

*An exploration of International Organization for  
Standardization (ISO) 17025 quality management in the  
Kansas Department of Agriculture Laboratory, and Food and  
Drug Administration (FDA) certification for a dairy analysis in  
a central laboratory*

Somia Jamma

Master of Public Health Candidate 2023

Kansas State University

# Presentation Outline

## OUTLINE

---

Introduction

---

Overview of ISO 17025

---

FDA certification

---

Public health problems

---

Applied Practice Experience

---

Project description

---

Lessons learned

---

MPH foundational competencies



# INTRODUCTION

## Overview of the ISO 17025 Quality Management Standard

- ISO 17025 is a global standard that outlines the general requirements for the competence of testing and calibration laboratories.
- The importance of ISO 17025 lies in its ability to provide confidence in the accuracy and reliability of testing and calibration results



**ISO 17025  
ACCREDITED  
LABORATORY**



# ISO 17025 in the Kansas Department of Agriculture Laboratory

- The laboratory has developed and implemented a quality management system that is designed to meet the requirements of ISO 17025.
- This system includes:
  - Management System
  - Personnel
  - Equipment
  - Measurement Traceability

# Benefits of ISO 17025



# FDA Certification



- FDA certification is a process by which laboratories can demonstrate that they meet the requirements set forth by the U.S. Food and Drug Administration (FDA) for the testing of food, drugs, and medical devices.
- The FDA sets standards and guidelines for laboratory testing to ensure that products are safe, effective, and comply with federal regulations.



## Obtain FDA Certification

To obtain FDA certification, a laboratory must meet a number of requirements , including:

- Personnel qualifications
- Quality control
- Analytical procedures





## An overview of the dairy analysis process at KDAL


- Sample collection
- Sample receipt and accessioning
- Sample preparation
- Testing and analysis
- Data analysis and reporting
- Quality control



## ISO 17025 and FDA certification

- Both are important quality management systems that ensure the accuracy and reliability of dairy analysis results
- By implementing these systems, laboratories like KDAL provide critical support to the dairy industry by ensuring the safety and quality of their products.

# Public Health Problems

- 
- 
- *Salmonella*, *Escherichia coli*, and *Campylobacter* are the most common bacteria that cause foodborne illness.
  - One concern regarding food safety is zoonosis, because it is one of the main barriers to the international trade of animal products.
  - The presence of tylosin—an antibacterial antibiotic—in animal feeds.
  - The presence of antibiotic in raw milk.



## Prevention of Foodborne illness in a laboratory setting

- Training and education
- Effective cleaning and sanitization
- Compliance with regulations
- Proper handling of food samples.
- Quality ontrol.



# APPLIED PRACTICAL EXPERIENCE

# APE Site



- Kansas Department of Agriculture Laboratory (KDAL)
- Started in August 2022
- Preceptor: Dr. Sally Flowers



# Learning Objectives

1. Define my understanding of the purpose and mission of the Kansas Department of Agriculture laboratory.
2. Become able to describe the purpose and relevance of ISO 17025 or other quality management systems in a laboratory testing environment.
3. Enhance my understanding of the impact of pesticides use in agriculture and the benefits and hazards of pesticide use.
4. Become familiar with structures of obtaining Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory.

# Activities at the Beginning of APE

1-Update certain lab procedures



2. Help with preparation of microbiology media.



3. Analyze the data



4. Work with microbiology team testing for raw milk follow FDA procedures.



# Project Description

# ACTIVITIES PERFORMED

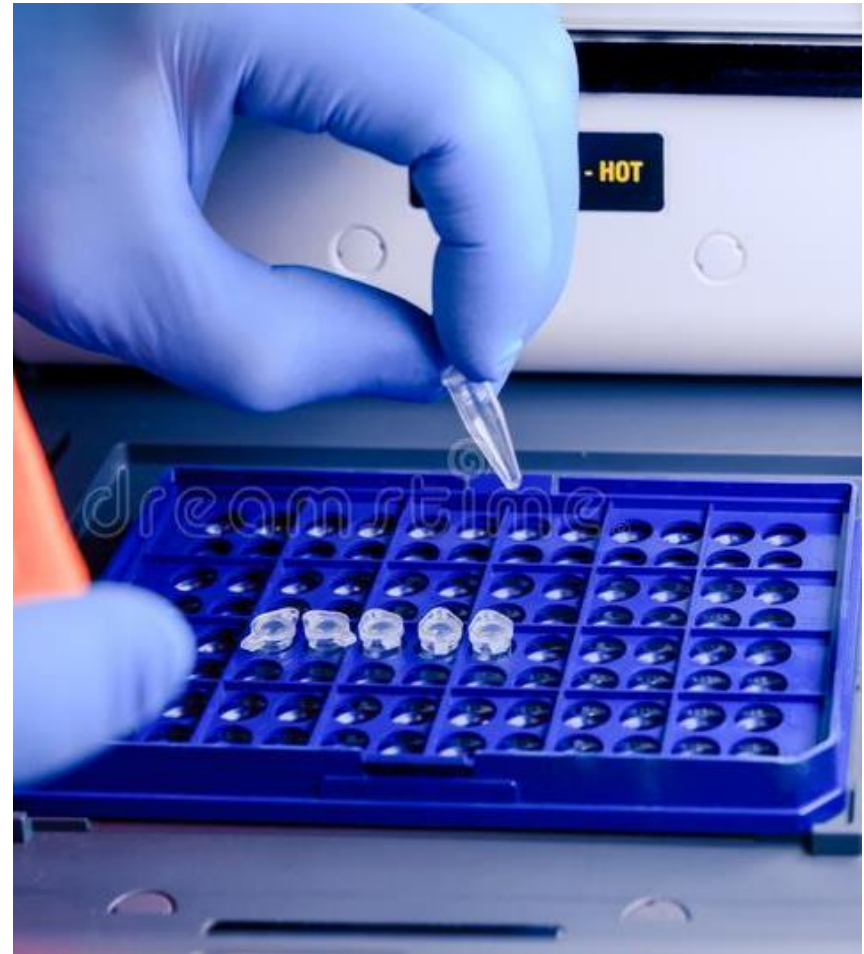
- I attended the Lab's annual ISO 17025 assessment with the Lab director.
- I worked with a microbiology lab testing team for testing raw milk following Food and Drug Administration (FDA) guidelines.
- Assisted with the sampling and preparation of chemistry extraction in the animal feed laboratory.
- Updated certain lab procedures for pesticides testing.
- I learned the principles of laboratory system management (ISO 17025) related to public health.
- I completed 20 online modules at the KDA Laboratory using its Qualtrax document management system to study how ISO 17025 is an important standard for testing and calibration laboratories.

## KDA laboratory's annual ISO 17025 assessment

- An independent, third-party accreditation body performs annual assessments to verify whether the laboratory system is meeting all requirements.
- A third party evaluated the laboratory methods used to implement any corrective action needed.
- It also examined the calibration record and performance of any equipment used.
- Guidance was provided on the degree of validation required for method modifications during laboratory activities.
- The annual assessment helps the lab improve its ability to consistently produce valid, accurate results for the customers and the community.

# The Polymerase Chain Reaction (PCR)

- Is used to amplify specific DNA fragments and detect microorganisms in food that cause human illnesses.
- To ensure food safety, it is important to detect the foodborne pathogen quickly and accurately because of the serious public threat they cause.
- Identifying the specific microorganisms and the source of the outbreak .
- The performance of ISO methods should be verified at the laboratory when PCR is used to quickly detect foodborne pathogens in food.



## Engage with microbiology lab testing team.

- I engaged with the team to conduct a Coliform Plate Count method (CPC) for a milk sample.
- I aliquoted a sample of milk onto an agar plate and incubated it for 24 hours.
- I counted the colonies that were formed using an automated colony counter.
- I discarded all the plates and culture tubes used in the biohazardous waste (and autoclaved them before washing and reusing them).

# My participation in the CPC method





# An overview of the history and food safety relevance of ISO 17025

# ISO 17025 and Lab Testing Results



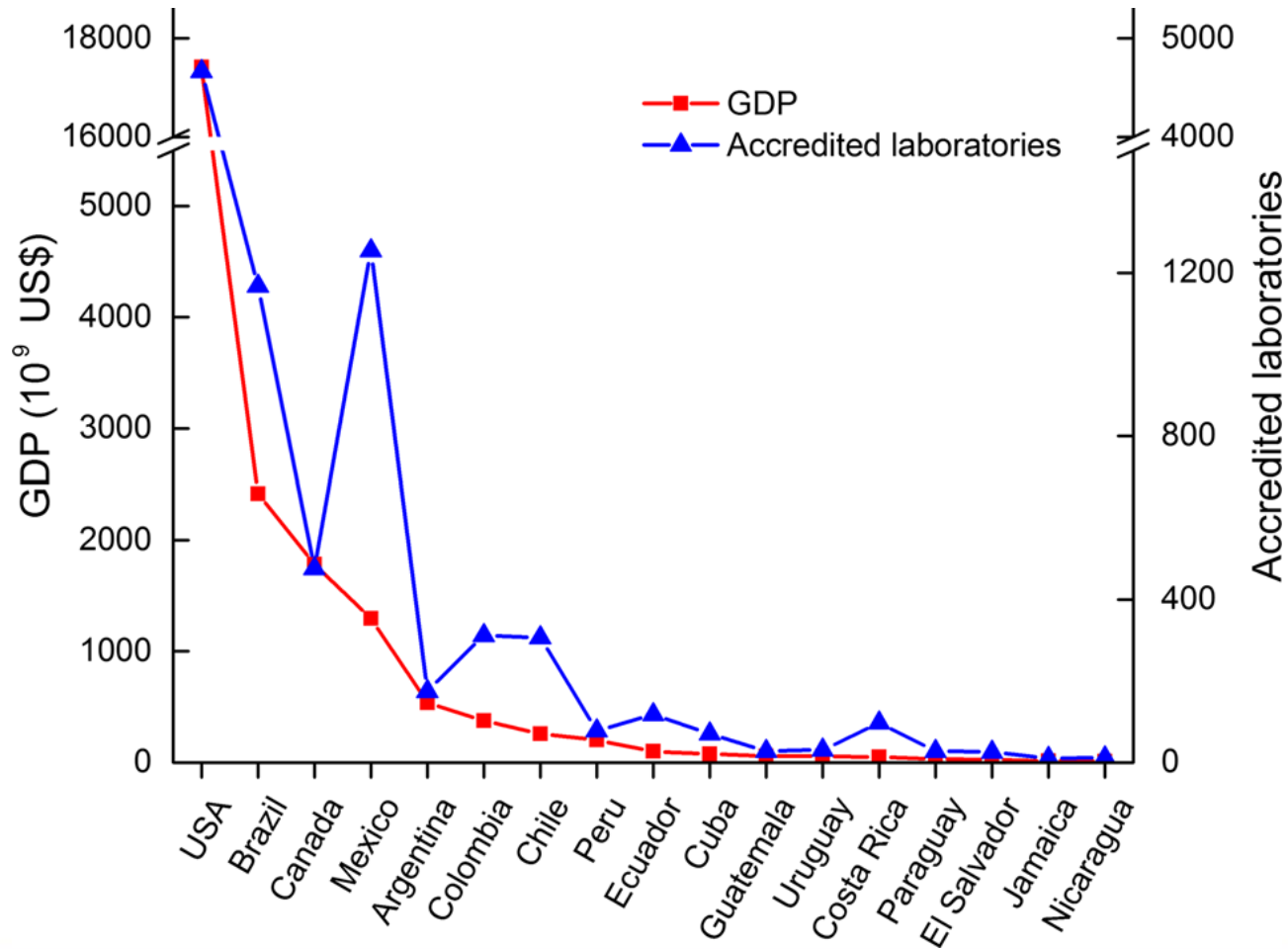
Over 50,000 accredited labs worldwide use ISO 17025



ISO 17025 improves lab quality outcomes and promotes food safety and human and animal health



## Number of Total Accredited Laboratories and Gross Domestic Product (GDP) per Country



# Metrology Traceability in KDA Laboratory

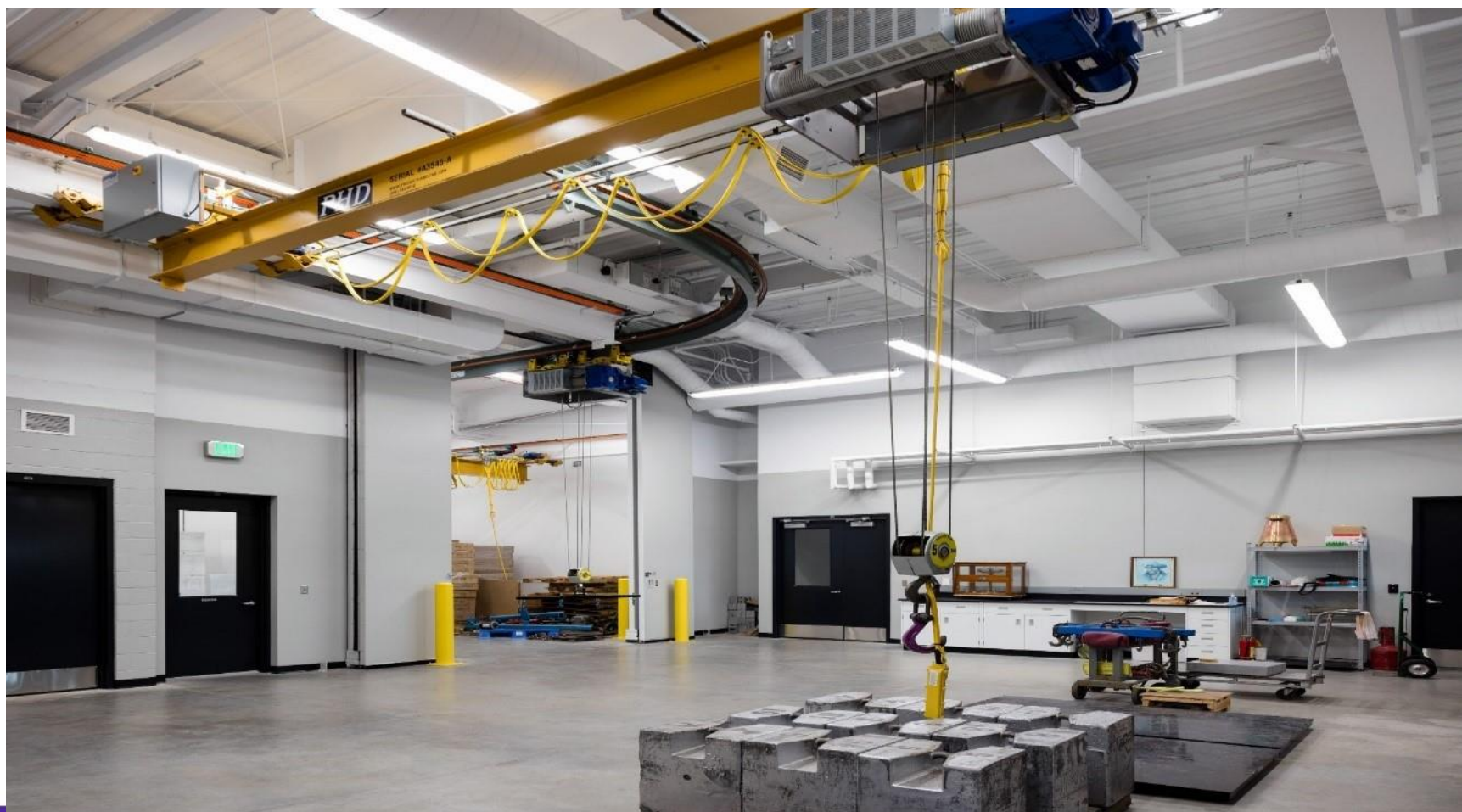


KDA Lab maintains metrology traceability through a documented chain of calibrations



Measurement results are traceable to the International System of Units (SI)

## *Kansas Department of Agriculture Metrology Lab*



# Calibration of Equipment



Metrology labs can calibrate equipment used in food testing, such as thermometers and pH meters



Proper calibration can ensure accurate and reliable measurement results

# Lessons Learned during APE



## Lessons learned that could be useful for other laboratories

- Importance of documentation
- Need for continuous improvement
- Training and qualification of personnel
- Importance of quality control
- Compliance with regulatory requirements
- Collaboration and communication

# Conclusion

- ISO 17025 plays a crucial role in promoting food safety by ensuring that food safety laboratories have the necessary quality management practices in place to provide accurate and reliable testing results.
- The accreditation process provides a framework for continuous improvement in laboratory testing.
- The KDA Laboratory's commitment to these practices is commendable and serves as an example for other laboratories seeking to improve their testing capabilities and achieve accreditation.



## MPH Foundation Competences

- Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence (16).
- Interpret results of data analysis for public health research, policy, or practice (4).
- Perform effectively on interprofessional lab teams (21).
- Select quantitative and qualitative data collection methods appropriate for a given public health context (2).



# Thank You

## ❖ Graduate Committee

- Dr. Justin Kastner
- Dr. Ellyn Mulcahy
- Dr. Abbey Nutsch

## ❖ APE/ILE Preceptor

- Dr. Sally Flowers

## ❖ MPH program

- Dr. Ellyn Mulcahy
- Barta Stevenson
- Rebecca Burks

## ❖ Family

- My husband, Ahmat, and daughters, Yageen and Yusra, and my sister, Eman

# References

- Ashish Singh, K., Nair, S. S., & Rai, R. (2023). Survival of Salmonella spp. and pathogenic Escherichia coli in food matrices and its relevance in the development of proficiency testing samples. *Journal of AOAC International*. <https://doi.org/10.1093/jaoacint/qsad011>
- Camino-Sánchez, F. J., Zafra-Gómez, A., Ruiz-García, J., Bermúdez-Peinado, R., Ballesteros, O., Navalón, A., & Vílchez, J. L. (2011). UNE-EN ISO/IEC 17025:2005 accredited method for the determination of 121 pesticide residues in fruits and vegetables by gas chromatography–tandem mass spectrometry. *Journal of Food Composition and Analysis*, 24(3), 427–440. <https://doi.org/10.1016/j.jfca.2010.11.009>
- de Camargo, P. W., do Nascimento, E. R., & de Aquino, M. H. (2017). Analysis of findings throughout the cycles of Accreditation of Veterinary Diagnostic Testing Laboratories for diseases transmitted by products of animal origin. *Accreditation and Quality Assurance*, 22(6), 361–367. <https://doi.org/10.1007/s00769-017-1284-6>
- Grochau, I. H., Caten, C. S., & de Camargo Forte, M. M. (2017). Current American landscape in laboratory accreditation according to ISO/IEC 17025. *Accreditation and Quality Assurance*, 22(2), 57–62. <https://doi.org/10.1007/s00769-017-1248-x>
- Grochau, I. H., Caten, C. S., & de Camargo Forte, M. M. (2018). Motivations, benefits and challenges on ISO/IEC 17025 accreditation of Higher Education Institution Laboratories. *Accreditation and Quality Assurance*, 23(3), 183–188. <https://doi.org/10.1007/s00769-018-1317-9>
- Hedman, J., Lavander, M., Salomonsson, E. N., Jinnerot, T., Boiso, L., Magnusson, B., & Rådström, P. (2018). Validation guidelines for PCR workflows in Bioterrorism Preparedness, Food Safety and Forensics. *Accreditation and Quality Assurance*, 23(3), 133–144. <https://doi.org/10.1007/s00769-018-1319-7>
- Joseph, L., Ramesh, P., Remya, N. S., Arumugham, V., & Rajesh, R. P. (2022). Significance of metrological tools in an ISO 17025 accredited quality system for a biological evaluation facility. *MAPAN*, 37(3), 683–691. <https://doi.org/10.1007/s12647-021-00517-2>
- Kansas Department of Agriculture Laboratory (2016). “Agricultural Laboratory,” <https://agriculture.ks.gov/divisions-programs/ag-lab>
- László, N., Lányi, K., & Laczay, P. (2018). LC-MS study of the heat degradation of veterinary antibiotics in raw milk after boiling. *Food Additives & Contaminants: Part A*, 35(9), 1698–1708. <https://doi.org/10.1080/19440049.2018.1469692>
- Miguel, A., Moreira, R., & Oliveira, A. (2021). ISO/IEC 17025: History and introduction of concepts. *Química Nova*, 44(5), 484–491. <https://doi.org/10.21577/0100-4042.20170726>
- Parkany, M. (2002). AOAC International, accreditation criteria for laboratories performing food microbiological and chemical analyses in foods, feeds, and pharmaceutical testing. *Accreditation and Quality Assurance*, 7(3), 127–127. <https://doi.org/10.1007/s00769-002-0445-3>

QUESTIONS?