Strategies for Obtaining and Sustaining ISO 17025 Accreditation: The Process, Preparing Your Lab, Implementation Best Practices, Quality Management Tracking, Funding
The Process

You must learn to embrace change.

Can we change anything we want to change?

No. You don't get to say what the changes are. I do that.

Will that situation ever change?

No.

Why not? You said change is good.

Change is good.

For other people.

So embrace it or I'll fire you.

We love change!!!
THE PROCESS

- Buy-in at the top (whoever is holding the purse strings)
- Buy-in
  - Lab Management
  - Lab Staff
- Find a leader/advocate
PREPARING YOUR LAB

• Training, training, training and some more training
  • Upper Management
  • Laboratory Management
  • Laboratory Staff, including support staff

• Dedicated QA staff
• Mentor Lab
• Hire consultant
PREPARING YOUR LAB - RESOURCES

• APHL Recourses
  https://www.aphl.org

• Partnership for Food Protection (PFP) - Laboratory Best Practices Manual (LBPM)
Accreditation Resources

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
Public Resources (click to expand)

- Success from the Field
- Updating to the ISO/IEC 17025:2017 Standard
  - Why Accreditation
    - The Value of FDAs Investment in Laboratory Accreditation
    - Building an integrated Laboratory System to Advance the Safety of Food and Animal Feed
    - Accreditation: Supporting Safe Food and Clean Drinking Water
    - Why Become an Accredited Laboratory?
    - Why Use an Accredited Laboratory?
    - Regulatory and Governmental Entities: Benefits of Using an Accredited Laboratory
    - Laboratories: Advantages of Accreditation
    - How to Select an Accreditation Body
    - Trends in Lab Accreditation and Training and Tips for Success
    - AFDO Topical Index for Laws and Guidance—Laboratory Accreditation
    - AFDO Topical Index for Laws and Guidance—General Laboratory Resources
- Proficiency Testing
- Method Validation/Verification
- Quality Improvement Resources & Tools
- Sampling
- Internal Audits
ISO/IEC 17025 Accreditation Training Resources

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, AFSO or AAFCO.

Resources

- 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
Accreditation for Food and Feed Testing Labs

APHIL is working in collaboration with the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO) to strengthen and integrate food and feed testing laboratories. This effort is supported by a five-year cooperative agreement from the US Food and Drug Administration (FDA) to advance the Food Safety Modernization Act (FSMA).

The agreement supports food and feed regulatory testing laboratories seeking to achieve, maintain or enhance ISO/IEC 17025:2005 accreditation. Over 70 members from APHIL, AAFCO and AFDO are working on the cooperative agreement to advance the creation of a National Integrated Food Safety System (IFSS).

Objectives of the work include:
- Developing laboratory training programs around accreditation
- Building a mentoring program for laboratories at various stages of accreditation
- Enabling direct electronic sharing of analytical data
LABORATORY ACCREDITATION

Chapter 1

Background and Objectives

Accreditation can be defined as an ongoing, ongoing, continuous improvement process that provides assurance to the public of the competence of laboratories to perform specific testing and measurement activities. Laboratory accreditation is the process by which a laboratory is certified as meeting specific standards and requirements. The goal of laboratory accreditation is to ensure that laboratories meet the needs of their clients and the public by providing high-quality, reliable test results.

The Partnership for Food Protection (PFP) is a public-private partnership that includes state and federal agencies, industry, academia, and other stakeholders. The PFP is responsible for developing and implementing the BEST PRACTICES MANUAL for Food and Feed Testing Laboratories. The PFP is committed to ensuring that laboratories are accredited and meet the highest standards of quality and integrity.

One of the main accreditation standards utilized by testing laboratories throughout the world is the International Laboratory Accreditation Cooperation (ILAC) MRA. The PFP's Accreditation Committee was charged with drafting the process for food/feed testing laboratories to become accredited to ISO/IEC 17025. The Subcommittee process for food/feed testing laboratories to become accredited to ISO/IEC 17025 includes the following steps:

1. Develop an outline for writing and implementing a management system that would meet the requirements of ISO/IEC 17025

2. Conduct a task force

3. Revise and publish the requirements of ISO/IEC 17025

Definitions

Accreditation: The process of recognizing a laboratory as meeting the requirements of ISO/IEC 17025. An accredited laboratory has demonstrated competence in performing tests and calibrations and is recognized as such by other laboratories.

Reference: The process of recognizing a laboratory as meeting the requirements of ISO/IEC 17025. A reference laboratory is one that has been accredited by a recognized accreditation body.

Task 1 - Steps to ISO/IEC 17025 Accreditation

The following steps were created to provide a guide for laboratories to achieve ISO/IEC 17025 accreditation:

1. Conduct an internal audit of the laboratory's procedures and processes

2. Identify and implement improvements to the laboratory's management system

3. Complete the external audit process and submit the audit report to the accreditation body

Training/Resources: Additional training and resources may be required to achieve ISO/IEC 17025 accreditation. The PFP encourages laboratories to review the standards and requirements of ISO/IEC 17025 and to seek additional training and resources to ensure compliance.
PFP LBPM – Chapter One

• Step 1 - Buy-in at all levels
• Step 2 - Establish Organization
• Step 3 - Training at Multiple Levels
• Step 4 - Choose the Accreditation Body
• Step 5 - Gap Analysis
• Step 6 - Identify Accreditation Requirements
PFP LBPM – CHAPTER ONE

- Step 6 – Identify Accreditation Requirements
- Step 7 – Write Quality Management System (QMS)
- Step 8 – Implement QMS
- Step 9 – Write Technical SOPs & Implement Changes
- Step 10 – Build Records
- Step 11 – Conduct Internal Audit(s) and Management Review
- Step 12 – Initial Assessment by Accreditation Body
PARTNERSHIP FOR FOOD PROTECTION – LABORATORY BEST PRACTICES MANUAL
LABORATORY BEST PRACTICES MANUAL

• Began work in the first draft in 2010
• Developed for food/feed testing laboratories to facilitate acceptance of laboratory analytical data by regulatory agencies
• 7 Chapters, 3 Appendix, over 90 workgroup members helped to develop
• Provides tools, definitions, references
• Issued as draft by the FDA in 2015
LABORATORY BEST PRACTICES MANUAL

• Chapter 1 – Accreditation
• Chapter 2 – Regulatory Elements
• Chapter 3 – Proficiency Testing
• Chapter 4 – Sampling - including GOOD Test Portions
• Chapter 5 – Methods
• Chapter 6 – Analytical Worksheet Packages
• Chapter 7 – Reporting

• Appendix 1 – Acknowledgements
• Appendix 2 – Links to supporting documents
• Appendix 3 – Abbreviations, Acronyms, and Definition of terms

ISO/IEC 17025:2017
There’s talk of paradigm-shifting innovation heading your way. Lock your door and hide under the desk.

WHAT TO EXPECT — REAL WORLD

• Growing Pains
• Push back from long time employees
• Retirements
QUALITY MANAGEMENT TRACKING

- Software programs
  - Audits
  - Corrective Actions
- Documents
  - Non-conformances

Pros
- Automated (in varying degrees)
- Once implemented frees up staff time

Cons
- Cost (annual)
- Set up time can be extensive
QUALITY MANAGEMENT TRACKING

• “Manually” using Excel
  • Audits
  • Corrective Actions

Pros
• Already have Excel in lab – no additional cost
• Easy to use

Cons
• Tracking “by hand”
• Need staff to use
## Microbiology SOP Master List

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QUALITY MGT TRACKING – NYDAM FOOD LABORATORY

• Communication
  • “All Lab” meetings (including support staff)
  • weekly “huddle” meetings
  • CAR/PAR wrap-up meetings
  • Audit wrap-up meetings
FUNDING

• Buy-in at the top *(whoever is holding the purse strings)*

• Buy-in
  • Lab Management
  • Lab Staff

• Grants
  • MFRPS – manufactured food
  • AFRPS – animal feed
FUNDING – PRICE OF QUALITY

Value

Quality

Price
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