food and Feed Testing
Data Generated in State
and Local Laboratories





Successes from the Field-Example of data acceptance in Florida:

January 2017

Listeria monocytogenes in frozen vegetable mix

- Added to sampling plan December 2016

May 2017

Listeria monocytogenes in finished pasteurized milk cheese product

- FDA accepted test data
- Worked with manufacturers to issue a voluntary recall/production and distribution of the product





Mutual Reliance project occurring between FDA and New York Agriculture and Markets

Results helping to shape improvements in data sharing





What's next?

Updated version of

ISO/IEC 17025 released late 2017

Laboratories will need to work towards accreditation to new version within the next couple of years, but as early as this summer (for new labs) and Fall 2018 (for some renewals)





Thank-you!

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