

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
 - o Provides FDA framework to better protect public health
 - o Strengthens food safety system
 - o 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

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



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)



Section 202 of FSMA Laboratory Accreditation for Analyses of Foods

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:
 - identified or suspected food safety problem
 - import alerts
- Results of testing to be reported to FDA
 - May be submitted by electronic means
 - 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!

