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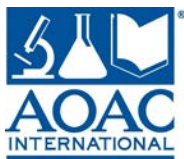
FDA's Collaborative Efforts to Promote ISO/IEC 17025:2005 Accreditation for the Nation's Food/Feed Testing Laboratories

Ruiqing Pamboukian, Ph.D.

Angele Smith

**Office of Regulatory Affairs/Office of Regulatory Science
U.S. Food and Drug Administration**

**AOAC 128th Annual Meeting and Exposition
Boca Raton, Florida
September 7 - 10, 2014**



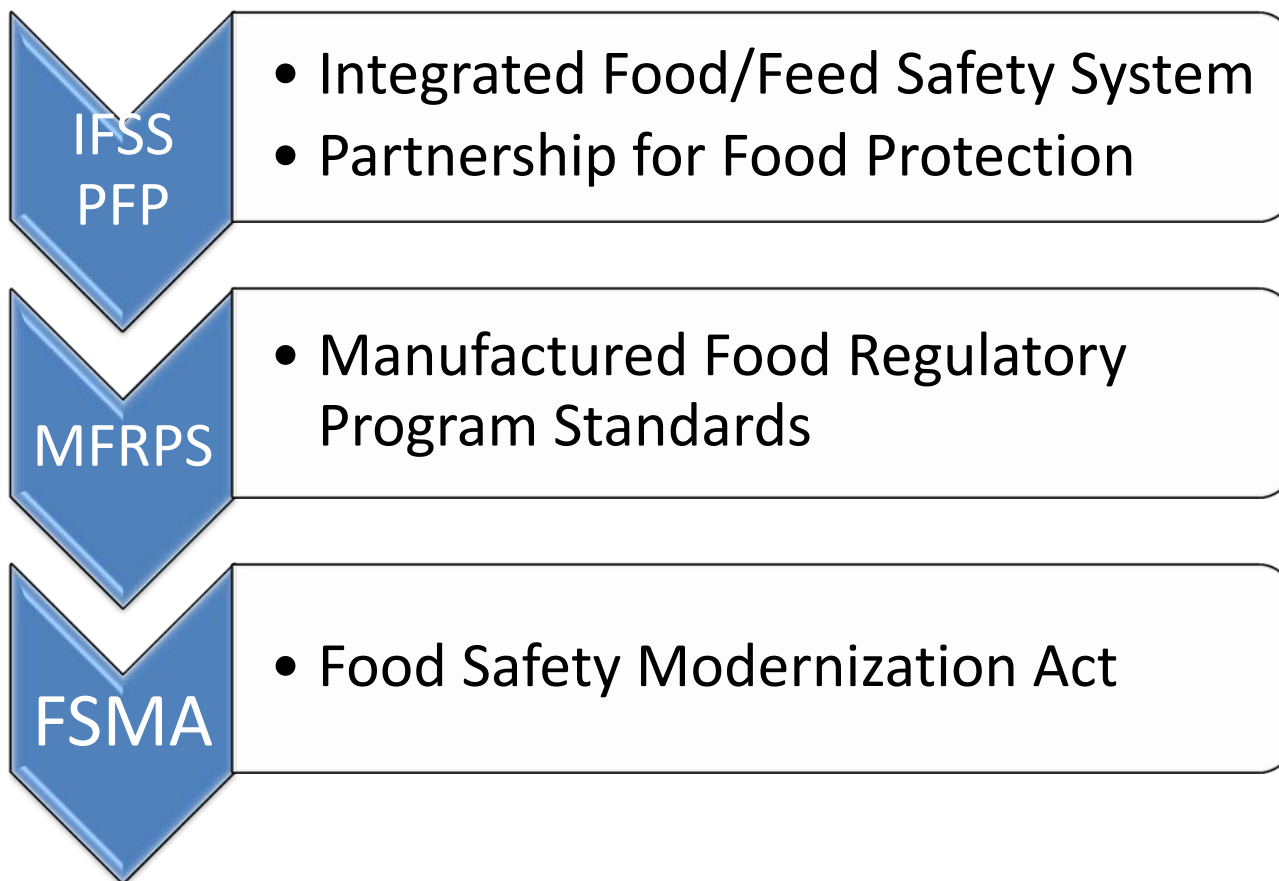


Outline

- Background
- FDA's role in laboratory accreditation
 - Funding
 - Supporting program
 - Collaboration, collaboration and collaboration



Driving Forces of Laboratory Accreditation





Background of the FDA/State ISO 17025 Accreditation Program

St. Louis Meeting (APHL, AFDO, AAFCO, USDA/FSIS, and FDA) – initiation of the FDA/State laboratory accreditation plan

ISO CAP –5-yrs grant, awarded 31 state laboratories

Association CAP – awarded APHL, AAFCO, AFDO

ISO CAP 2nd Annual meeting in Irvine, CA

2010

2011

2012

2013

2014

..... 2017

IFSS & PFP

MFRPS- Standard 10 contract

FSMA (section 202)

ISO CAP 1st Annual meeting at Raleigh, NC

FSMA Accreditation Rule is in the making

- Model laboratory Standard



St. Louis Meeting - September 22-23, 2010

- Attendees
 - FDA, FSIS/USDA, APHL, AFFCO, AFDO
 - State laboratories
- Objectives:
 - discuss the FDA Laboratory Accreditation Project
 - Achieve mutual agreement on accreditation plan
- The FDA presented an overview of the food safety policies undergoing changes in Congress and the advantages of Laboratory Accreditation
- FDA invited the attendees to engage in the design of a workable accreditation plan



Agreement in St. Louis Meeting

- To develop outreach activities to inform interested labs about the FDA Accreditation Program.
- To provide an Initial Assessment based on ISO 17025, Gap Analysis, and a Time-line Plan to labs that commit to obtaining accreditation under the FDA assistance.
- To determine milestones and accreditation costs within the timeline plan for the labs pursuing accreditation under FDA support.
- To provide potential financial assistance based on the lab's accreditation standing, economic resources, and progress on the pathway to accreditation.
- To provide support for already accredited labs to maintain and expand their accreditation.



Background of the FDA/State ISO 17025 Accreditation Program

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IFSS and PFP

- Establishing a fully Integrated National Food Safety System with strengthened inspection, laboratory and response capacity
- PFP -Partnership for Food Protection
 - the “Best practices Manual”
 - laboratory accreditation has been identified as a critical element for ensuring the integrity and accuracy of laboratory analytical testing
 - Ensure defensible data
 - Data acceptance by regulatory agency





Manufactured Food Regulatory Program Standards (MFRPS)

Goal:

To implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States.

- Ten standards contain critical elements of a regulatory program
 - **Standard No. 10 - Laboratory Support**
 - **State program utilizes laboratories that either accredited or have quality assurance programs that incorporate management and technical requirements found in ISO/IEC 17025:2005**
- 2011 – MFRPS one year contract – given to 20+ laboratories to support their laboratory accreditation efforts
- 2012 – 5 year grant – 31 awardees



Section 202 of FSMA

Laboratory Accreditation for Analyses of Foods

Key Deliverables

- Establish lab accreditation program
 - Develop a process and criteria for recognition and accreditation
 - Develop a process and criteria for periodic review
 - **Develop model standards for testing labs**
 - Develop internal database to support program
- Establish public registry of recognized ABs and accredited labs
- **Accredited labs to conduct food testing**
 - Develop process for electronic submission of data
- **Develop process for reviewing State/local labs results for purposes of recall, CE activities**



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FDA ORA/ORS Laboratory Accreditation Program

- Who we are:
 - a group of Regulatory Scientists with laboratory experience and ISO Auditor training
- What we do:
 - provide guidance and technical assistance to the ISO CAP grantees and the Ad Hoc group (laboratories are interested in becoming accredited, but have not received funding)
 - Coordinate Mentor-Mentee and training
 - Collaborate with APHL, AAFCO and AFDO to provide laboratory accreditation support



Guidance

**Standard
Purchase**

ISO training

**Establish QA
manager**

**Scope of
Accreditation**

Action Plan

**Proficiency
Testing**

**Mentor/Mentee
program**



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Scope of Accreditation

- FDA Regulated Products
- Identify Methodology
- Identify Accrediting Body





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Action Plan



- Training to be completed
- Proficiency Testing schedule
- Documents to be written
- Worksheets/Records to be developed
- Practices to be deployed

Proficiency Testing

- Approved Providers
- Testing Cycles
- In-House Testing





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Mentor/Mentee Relationship

Mentor – Accredited Labs

Mentee – Non-Accredited Labs

- Goal – to share best practices, experiences, and offer practical knowledge
- Mentor activities:
 - On-site visit
 - pre-scheduled calls to discuss any issues and questions from the mentee labs
 - Share SOPs, quality manuals, etc.

LAB MENTORS & MENTEEES

The map displays the following locations:

- Mentors (Yellow Boxes):** WASHINGTON, WA, WA, OH, NY, FLORIDA
- Mentees (Colored Boxes):** Minnesota (pink), Wisconsin (purple), Michigan (yellow), Ohio (orange), New York (green), North Carolina (blue), Florida (green)
- Connections (Arrows):**
 - Blue arrow from WASHINGTON to Oregon
 - Green arrow from NY to New York
 - Orange arrow from OH to Ohio
 - Blue arrow from FLORIDA to Florida

Other states shown on the map include: Montana, North Dakota, South Dakota, Wyoming, Idaho, Nevada, Utah, Colorado, Arizona, New Mexico, Texas, Louisiana, Arkansas, Missouri, Illinois, Indiana, Kentucky, Tennessee, Mississippi, Alabama, Georgia, South Carolina, North Carolina, Virginia, West Virginia, Maryland, Delaware, Pennsylvania, New Jersey, Connecticut, Rhode Island, Massachusetts, New Hampshire, Vermont, Maine.

Alaska

Hawaii



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Review

- GAP Analysis Checklist
- Document Review
- On-site Assessment and/or desk audits



GAP Analysis Checklist

- Completed bi-annually to show progress
- Used to establish quarterly action plans





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Document Review



- Quality Manual
- Quality Documents
 - Standard Operating Procedures
 - Work Instructions
 - Forms/Templates
 - Internal Audits
 - Management Review
 - Non-Conformances
 - Training Records



On-Site Assessments and/or Desk Audits

Sample Flow through Laboratory

- Sample Integrity
- Document Control
- Quality Control
- Methods and Calibrations
- Purchasing and supplies
- Trace Backs



Training

- Webinars hosted by Mentor Labs
- Webinar links on topics of interest
- Collaboration with APHL





Program Outcomes

- Increase the number of accredited food and feed testing laboratories
- Increase testing capacity by accredited laboratories
- Increase the level of accountability in laboratory performance
- Harmonize laboratory standards throughout the country
- Enhance Federal-State partnerships in building the nation's Integrated Food/Feed Safety System.



Summary

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Accreditation successfully achieved and expanded!!

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Vision for the Future

- Continue to promote laboratory accreditation
- Continue to Implement PFP best practices
- Develop and Implement FSMA model laboratory standards
- State laboratories participate in National Surveillance Program
- Greater use of state data for regulatory action
- Coordinated, faster and more effective response to food safety events



Acknowledgement

Office of Regulatory Science

Timothy McGrath
Donald Burr
Angele Smith
Ann Westerman
Dean Turco
Toni Morale
Sunee Himathongkham
Anthony Adeuya
Peggy Carter
Mohammed Islam

Office of Partnership

Abe Brown
Erin Woodom-Coleman
Tim Weigner and the group



Thank You!

Ruiqing.pamboukian@fda.hhs.gov

Phone: 301-796-8157

Timothy.McGrath@fda.hhs.gov

Donald.Burr@fda.hhs.gov