Data Acceptance Workgroup

Encouraging acceptance and use of laboratory data by end users

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Introduction

• Food Safety Modernization Act (FSMA)
  – Aims to provide a level of consistency in the laboratory through ISO/IEC 17025 accreditation
  – Recommends having a quality system in the laboratory

• Laboratories needed guidance
  • Keys elements of a quality management system (QMS)
  • Factors to consider to ensure data acceptance by end users
  • Scope of methods and analytes covered under accreditation
    – Labs may limit scope to more critical/widely used methods

• What happens to data produced by unaccredited methods?
Data Acceptance Workgroup

- APHL formed the Data Acceptance Workgroup

- The workgroup is comprised of members from:
  - Association of Public Health Laboratories (APHL)
  - Association of Food and Drug Officials (AFDO)
  - Association of American Feed Control Officials (AAFCO)
  - Food and Drug Administration (FDA)
  - Food Safety Inspection Services (FSIS) with the United States Department of Agriculture (USDA)
  - Unaffiliated state laboratories
Data Acceptance Workgroup

- Co-chairs: Kathryn Wangsness (AZ) and Yvonne Salfinger (APHL consultant)

- Tasked with developing best practices state and local laboratories can take to encourage acceptance and use of laboratory data by end users, irrespective of laboratory accreditation status
Why is this needed?

- FDA may not take regulatory action on state data if that laboratory is not accredited, but may be more likely to do so if the lab is accredited.

- Laboratories are encouraged to become accredited to ISO/IEC 17025:2005 standard
  - Not always feasible
    - Only frequently used methods are accredited
    - More work = more staff needed

- Laboratories may have QMS in place
  - May not cover their food testing/FERN work if they are not working towards ISO
  - Demonstrates their ability to provide reliable data
  - Can use these Best Practices to increase data acceptance
What did the Workgroup Create?

• Working with federal and state partners, the workgroup developed minimum elements to assess data acceptability and a checklist with which laboratories and data users can evaluate the lab quality management system.
Data Acceptance Best Practices for State and Local Food and Feed Laboratories

- Intended for labs that: are accredited, are not accredited, or whose data falls outside their scope of accreditation
- Assists laboratories in identifying specific policies, procedures, and records that should be in place in order to share data with end users
- Outlines the foundation for a QMS
Key Elements

- Quality Management System
  - Pre-analytical
  - Analytical
  - Post-analytical
Key Elements

• Requirements for Representative Sampling
  – Essential to achieve consistent results
  – Sample Quality Criteria (SQC)
  – Harmonized sampling protocols should be used
  – Working with the inspection program is key
  – GOODSamples
Key Elements

• Requirements for Regulatory Programs
  – Data should be accurate, timely and reliable
  – Use appropriate test methods that meet customer needs
  – Various regulatory programs have specific requirements
Key Elements

• Evaluation of Data by Programs
  • Performed by the customers
    – Within the same agency
    – Contracting with the laboratory
    – Regulatory agencies
  • May have specific requirements that should be provided
Data Acceptance Checklist

• Transforms information from DA document into an easy-to-read checklist
• Assists labs in seeing what is needed to work towards having their data accepted
• Excellent resources for labs just starting out
  – Bolded sections are recommended starting points
  – Aid in development of a QMS
Where will it be published?

- APHL will publish the Best Practices document and the Checklist as a white paper.
- PFP Best Practices Manual as Chapter 2 “Regulatory Elements”
A System-Wide Effort

- Communication is key
  - Between samplers and labs
  - Between labs and end users
- Know how end users view the document
- Build trust before an outbreak or event
THANK YOU

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