Master of Public Health

Applied Practice Experience

An exploration of International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 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

by
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MASTER OF PUBLIC HEALTH

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Chapter 1 - Background, Portfolio Products, and Activities

I completed my Applied Practice Experience (APE) with the Kansas Department of Agriculture Laboratory (KDAL). This opportunity was pursued under the direction of the KDAL director, Dr. Sally Flowers. The lab relocated from Topeka to Manhattan in March 2020. The KDAL was established to help maintain and improve food safety, consumer protection, and support inspections that rely on scientific analysis to identify problems in food products. The KDAL has 50 agricultural testing methods on its international Organization for Standardization (ISO 17025) scope of accreditation. ISO is a worldwide federation of national-standards bodies. The work of preparing international standards is normally carried out through ISO technical committees. The KDAL performs different tests for dairy, meat, feed and fertilizer, and pesticides. The KDAL performs microbiological, chemical, and metrological testing. The microbiology lab has a dairy testing area with biosafety level 2 protocols. The chemistry lab has feed and fertilizer testing for animals, pesticide analysis, and hemp testing. The metrology laboratory provides accurate and reliable measurements to ensure KDAL legal weights and measures. All weights and balances must be calibrated, and traceable to recognized national or international calibration units. Accrediting bodies may require initial calibration by an ISO 17025 accredited calibration laboratory. The mission of the lab regarding environmental data is to ensure that all data generated and processed be appropriate for its intended use, be scientifically valid and of known precision and accuracy, be acceptably complete, and legally defensible. The mission of the KDAL is to develop and protect human and animal health.

During my Applied Practice Experience (APE) at the KDAL, I was involved in food safety related activities that included identifying the test results for dairy products, and analysis of data for public health improvement. I used instrumentation that has been calibrated to provide traceable results. I learned the principles of laboratory system management (ISO17025) related to public health issues. I attended weekly lab team meetings. I assisted with sampling and preparation of chemistry extraction in the animal feed laboratory. I stored the samples under specified environmental conditions. I updated some of the lab procedures for pesticides testing. I helped with preparation of microbiology media. Every batch of media should be examined to ensure it was suitable for use and should undergo Quality Control (QC) verification. I conducted multiple dairy tests to help improve laboratory productivity. I used Polymerase Chain Reaction (PCR) methods for automated pathogen detection. Overall, I had the pleasure of working 10 weeks (about 2 and a half months) with the KDAL staff.

My APE involved the emphasis of specific Master of Public Health (MPH) core competencies while I engaged in the creation of seven different outputs, or products. These are summarized below in Tables 1.1 and 1.2.

Table 1.1 Summary of Portfolio Products

Portfolio Product		Description
1	Personal journal notes from my work with a Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory.	I worked with a microbiology lab testing team for testing raw milk following FDA guidelines. We used samples collected from individual dairy producers. I performed a swab method for milk containers following FDA guidelines. The procedure described the method for enumerating aerobic bacteria and coliforms present in a single services container to ensure that bacteria counts do not exceed federal regulations. Federal regulation, such as those set by the U.S. Food and Drug Administration (FDA) or U.S. Department of Agriculture establish limits on the acceptable levels of coliform bacteria in food products.
2	Personal journal notes from my engagement with CPC analysis of dairy samples.	I helped conduct Coliform Plate Counts (CPCs) for dairy samples. I aliquoted a sample of milk onto an agar plate and incubated for 24 hours. I counted the colonies that were formed using automated colony counters to verify accuracy against manual count. I discarded all the plates and culture tubes used in the biohazardous waste and autoclaved to calibrate the temperature sensing system before being washed and re-used.
3	Personal notes recorded during online education regarding laboratory system management (ISO 17025) related to public health.	I completed 20 online modules at the KDAL, using its Qualtrax document management system about how ISO 17025 is an important standard for testing and calibration laboratories. ISO confirmed that a particular laboratory can

		produce accurate test results and calibration data.
5	Manual-directed notes taken during chemistry extraction in the animals feed laboratory.	I conducted a procedure to determine Tylosin in animal feed. I sampled and weighed 20g of animal feed into a 250 ml (about 8.45 oz) Erlenmeyer flask and extracted it with acidified methanol. Samples were sonicated for 20 minutes, and then transferred to a mechanical shaker for 1 hour. The sample was centrifuged and diluted, as necessary, before passing through a filter and injected on a LC (Liquid Chromatography) and MS/MS (Mass Spectrometry). A Chromatographic system was used to detect response for the analytical methods.
6	Interactive note-taking while reading report for the Kansas Department of Agriculture laboratory	The management review/quality system summary report is an overview of the activities covering all portions of the quality management system. The assessment of the quality system addresses all aspects of the ISO 17025general requirements. The actions of the review are reported on Kansas Department of Agriculture Laboratory (KDAL) document.
7	Personal notes during 8-hour-long annual laboratory ISO 17025 assessment	I attended the KDAL's annual ISO 17025 assessment with Dr. Flowers. An independent, third-party accreditation body performs annual assessments to verify whether the laboratory system is meeting all the requirements. The lab annual assessment helps the lab improve its ability to consistently produce valid, accurate results for the customers and the community.

Table 1.2 Portfolio Products and MPH Core Competencies Addressed

Portfolio Product		**Competency (or competencies) addressed**	
1	Personal journal notes from my work with a Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory.	4	Interpret results from data analysis for public health practice.
2	Personal journal notes from my engagement with CPC analysis of dairy samples.	4	Interpret results from data analysis for public health practice.
3	Personal notes recorded during online education regarding laboratory system management (ISO 17025) related to public health.	12	Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence
4	Manual-directed notes taken during chemistry extraction in the animals feed laboratory.	21	Perform effectively on interprofessional lab teams.
5	Interactive note-taking while reading report for the Kansas Department of Agriculture laboratory	2	Select quantitative and qualitative data collection methods appropriate for a given public health context.
6	Personal notes during 8-hour-long annual laboratory ISO 17025 assessment	16 21	Apply principles of leadership, governance, and management, which include creating a vision, empowering others, fostering collaboration, and guiding decision making. Perform effectively on interprofessional lab teams.
7	Personal journal notes from my work with a Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory.	2	Select quantitative and qualitative data collection methods appropriate for a given public health context.

In addition to creating the above products, I engaged in other meaningful activities during my APE with KDAL. These activities included helping with the testing for antibiotics in raw milk, helping update 150 pages of laboratory procedures for pesticide testing, and conducting microbiological analysis (for *E. coli* and *Salmonella*) in ground beef.

Chapter 2 - MPH core competencies and Food Safety and Biosecurity emphasis area competencies

My APE involved the pursuit of specific MPH core competencies; these are indicated below in Table. 2.1. The competencies are given, along with a description and designation of the product created.

Table 2.1 Summary of MPH Foundational Competencies

Number and Competency		Description and example of product created
16	Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence.	I worked closely with my preceptor Dr. Sally Flowers and discussed with her the policies and procedures appropriate and important for laboratory testing. I discussed how a standard ISO policy was a type of policy that was drafted by International Organization for Standardization (ISO 17025) to ensure the quality and safety of food product system. The laboratory had a policy for how and when manual processing and integrating of chromatographic data was appropriate. The laboratory was responsible through legally enforceable commitments for the management of all information obtained during the performance of laboratory activities. This competency was emphasized during portfolio product 6 (personal notes during 8-

		hour-long annual laboratory ISO 17025 assessment)
4	Interpret results of data analysis for public health research, policy or practice.	This competency was achieved during my creation of portfolio product 1 (personal journal notes from my work with a Food and Drug Administration certification for a dairy analysis in a central laboratory) and portfolio product 2 (personal journal notes from my engagement with CPC analysis of dairy samples)
12	Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence	This competency was achieved by completing the online education regarding laboratory system management (ISO 17025) related to public health (portfolio product 3)
21	Perform effectively on interprofessional lab teams.	I worked with lab teams under Dr. Sally Flowers's supervision. I attended all lab meetings regularly during my APE. Portfolio products 6 and 4 illustrate this.
2	Select quantitative and qualitative data collection methods appropriate for a given public health context.	This competency was achieved by collecting data (specifically during portfolio products 5 and 7).

In addition to the MPH core competencies indicated above, several "emphasis area" competencies were achieved during my APE. As a Food Safety and Biosecurity (FSB) emphasis area student, I pursued the competencies indicated in Table 2.2. below. After the table, I explain how my APE emphasized each of these.

Table 2.2 Summary of MPH Emphasis Area Competencies (Food Safety and Biosecurity emphasis area)

MPH Emphasis Area:	
Number and Competency	**Description**

1	Food safety and biosecurity	Evaluate solutions appropriate for different food safety, biosecurity, and defense issues in the food production continuum.
2	Threats to the food system	Examine specific threats to the food system and scientifically investigate how each can be prevented, controlled, and / or mitigated in the food production system.
3	Food safety laws and regulations	Differentiate key U.S food safety regulatory bodies and their unique legislative authorities, missions, and jurisdictions.
4	Food safety policy and the global food system	Analyze and distinguish how food safety and governmental biosecurity policies, globalization, and international trade cooperation influence public health.
5	Multidisciplinary leadership	Contrast the food safety and biosecurity technical needs of different stakeholders and make judgments as to the appropriate as to the appropriate methods of collaboration

I achieved Food Safety and Biosecurity (FSB) competency #1 during my internship with the KDAL. I was tasked with swab methods for pasteurized milk containers; this procedure is applicable to non-intact products to verify the containers are produced under sanitary conditions so as not to contaminate the pasteurized dairy products. For FSB competency #2, I tested raw milk three times for antibiotics. Antibiotics are used on many farms to treat mastitis infection. Cows under antibiotic treatment for mastitis infection may have antibiotic residues in their milk. I also examined the somatic cell count (SCC), standard plate count (SPC) tests to determine milk quality and measure the white blood cells present in milk. The quality of raw milk was the primary factor determining the quality of milk products. For FSB competency #3, I learned about the procedures for obtaining Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory. The certification of dairy (milk) laboratory analysis by the FDA was followed by the evaluation of the state central milk laboratory. The process to become a certified milk laboratory

analyst usually takes one year or more. The Food and Drug Administration requires testing for dairy (milk) by an FDA-certified analyzer to demonstrate satisfactory compliance of the milk laboratory, and to improve the safety of the U.S. dairy supply. For FSB competency #4, I attended the lab's annual International Organization for Standardization (ISO 17025) assessment. This involved an independent, third-party accreditation body performing an annual assessment to verify whether the KDAL is meeting all the requirements. It happens every year. During this process, I learned about how the principles of laboratory system management by the International Organization for Standardization (ISO 17025) are relevant to public health. Finally, for FSB competency #5, I learned how Dr. Sally Flowers goes about her management reviews. This effort involves addressing all portions of the Quality Management system such as changes in internal/external issues, volume of work, and customers' feedback and complaints relevant to the laboratory.

Appendix

Portfolio product 5: Manual-directed notes taken during chemistry extraction in the animal feed description of the procedure used to determine Tylosin in animal feed laboratory:

- Sample and weight 20 g of animal feed into 250ml (about 8.45oz) Erlenmeyer methanol.
- Extracted the sample with acidified methanol by adding 100 ml of acidified methanol (prepared by adding 1% formic acid to methanol.
- Sonicated the sample for 20 minutes.
- Transferred the sample to a mechanical shaker and shaken for I hour.
- Centrifuged the sample and diluted it, as necessary, with a 50:50 mixture of methanol and water.
- Passed the dilution sample through a filter.
- Injected the sample on an LC (Liquid Chromatography) and MS/MS (mass Spectrometer) system.
- Used a Chromatographic system to detect response for the analytical methods.

Portfolio Product 2: Personal journal notes from engagement with CPC analysis of dairy samples:

Coliform Plate Counts (CPCs) are a microbiological analysis method used to determine the level of coliform bacteria in dairy samples. Coliform bacteria are a group of bacteria commonly found in the environment, including soil, water, and animal feces. In the context of dairy samples, coliform bacteria are an indicator of the hygiene and sanitary conditions during the milk production, handling and storage.

The procedure for CPCs involves taking a sample of the dairy product, diluting it in a sterile solution, and then spreading the diluted sample onto a special agar plate that promotes the growth of coliform bacteria. After incubation, the number of colonies of coliform bacteria that have grown on the plate are counted and expressed as colony-forming units (CFUs) per milliliter (or gram, depending on the sample type).

- Collect the sample: Collect a representative sample of the milk to be tested using a sterile sample container. It is recommended to use aseptic techniques to avoid contamination.
- Dilute the sample: Depending on the expected concentration of coliform bacteria in the sample, prepare a series of dilutions of the milk. The dilutions can be made by adding a specific amount of milk to a specific amount of sterile water or buffer solution. A dilution of 1:10 is a good starting point.
- Prepare the culture medium: Prepare the culture medium according to the manufacturer's instructions. The most commonly used medium for milk samples is the Violet Red Bile Agar (VRBA) or the MacConkey Agar (MCA).
- Plate the dilutions: Using a sterile pipette or a loop, transfer a small amount (usually 0.1 ml) of each dilution onto the surface of a sterile agar plate containing the culture medium. Spread the sample evenly over the surface of the plate using a sterile spreader.
- Incubate the plates: Incubate the plates upside down at 35-37°C for 24-48 hours.
- Count the colonies: After the incubation period, count the number of red or pink colonies that have grown on each plate.
- The colonies should be counted on the plate with a dilution that has between 30 and 300 colonies, as this range provides the most accurate estimate of the bacterial concentration.
- Calculate the coliform count: Multiply the number of colonies counted on the plate by the dilution factor to obtain the number of coliform bacteria per ml of sample. For example, if you counted 100 colonies on a plate that was prepared using a 1:100 dilution, the coliform count would be 10,000 CFU/ml.
- Interpret the results: Compare the coliform count to the regulatory limits or guidelines to determine if the sample meets the criteria for safe consumption. In most countries, the limit for total coliform bacteria in milk is 10 CFU/ml.

Portfolio Product 1: Personal journal notes from work with a Food and Drug Administration (FDA) certification for a dairy analysis in a central laboratory:

Food and Drug Administration (FDA) certification is a regulatory requirement for central laboratories that conduct dairy product analysis. The FDA sets guidelines and standards for the testing of dairy products to ensure their safety and quality. Laboratories that test dairy products for compliance with FDA regulations must be certified by the FDA.

To obtain FDA certification, a central laboratory must demonstrate that it meets certain requirements, such as having qualified personnel, following standardized testing procedures, maintaining appropriate documentation and record-keeping, and using validated testing methods and equipment.

Once a laboratory is certified by the FDA, it is authorized to conduct testing on dairy products and issue reports that can be used for regulatory compliance and quality control purposes. FDA certification provides assurance to the public and the dairy industry that the laboratory's testing methods and results are reliable and accurate, and that the dairy products tested meet regulatory standards for safety and quality.