Let’s Go, ISO! How Your Colleagues Began Their Path to ISO Accreditation.

APHL Annual Meeting Pre-Conference Workshop
June 1, 2014

Objectives

At the end of the session, the participant will be able to:

• Identify three significant reasons why it is valuable to implement systematic processes to support ISO in the laboratory
• Discuss possible approaches/pathways a laboratory may follow to achieve ISO accreditation
What’s all the fuss?

- Big push for food and feed testing laboratories to become accredited
- Food Safety Modernization Act (FSM)-1/4/2011
  - Provides FDA framework to better protect public health
  - Strengthens food safety system
  - Ensure safety of US food supply, shifting focus to prevention of contamination through enhanced partnerships & integration

Title II – Improving Capacity to Detect and Respond to Food Safety Problems

- Sec. 201. Targeting Inspection Resources
- **Sec. 202. Laboratory Accreditation**
- Sec. 203. Integrated Consortium of Laboratory Networks
- Sec. 204. Enhancing Tracking and Tracing of Food and Recordkeeping
- Sec. 205. Surveillance
- Sec. 206. Mandatory Recall Authority
- Sec. 207. Administrative Detention
- Sec. 208. Decontamination and Disposal Standards and Plans
- Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials
- Sec. 210. Enhancing Food Safety
- Sec. 211. Improving the Reportable Food Registry
Section 202 of FSMA
Laboratory Accreditation for Analyses of Foods

202(a) – Recognition of Laboratory Accreditation
• Establish an accreditation program
  o Criteria for recognition of accreditation bodies
  o Accredited labs to include Federal/State/Local labs and independent private labs
  o Accreditation standards also applicable to foreign laboratories
  o Recognized ABs and ALs required to report any changes to FDA
• Establish a publicly available registry of recognized accreditation bodies and accredited laboratories
• Increase the number of qualified laboratories
• Develop model laboratory standards
• Periodic review of recognition (at least once in 5 y)

202(a)(6) – Model Laboratory Standards
• FDA to develop model standards required to be met by laboratories for accreditation for a specified sampling or analytical testing methodology
• FDA shall consult existing standards for guidance
• Model standards requirements:
  o Appropriate sampling, analytical procedures
  o Internal quality systems
  o Procedures to handle complaints
  o Qualified lab personnel
  o Any other appropriate criteria established by FDA
Section 202 of FSMA
Laboratory Accreditation for Analyses of Foods

202(b) – Testing Procedures
• Testing by accredited labs
• Testing conducted “by or on behalf of an owner or consignee” in cases of:
  o identified or suspected food safety problem
  o import alerts
• Results of testing to be reported to FDA
  o May be submitted by electronic means
  o By regulation, may exempt results from submission requirement
• Testing procedures may be waived for new validated methodologies as needed for food emergency/ outbreaks

IFSS
Since 2008, the PFP (Partnership for Food Protection) has been working to develop an IFSS (Integrated Food Safety System)
• National standards
• Accrediting food and feed testing laboratories is one measure to ensure rapid acceptance of laboratory data for compliance and regulatory actions
LET’S BEGIN!