E-1 Accreditation & Certification

Definition: The process by which an authoritative body gives formal recognition that an organization is competent to carry out specific task (accreditation); a process by which a third party gives written assurance that a service or person conforms to specified requirements (certification).

Level 2 Course TLO: Perform job duties consistent with the quality management system.

Level 3 Course ELOs:

- Communication
  - Describe the quality management system.
- Leadership
  - Explain how laboratory activities support the quality management system.
- Programmatic
  - Follow the requirements of the quality management system.
- Technical
  - Apply knowledge of accreditation requirements when performing analytical work.

Foundations	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to the accreditation and certification processes. **Level 4 Module TLO:** Discuss the purpose of quality oversight programs. **Level 5 Module ELOs:** • Describe accreditation. • Explain ISO/IEC 17025. • Explain the importance of a standard. • Describe scope of accreditation. • Explain the relationship between accreditation and a quality management system. • Describe certification. • Give examples of certification programs applicable to food testing.	The laboratory analyst understands the importance of staying relevant. • Independent authoritative assessment of the quality system of the lab • Gives the lab the designation of quality which is considered a gold standard • Gives the lab a designation of quality which has international recognition The laboratory analyst has knowledge of accreditation attributes. • Build a standardized quality system • Harmonization/comparable methods • Gives the laboratory a road map for designing and maintaining quality systems The laboratory analyst has knowledge of certification attributes.	The laboratory analyst understands the difference between accreditation and certification. • Accreditation is about developing a process to do your business • Certification is about how you do your business

	• Identical processes across agencies • Standardization methods The laboratory analyst has knowledge of outcome attributes. • Legal defensibility of results • Increased confidence in results • Facilitate sharing of results across agencies	

Accreditation/Certification Process	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The steps required to attain and maintain accreditation/certification. **Level 4 Module TLO:** Discuss the accreditation/certification process. **Level 5 Module ELOs:** • Describe how a lab acquires accreditation/certification. • Describe how a lab maintains accreditation/certification. • Identify the laboratory's accreditation/certification body. • Summarize what to expect during an on-site assessment.	The laboratory analyst understands the basic steps to accreditation/certification. • Understand the requirements of the accreditation or certification standards • Understand the cost of the initial and ongoing process • Designated quality manager • Develop a quality manual • Choosing the tests and/or technologies for which you want to be accredited or certified • Develop SOPs • Develop policies • Develop forms and amass records • Learn and train to the standard • Perform gap analysis • Develop a PT schedule • Perform relevant proficiency tests • Perform management review • Compile training records • Perform verification or calibration of equipment Ensure traceability and fitness of consumables	The laboratory analyst understands that accreditation/certification is not static. The laboratory analyst understands that they may take an active role in the accreditation/certification process. The laboratory analyst may have previous experience with the process.

	• Audit for consistency in performance • Choose accreditation or certification body • Undergo a pre-assessment • Undergo an onsite assessment by the accreditation or certification body • Correct any deficiencies cited during the onsite assessment • Respond to findings from onsite assessments • Continuous improvement	

E-2 Basic Communication Skills

Definition: Ability to effectively and appropriately interact with others in order to achieve desired goals.

Level 2 Course TLO: Exchange information.

Level 3 Course ELO:

- Communication
  - **Level 3 competency for communication domain of basic communication skills is not required.**
- Leadership
  - Collaborate with others.
- Programmatic
  - Describe laboratory communication policies.
- Technical
  - Implement laboratory policies and processes.

Basic communication elements	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Skills and concepts used to convey information. **Level 4 Module TLO:** Apply communication principles. **Level 5 Module ELOs:** • Select mode of communication. • Adapt communication to audience. • Perform active listening. • Recognize the effect of non-verbal communication. • Differentiate fact from opinion.	The laboratory analyst can recognize the various modes of communication. • Written • Oral • Electronic • Non-verbal o Tone o Emotion o Body language The laboratory analyst can use various modes of communication effectively. • Written • Oral • Electronic • Non-verbal o Tone o Emotion o Body language The laboratory analyst can actively listen to others so individuals feel they have been heard and understood • Ask questions	The laboratory analyst can determine the appropriate communication for the situation. • Electronic vs in-person • Timeliness • Correct recipient • Content The laboratory analyst can adapt communication to audience.

	o Check for understanding • Pay attention • Respond appropriately	

Professionalism	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Communication conduct expected from the laboratory professional. **Level 4 Module TLO:** Convey professionalism. **Level 5 Module ELOs:** • Recognize when to communicate opinion. • Incorporate constructive feedback. • Express constructive feedback. • Express honesty. • Show respect for others. • Demonstrate objectivity. • Demonstrate integrity.	The laboratory analyst can define professionalism. • Show respect for others • Honesty • Integrity • Objectivity The laboratory analyst can act in a professional manner. • Accountability • Reliability • Demeanor • Adhere to dress code The laboratory analyst can define constructive feedback. The laboratory analyst can recognize when to communicate opinion. • Differentiate fact from opinion	The laboratory analyst can incorporate constructive feedback. The laboratory analyst can seek out a mentor.

Laboratory Communication Protocols	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Communication rules that explain the correct conduct and procedures to be followed by laboratory professionals. **Level 4 Module TLO:** Apply laboratory-specific communication policies. **Level 5 Module ELOs:** • Comply with policies regarding internal laboratory communication. • Comply with policies regarding communication with external sources.	The laboratory analyst can explain harassment. The laboratory analyst can explain bullying. The laboratory analyst can demonstrate proper application of internal lab policies. • Cell phone/phone usage • Email etiquette • Computer usage • Chain of command The laboratory analyst can explain the social media policy. • Discretion	The laboratory analyst can identify the person(s) responsible for communicating with the media.

• Comply with laboratory code of conduct.	• Use during work • Personal time • Use of lab's social media page The laboratory analyst can explain the policies for communicating with the media. • Official spokesperson • Official comments • Confrontation • Messaging The laboratory analyst can demonstrate proper application of policies related to external communication. • Public record policy requirements	

E-3 Basic Laboratory Math

Definition: Math for analytical work.

Level 2 Course TLO: Apply mathematics to sample analysis.

Level 3 Course ELOs:

- Communication
  - Explain mathematics used in the laboratory.
- Leadership
  - Review data for essential elements.
- Programmatic
  - Use appropriate measurements and calculations.
- Technical
  - Apply mathematics to analytical work.

Math vocabulary used in the laboratory	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Common mathematical terminology used in the laboratory. **Level 4 Module TLO:** Describe laboratory math vocabulary. **Level 5 Module ELOs:** • Define mathematical terminology. • Recognize how symbols are used in a mathematical operation. • Apply exponents • Define acronyms	The laboratory analyst has knowledge of vocabulary related to portions. • Aliquot • Sample versus sub-sample • Dilution • Proportional • Ratio • Concentration • Percent The laboratory analyst has knowledge of vocabulary related to data sets. • Mean • Median • Mode • Range The laboratory analyst has knowledge of exponents. • Exponential numbers • Logarithm • Scientific notation	The laboratory analyst can use resources. The laboratory analyst has knowledge of absolute value. The laboratory analyst has knowledge of the origin of constants. • Pi • Avogadro's number

	The laboratory analyst has knowledge of symbols. • <, >, Greek letters, etc. The laboratory analyst has knowledge of acronyms. • Ppm, ppb, mg, L, cfu, ug The laboratory analyst has knowledge of vocabulary related to significant figures. • Rounding rules • Decimal offset The laboratory analyst has knowledge of vocabulary related to units of measure. • Mass • Volume • Temperature Kelvin, C, F The laboratory analyst has knowledge of vocabulary related to molecular weight. • Normality • Molarity • Equivalent • Avogadro's number	

Basic mathematical concepts used for science	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Laboratory calculations using basic mathematical concepts. **Level 4 Module TLO:** Perform laboratory calculations using basic mathematical concepts. **Level 5 Module ELOs:** • Apply mathematical conventions • Calculate test results • Evaluate test results • Perform unit of measure conversions • Perform basic graphing • Apply mathematical tools	The laboratory analyst can use basic arithmetic. The laboratory analyst can apply mathematical conventions • Significant figures • Rounding • Serial dilutions • Ratios • Exponential numbers • Aliquot (sub sample) • Logarithm The laboratory analyst can perform a result assessment.	The laboratory analyst can take independent action. • No guidance • Self-corrects • Ask questions • Critical thinking The laboratory analyst can build formulas in excel. The laboratory analyst can apply math concepts. • Order of operations • Understands the concept behind the equation

	• Explain average, mean, and median • Precision between two different results • Percent recovery calculations • Calculating spike recovery • Derive final results from testing data and test inputs The laboratory analyst has knowledge of units of measure and can perform unit conversions. • Conversion between different units of measurement • ppm versus ppb • Molecular weight conversions • Mass volume versus mass mass The laboratory analyst has knowledge of graphing. • Extrapolation • Interpolation The laboratory analyst can use mathematical tools. • How to use a scientific calculator • Basic spreadsheet The laboratory analyst can given a spiked amount determine a percent recovery given the final analyte concentration. The laboratory analyst can perform a calculation which gives the matrix concentration in the test portion done after an extraction, concentration step, and dilution. • Gram to g/ml	• Unit of measure cancellation • Derive a mathematical formula The laboratory analyst can use a found extraction concentration to determine a percent recovery when given a spiked amount • Performs unit conversions to create a reportable unit of measure. The laboratory analyst can when given a final analyte concentration from an instrument use the extraction concentration to determine the analyte concentration in a given matrix.

Mathematical applications for laboratory analysis	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Commonly used mathematical applications for laboratory analyses.	The laboratory analyst can perform serial dilutions. • Aerobic plate count	The laboratory analyst can take Independent action. • No guidance

Level 4 Module TLO: Demonstrate mathematical applications for laboratory analyses. **Level 5 Module ELOs:** • Describe differences between various units of measure. • Illustrate the use of significant figures. • Perform unit conversion. • Construct a formula. • Diagram serial dilution scheme. Application in Bloom's	• Most probable number • Volume and mass dilutions The laboratory analyst can report test results with correct number of significant figures. • Rounding The laboratory analyst can convert units of measure. The laboratory analyst can use pre-established math formulas. • Use excel to perform calculations The laboratory analyst can scale up and scale down. The laboratory analyst can perform graphing. • Interpolate a concentration from a curve • Create a linear curve from test data	• Self-corrects • Ask questions • Critical thinking The laboratory analyst can explain what they are doing. The laboratory analyst can build a mathematical formula for a modified test method. The laboratory analyst can use molecular weights to calculate equivalent concentrations.

E-4 Basic Laboratory Statistics

Definition: Statistics for analytical work.

Level 2 Course TLO: Utilize statistics in analytical work.

Level 3 Course ELOS:

- Communication
  - Describe basic statistics.
- Leadership
  - Discuss the application of basic statistics to analytical work.
- Programmatic
  - Use approved statistical tools.
- Technical
  - Apply appropriate statistical methods to obtain unbiased data.

Basic statistical concepts	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Characterize data using fundamental statistics. **Level 4 Module TLO:** Discuss basic statistical concepts used to characterize data. **Level 5 Module ELOs:** • Describe the various distributions of data sets. • Describe statistical parameters used to explain population distributions. • Describe statistical parameters used to define variation in data sets.	The laboratory analyst has knowledge of data sets. • Normal distribution • Standard deviation • Mean • Median • Mode • Probability • Range • skewness The laboratory analyst has knowledge of relatedness. • Precision • Accuracy • Randomness • Relative percent difference • Replicates • Correlation • Trend	The laboratory analyst has knowledge of estimation of variance. • Degrees of freedom • T-test • T-score • Data outliers • Z-test • Z-score • Confidence Interval • Confidence level • Analysis of variation The laboratory analyst has knowledge of higher order distribution. • Chi square • Polynomial The laboratory analyst has knowledge of regression analysis. • Independent variable • Dependent variable

	The laboratory analyst has knowledge of method performance. • Specificity • Selectivity • Sensitivity • Limit of detection • Limit of quantitation • Reporting limit The laboratory analyst has an awareness of measurement uncertainty.	• Correlation coefficient

Statistical applications	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Assessing the validity of results with statistics. **Level 4 Module TLO:** Use statistics to assess the validity of results. **Level 5 Module ELOs:** • Recognize data handling tools • Calculate statistical parameters • Evaluate laboratory data	The laboratory analyst has an awareness of statistical tools. • Spreadsheets • Control charts • Software packages The laboratory analyst can apply pre-programmed formulas. • Regression analysis • Standard deviation The laboratory analyst can make determinations from data. • Standard deviation • Relative standard deviation • Mean • Most probable number • T statistic • Z score • F statistic • Relative percent difference The laboratory analyst can evaluate data. • Assess a calibration curve • Perform Z-test • Assess control chart • Use a T table to assess the significance of a result • Perform a regression analysis on a data set	The laboratory analyst can use statistical software to perform statistical analysis of large data sets. • SAS • SPSS The laboratory analyst can use software tools to build queries. • Access • Other database software • SQL The laboratory analyst can mentor others. The laboratory analyst can create a control chart. The laboratory analyst can perform significance testing, comparing statistical parameters of data sets.

E-5 Basic Laboratory Techniques

Definition: Basic tools, materials, and applications used for analytical work.

Level 2 Course TLO: Discuss basic laboratory techniques for analytical work.

Level 3 Course ELOs:

- Communication
  - Explain basic techniques used in analytical work.
- Leadership
  - Determine the readiness of analytical tools/materials.
- Programmatic
  - Use approved laboratory techniques.
- Technical
  - Apply basic techniques to analytical work.

Quality Assurance	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Basic elements of quality assurance related to testing performance. **Level 4 Module TLO:** Discuss the basic elements of quality assurance related to testing performance. **Level 5 Module ELOs:** • Describe the function of method controls. • Recognize when traceability will be applied. • Recognize the importance of SOPs.	The laboratory analyst understands the purpose of controls. • Standard reference materials • Reference standards o NIST traceable • Reference cultures • Environmental controls The laboratory analyst has an awareness of traceability. • Certificate of o Assurance o Sterility o Compliance • Documentation/records/forms The laboratory analyst has an awareness of verification.	The laboratory analyst can explain the role of audits. The laboratory analyst understands root cause and the corrective actions process. The laboratory analyst understands the hierarchal difference between quality management system and quality assurance and quality control.

• Recognize the need for root cause analysis for non-conforming work.
• Report deviations from specifications for lab supplies.
• Differentiate the functions for various types of labware.
	• Data
	  o ICV (initial control verification)
	  o CCV (continuing control verification)
	• Peer reviews
	• Method
	• Control limit and warning limit
	• Spikes and blanks
	• Replicates
	• Percent recovery
	• Precision and accuracy
	
	The laboratory analyst has an awareness of procedures.
	• SOPs (standard operating procedures)
	• Official methods
	
	The laboratory analyst has an awareness of lab performance.
	• External and internal audits
	• Proficiency testing
	• Demonstration of competency
	• Test validations
	• Training
	
	The laboratory analyst has an awareness of equipment requirements.
	• Daily qualification
	• Calibration
	• Preventive maintenance
	• Volumetric labware classification (class A, class B)	

Pre-analytical	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Practices to prepare for testing. **Level 4 Module TLO:** Describe practices to prepare for testing. **Level 5 Module ELOs:**	The laboratory analyst has an understanding procedure specific safety requirements. The laboratory analyst reviews procedures. • Read and understand SOPs before each use	The laboratory analyst can be proactive. • Coordinate with co-workers • Batching • Multi-tasking • Initiate improvements to procedures

• Explain the purpose of preventing cross contamination. • Describe the movement of a sample through its lifetime.	• Locate most current version of SOPs • Read and understand method The laboratory analyst recognizes the importance of setting up a work area. • Be aware of possible cross-contamination sources • Clean up lab spaces • Locate labware • Ensure equipment is available for use • Make sure equipment is operational • Maintain sample integrity The laboratory analyst utilizes time management. • Consolidate your media requests • Assess procedure specific time requirements • Acquire needed forms • Make sure sample is available The laboratory analyst assures that authorization to perform work is documented. The laboratory analyst can manage reagents. • Assure all reagents are available • Prepare reagents • Ensure kits are not expired • Assure reagents are of correct purity	• Report problems with reagents • Review corrective actions related to procedure

Laboratory Techniques	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Basic skills required in the laboratory setting. **Level 4 Module TLO:** Apply the basic skills required in the laboratory setting.	The laboratory analyst can perform quantitative transfers. • Pipetting • Syringe use • Volumetric labware	The laboratory analyst has appropriate personal skills. • Able to mentor others • Self-corrects

Level 5 Module ELOs:
• Perform basic equipment calibration.
• Apply basic computer skills.
• Explain reagent specification requirements.
• Differentiate the properties of various filters.
• Describe the types of general laboratory equipment.
• Describe the types of sample preparation equipment.
	• Dilutions
	  o Volume dilution versus mass dilution
	  o Serial versus parallel dilutions
	• Reading graduated measurements
	  o reading a meniscus
	  o estimating between graduated measurements
	• Dispense aliquot
	• Analytical transfer
	
	The laboratory analyst can use support equipment.
	• Using a balance
	• Using a pH meter
	• Centrifuge use
	• Using a microscope/dissecting scope
	• Using a vortex mixer
	• Use of blending equipment
	• Data logger use
	• Thermocouple
	• Using incubators
	• Filter selection
	• Heat block
	• Water baths
	• Refrigerators and freezers
	• Ovens
	• Desiccators
	• Shakers
	• Thermometers
	
	The laboratory analyst can demonstrate basic computer skills.
	• Word processing
	• Spreadsheets
	• Database
	• Email
	• calendar
	
	The laboratory analyst can prepare various items needed to perform an analysis.
	• Reagents
	• Standards
		• Efficient time management skills
		• Organizational skills
		• Efficiently using resources
		
		The laboratory analyst can use laboratory instrumentation.
		• Use complex instrumentation
		• Calibrate or standardize equipment
		• Troubleshoot
		• Choose fit for purpose equipment

	• Composites • Sub-samples The laboratory analyst can perform housekeeping. • Cleanliness • Sterilization • Washing glassware The laboratory analyst can maintain paperwork. • Labeling and documentation • Filling out worksheets • Record keeping • Calculations	

E-6 Chain of Custody

Definition: Procedures for formal chronological documentation that records the sequence of collection, custody, control, transfer, receipt, analysis, and disposition of samples.

Level 2 Course TLO: Apply knowledge to control samples in a manner that maintains sample integrity and sample security.

Level 3 Course ELOs:

- Communication
  - Describe the reasons for maintaining sample integrity and sample security.
- Leadership
  - Demonstrate actions to maintain chain of custody.
- Programmatic
  - Describe laboratory policies and procedures for sample chain of custody.
- Technical
  - Apply protocols to maintain sample integrity, traceability, and security.

The Purpose of Chain of Custody	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The role of chain of custody in maintaining evidentiary integrity. **Level 4 Module TLO:** Discuss the role of chain of custody in maintaining evidentiary integrity. **Level 5 Module ELOs:** • Explain the importance of chain of custody in legal proceedings. • Explain the importance of chain of custody in supporting regulatory enforcement actions..	The laboratory analyst understands the importance of chain of custody within a regulatory environment. • Contributes to legal defensibility • Mitigates a legal vulnerability • Samples are evidence • Not known ahead of time which samples will be violative The laboratory analyst understands the importance of chain of custody related to traceability.	The laboratory analyst demonstrates situational-awareness. • Understands the necessity of reporting issues • Knows that chain of custody records are evidence • Knows that all chain of custody records shall be consistent • Knows that they may be asked to testify to their role in chain of custody

	• Assures that samples and associated test results are linked to the product/lot of inspection • Able to trace sample from origin to disposition • Provides a chronological history • Identifies who has handled the samples The laboratory analyst understands the importance of chain of custody related to integrity. • Documents sample is not compromised • Document sample is viable for testing The laboratory analyst understands the importance of chain of custody related to security. • Documents the process is not compromised • Established sample security • Documents that samples were held in an appropriate storage area • Documents that no tampering occurred	

Traceability	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The ability to verify the history, location, or possession of a laboratory sample by means of documentation or record. **Level 4 Module TLO:** Discuss the role of chain of custody in retracing the custody of the sample. **Level 5 Module ELOs:** • Describe how traceability is essential to support regulatory action.	The laboratory analyst understands the linkages in a chain of custody system. • Assures that samples and associated test results are linked to the product/lot of inspection • Documents sample locations which link to sample security • Document storage locations which link to sample conditions which links to sample integrity	The laboratory analyst demonstrates personal situational-awareness. • They understand the consequences of a break down in chain of custody • They see the process as a whole The laboratory analyst understands implied connections. • It links the unique inspector sample ID to an unique lab ID

• Describe how documentation is used as evidence in chain of custody. • Describe steps for sample disposal.	• Evidence defensibility The laboratory analyst understands the relationship between time, people, and location. • Documents all who handle samples • Documents the chronology of sample movement from receipt to disposition • Documents the timing of sample transfers • Unique sample identification The laboratory analyst can generally describe the sample disposal process.	• It provides a segue from inspection to lab analysis • Timing of transfers links the sample to the respective test results The laboratory analyst can describe in detail the sample disposal process. The laboratory analyst has knowledge of the sample disposal process. • Samples are disposed of according to procedure o Verify identity of sample being disposed • Samples disposed by testing area o Is the remaining sample perishable o Was the sample consumed during analysis • Samples disposed by intake area • Is the sample to be disposed or returned to the manufacturer or consumer • Final disposition is recorded as chain of custody information The laboratory analyst has knowledge of safety considerations. • Submit to appropriate area (hazardous waste, autoclave, etc.) o Direct waste to an appropriate area (hazardous waste, autoclave, etc.) • Samples which are hazardous are disposed according to chemical hygiene requirements • Disposal of controlled substances

Sample Integrity	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The methods used to ensure physical and analyte integrity. **Level 4 Module TLO:** Describe how integrity is maintained. **Level 5 Module ELOs:** • Discuss appropriate storage attributes to maintain sample integrity. • Discuss ways to assess sample integrity.	The laboratory analyst has knowledge of fit for purpose storage. • Environmental monitoring • Storage locations have appropriate climate control • Intermediate storage locations are appropriate The laboratory analyst can prevent cross-contamination. • Appropriate use of sample container • Storing samples and standards separately The laboratory analyst has knowledge of sample acceptance. • Adhere to required timeframes • Sample rejection criteria is in place for sample receipt • Official seal is intact on receipt • Appropriate sample preservation • Labeling issues	The laboratory analyst understands that storage location identifiers are linked to climate control records. The laboratory analyst understands that sample anomalies need to be reported and recorded. The laboratory analyst has an intimate knowledge of the process of maintaining sample integrity.

Sample Security	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The practices used to limit access to samples. **Level 4 Module TLO:** Describe how access to samples is limited. **Level 5 Module ELOs:** • Discuss maintaining sample security. • Give examples of measures to limit access to samples.	The laboratory analyst understands how restricted access helps maintain security. • Limiting visitor access within the facility • Limiting employee access to samples • Lockable storage • Secured storage • Authorization for access to samples	The laboratory analyst understands and adheres to security policies and procedures. • Don't allow unknown visitors • Report unusual activity • No unauthorized tours

	The laboratory analyst understands how seals help maintain security. • Sample container • In process samples • Shipping containers	

E-7 Ethics

Definition: Practices governing the conduct of an individual.

Level 2 Course TLO: Apply ethical principles.

Level 3 Course ELOs:

- Communication
  - Describe ethics.
- Leadership
  - Discuss ethical principles in the workplace.
- Programmatic
  - Discuss policies and procedures related to ethical behavior.
- Technical
  - Apply scientific integrity in the production of test results.

Organizational Code of Conduct	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The policies used to describe expected behaviors in organizational members. **Level 4 Module TLO:** Describe the role of code of conduct for people working in a regulatory laboratory. **Level 5 Module ELOs:**	The laboratory analyst understands that a Code of Conduct provides expectations for behavior. • Requires adherence to laboratory policies and procedures • Requires the disclosure of conflict of interest • Requires confidentiality	The laboratory analyst understands a personal responsibility to hold oneself and others accountable to a Code of Conduct. The laboratory analyst understands the implications of one's behavior and consequences of one's actions.

• Discuss the purpose of a code of conduct. • Discuss elements of a code of conduct. • Explain the importance of maintaining confidentiality of testing.	• Prevents unauthorized information posting to social media The laboratory analyst understands how a Code of Conduct leads to public trust. • Leads to impartial results • Prevents falsification of test results	

Personal Behavior	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The personal values that influence behavior in the workplace. **Level 4 Module TLO:** Discuss the impact of personal behavior. **Level 5 Module ELOs:** • Describe credibility as it relates to sample results. • Give examples of positive ethical attributes.	The laboratory analyst understands how behaviors affect the organization. • Being trustworthy leads to confidence in results • Abstaining due to conflict of interest eliminates the appearance of bias • Taking initiative promotes efficiency • Following policy leads to data integrity • Being law abiding supports legal defensibility of results • Bad behavior leads to low morale leads to complacency leads to mistakes • Loyalty leads to improved collaboration • Teamwork attitude promotes exchange of ideas for improvement • Acquiring broader knowledge adds value to the workplace • Openness leads to the resolution of problems in a timely manner • Having a sense of humor leads to outstanding morale	The laboratory analyst exhibits leadership habits. • Self-awareness leads to professional growth • Striving for continuous improvement leads to teamwork, efficiency, effectiveness • Having a good work ethic inspires co-workers

Ethical Challenges	**Based Upon Leve 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**

Definition: Personal behaviors that can have a negative impact upon laboratories. **Level 4 Module TLO:** Discuss ethical challenges faced by laboratories. **Level 5 Module ELOs:** • Give examples of ethical challenges faced by laboratories. • Discuss the importance of maintaining impartiality. • Describe how public perception can impact an organization's credibility. • Describe how personal behaviors impact scientific integrity in the production of test results. • Explain the importance of confidentiality in testing.	The laboratory analyst has knowledge of types of illegal activities. • Dry labbing • Falsifying results • Intentionally manipulating equipment to affect results • Insider information for stocks/bonds • Misuse of resources or tools • Theft The laboratory analyst can recognize sources of resource waste. • Government budgeting • Destroying perfectly good food • Complacency • Poor time management The laboratory analyst has knowledge of external influences. • Politics can influence decision-making • Rule of law takes primacy over personal motives • Insufficient resources can lead to cutting corners • Releasing public records is in conflict with personal motivation The laboratory analyst recognizes the importance of the public trust. • Negative news leads to lack of public trust for all parts of the organization, negative public perception is extremely difficult to overcome • The public has zero tolerance for mistakes so there can be a reluctance to own up to mistakes • Covering up a mistake leads to lack of public confidence	The laboratory analyst understands that unethical behavior can lead to incorrect lab results which has outstanding impact on stakeholders. The laboratory analyst has an awareness that personal activities and personal associates may present conflict of interest.

	• Improper disclosure of results or release of preliminary results leads to confusion or lack of public trust.	

E-8 Incident Command System (ICS)

Definition: The systematic tool used for the command, control, and coordination of emergency response.

Level 2 Course TLO: Explain ICS principles during emergency response and recovery.

Level 3 Course ELOs:

- Communication
  - Describe ICS.
- Leadership
  - Discuss roles of laboratories in ICS.
- Programmatic
  - Apply ICS principles.
- Technical
  - Operate within the ICS.

National Incident Management System (NIMS)	Based Upon Leve 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**

Definition: An overview of the National Incident Management System (NIMS) and the role of the laboratory in managing incidents.
 	
Level 4 Module TLO: Describe NIMS.
 	
Level 5 Module ELOs:
• Define NIMS.
• Describe the role of the laboratory in the NIMS.
	The laboratory analyst can identify some of the players in the NIMS.
	• Federal agencies
	  o FEMA
	  o EPA
	• State agencies
	• Private sector
	• Non-governmental organizations
	  o Red Cross
	  o Salvation Army
	• Local agencies
	
	The laboratory analyst can understand the purpose of the NIMS.
	• Well organized response to an incident
	• Less chaotic	

Incident Command System	Based Upon Leve 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: An overview of the Incident Command System (ICS). **Level 4 Module TLO:** Explain the ICS. **Level 5 Module ELOs:** • Describe the features and principles of ICS. • Describe the five functional areas in an ICS structure. • Describe the incident commander and command staff functions. • Give examples of when ICS is used.	The laboratory analyst can define ICS. • Standard organizational structure • Unified chain of command • Scalable The laboratory analyst can give examples of where ICS could be used. • Earthquakes • Hurricanes • Terrorism • Pandemics • Nuclear • Foodborne Illness Outbreaks • Environmental incidents(oil spills) The laboratory analyst can explain the relationship between ICS and NIMS.	

The Laboratory analyst Role in ICS	Based Upon Leve 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: The role of laboratory analysts in ICS. **Level 4 Module TLO:** Describe how laboratory analysts may be involved in ICS. **Level 5 Module ELOs:** • Describe the role of the laboratory in an incident. • Give examples of activities a laboratory analyst may be asked to do in an incident.	The laboratory analyst can follow directions of the chain of command. The laboratory analyst can demonstrate an awareness that their role may change. • Different tasks • Different locations • Work station • Chain of command • Hours The laboratory analyst can have an awareness of training courses related to ICS.	

E-9 Integrated Food Safety System (IFSS)

Definition: Introductory knowledge related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial human and animal food protection agencies working in concert to protect the U.S. human and animal food supply.

Level 2 Course TLO: Describe how the Integrated Food Safety System (IFSS) protects public health.

Level 3 Course ELOs:

- Communication
  - Explain the purpose of the IFSS.
- Leadership
  - Support the IFSS.
- Programmatic

- List stakeholder roles in the IFSS.
- Technical
  - Describe laboratory contributions to the IFSS.

Overview of the IFSS Concept	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: A collaborative of food safety stakeholders. **Level 4 Module TLO:** Discuss the role of the laboratory within the IFSS. **Level 5 Module ELOs:** • Distinguish regulatory roles in a global environment. • Describe existing lab networks which contribute to IFSS.	The laboratory analyst understands the role of the various agencies within the IFSS. • Federal Agencies o FDA o USDA o CDC o DHS • Territories • Tribal Governments • State Agencies • Local Agencies The laboratory analyst understands how the laboratory can engage in partnerships. • Support • Promote cooperation within the laboratory community • Promote information sharing within the laboratory community • Promote capacity and capability to regulatory entities The laboratory analyst understands how lab results are effectively shared. • Harmonization of methods • Standardization of quality systems • Standardization of data elements for reporting	The laboratory analyst can describe existing laboratory networks. • ICLN (DHS) • FERN (USDA & FDA) • LRN (CDC) • ELRN (EPA) • DLN (DoD) • Vet-LIRN (FDA CVM) • NAHLN (USDA) • NPDN (USDA APHIS)

E-10 Laboratory Information Management System (LIMS)

Definition: A software-based system that processes, stores and manages data in support of laboratory operations.

Level 2 Course TLO: Explain the importance of LIMS.

Level 3 Course ELOs:

- Communication
  - Describe basic functions of LIMS.
- Leadership
  - Report LIMS issues.

- Programmatic
  - Describe the role of LIMS.
- Technical
  - Use LIMS.

Foundations	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to electronic data management. **Level 4 Module TLO:** Discuss elements of electronic data. **Level 5 Module ELOs:** • Define electronic data. • Identify sources of electronic data. • Describe how electronic data is used.	The laboratory analyst can define electronic data. • What data are captured and why The laboratory analyst understands where does data come from. • Internal • External The laboratory analyst understands what you can do with electronic data. • Generate information from data • Prepare reports • Save data	The laboratory analyst can specify types of data. • Numerical • Text • Graphical • Comparative The laboratory analyst can specify internal and external sources of data. • Entered manually • Entered by instrument • External sources (inspections, other laboratories, etc.) • Raw vs treated data The laboratory analyst understands inter-relationships between data. • Sample collection => testing=> reports The laboratory analyst has a basic understanding of where and how data are stored.

Capabilities of LIMS	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Features of a LIMS. **Level 4 Module TLO:** Describe the importance of a LIMS. **Level 5 Module ELOs:** • Describe the purpose of a LIMS.	The laboratory analyst understands the purpose of the LIMS. • Relates to QMS • Capture lab workflow • Chain of custody • Official record of sample management	The laboratory analyst understands how the LIMS relates to QMS and/or accreditation. • Relationship to customer requirements • Standardization • Means to track trends, i.e. QC data(statistics)

• List important features of a LIMS. • Discuss interactions with other applications/instruments.	• Capture corrective actions or preventive actions • Importance of audit trail • Enter test data • Provides customer reports • Data storage • Capture sample data The laboratory analyst has knowledge of the qualities of a LIMS. • How reliable the LIMS is • Secure system to capture and store data • Faster and easier to track data • Real time access to sample status, testing status, and results • Provides searchable means to data • Standardization • Relates to accuracy of results • Streamline	The laboratory analyst explains the role LIMS plays as a centralized data capture system. • Integrate with other electronic systems both internal and external • Used to retrieve data/information for regulatory action The laboratory analyst supports laboratory operations. • LIMS functions to enhance productivity • Allow performance metrics to be tracked • Means to track performance trends • Basis for fast and reliable custom reports • Customizable to meet new needs • Organizational dashboard

LIMS Administration	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Administration of a LIMS. **Level 4 Module TLO:** Describe LIMS administration in laboratory operations. **Level 5 Module ELOs:** • Discuss the role of a LIMS administrator. • Discuss LIMS administration tasks.	The laboratory analyst can discuss LIMS operations. • Identify role of LIMS administrator • Other roles within LIMS • Know who to contact with questions • Where to find the SOPs • Recognize when something goes wrong The laboratory analyst can discuss data security. • Use of passwords • Permission levels • Roles The laboratory analyst has knowledge of data management. • Changing data into information • Procedures for data entry	The laboratory analyst can create reports. • Retrieve data • Create report templates The laboratory analyst can solve problems. • Assist other with performing LIMS entry • Resolve identified problems • Identify data errors The laboratory analyst can improve LIMS system. • Make recommendations for enhancements • Identify reports that enhance workflow

	• When the data is entered • Data entry accuracy • Data correction processes • Understand quality review of data entry or e-data • Saving data • Release of data • Retrieving data • What to do with transmitted data(peer to peer) • Preparing reports • How to do calculations in LIMS	

E-11 Laboratory Sampling

Definition: All manipulations performed on the laboratory sample after receipt and acceptance through selection of the test portion.

Level 2 Course TLO: Apply defensible laboratory sampling principles (defensible is not a qualifier. Implies a set of principles from *Good Test Portions*).
Level 3s Course ELOs:

- - Communication
  - o Discuss principles of laboratory sampling.

- - Leadership
  - Resolve sampling challenges.
- - Programmatic
  - Discuss the impact of laboratory sampling procedures on the organization's mission.
- - Technical
  - Perform defensible lab sampling.

Foundations	**Based Upon Level 5 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Theory and principles of sampling. **Level 4 Module TLO:** Summarize the concepts of sampling theory. **Level 5 Module ELOs:** • Explain decision unit. • Incorporate sample descriptors into daily activities. • Explain representivity. • Describe evidentiary integrity. • Give examples of practices to maintain analyte integrity. • List components of Sample Quality Criteria (SQC). • List components of Global Estimation Errors (GEE). • Discuss the use of laboratory sampling terms.	The laboratory analyst can define decision units. The laboratory analyst can explain the importance of representing the decision unit. The laboratory analyst can explain the importance of accessibility to all elements of the material being sampled. The laboratory analyst has a general awareness of the purpose of theory of sample (TOS). The laboratory analyst can define the following terms: • Sample as defined by TOS • Primary sample • Laboratory sample • Analytical sample • Test portion • Replicate sample • Split sample • Composite sample The laboratory analyst uses sample terms in daily activities. The laboratory analyst can explain representivity in terms its relationship to • random error • bias • sample correctness	The laboratory analyst can help instruct others in understanding decision units. The laboratory analyst uses proper sample terms in laboratory documents. The laboratory analyst can estimate random error. The laboratory analyst can suggest equipment to increase the number of increments selected. The laboratory analyst can suggest new practices to control error. The laboratory analyst can contribute to organizational policies and procedures related to: • Trace back • Maintaining sample representivity • Analyte integrity The laboratory analyst can recognize/report: • Potential loss of analyte integrity • Errors that might contribute to the loss of analyte integrity The laboratory analyst has an awareness of the importance of including management and sampling personnel in the development of SQC. The laboratory analyst can participate in establishing SQC.

	The laboratory analyst can discuss the impact of number of increments on representivity. The laboratory analyst can discuss the impact of mass on representivity. The laboratory analyst can define evidentiary integrity. The laboratory analyst can relate laboratory sampling to legal defensibility. The laboratory analyst can discuss the importance to evidentiary integrity of: • Trace back (including chain of custody) • sample representivity • analyte integrity The laboratory analyst can follow organizational policies and procedures to maintain: • sample representivity • analyte integrity • trace back (including chain of custody) The laboratory analyst can define analyte integrity. The laboratory analyst can explain techniques to maintain analyte integrity such as: • pH adjustment / buffers • Temperature control • Humidity control • Holding times • Sterility control • Proper handling techniques • Sample containers • Packaging • Transportation • Storage	The laboratory analyst can explain how SQC is necessary for making defensible decisions. The laboratory analyst can discuss many specific non-selection and selection errors such as: • Non-selection errors (all systematic errors) • Extraneous Material Error • Mass Recovery Error • Contamination Introduction Error • Analyte Integrity Error • Selection errors • Random errors • Fundamental sampling error • Grouping and segregation error • Systematic errors • Increment delimitation error • Increment extraction error ▪ Contamination introduction error ▪ Analyte integrity error • Increment weighing error The laboratory analyst can utilize advanced sampling terms in daily written and oral communication such as: • Extraneous material error • Mass recovery error • Contamination Introduction error • Analyte integrity error • Increment delimitation error • Increment extraction error i.Contamination Introduction error ii.Analyte integrity error • Increment weighting error

	The laboratory analyst can define inference. The laboratory analyst can discuss SQC components: • What is the question/objective. o What is the analyte of interest? o What is the concentration of interest? (action limit) o How will inference be made? • What is the decision unit? • What is the desired confidence? The laboratory analyst can define GEE. The laboratory analyst can discuss components of GEE: • Total Sampling Error o Error from non-selection processes o Error from selection processes • Total Analytical Error The laboratory analyst can explain their contribution to GEE. The laboratory analyst will utilize the proper sampling terms in daily written and oral communication such as: • Sample terms (refer to sample terms listed above) • Comminution • Element	The laboratory analyst can demonstrate leadership in advancing the proper use of terminology. Potential for advanced course

	• Finite element • Infinite element • Extraneous material • Inference • Increments • Selection process • Non-selection process • Compositional heterogeneity • Distributional heterogeneity • Probabilistic sampling • Sample correctness • Extraneous material • Splitting • Mass reduction • Systematic error (bias) • Random error (imprecision) • Fundamental sampling error • Grouping and segregation error	

Material Properties	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**
Definition: Physical characteristics of lab sample. **Level 4 Module TLO:** Describe the physical characteristics of laboratory samples that can introduce error into sample manipulation processes. **Level 5 Module ELOs:**	The laboratory analyst can explain the difference between infinite and finite element materials. The laboratory analyst can list the different physical states of laboratory sample: • Liquid • Slurries and liquids with suspended solids • Semi solid • Solid	The laboratory analyst can explain the difference in sampling protocols for finite and infinite element materials. The laboratory analyst can suggest new tools or equipment to improve sample correctness. The laboratory analyst can identify and mitigate unexpected heterogeneity challenges.

• Distinguish between infinite and finite element materials. • List the physical states of a laboratory sample. • Define heterogeneity as the term applies to a laboratory sample. • Differentiate between compositional heterogeneity and distributional heterogeneity. • Relate the impact of particle size on sampling errors.	• Gas The laboratory analyst can explain how the physical states relate to sample correctness: • Choosing proper tools/equipment • Using proper tools/equipment correctly The laboratory analyst can explain the impact of heterogeneity on laboratory sampling. The laboratory analyst can explain the difference between compositional and distributional heterogeneity. The laboratory analyst can give examples of compositional and distributional heterogeneity in materials encountered in the lab. The laboratory analyst can give examples of techniques to mitigate: • Compositional heterogeneity • Distributional heterogeneity The laboratory analyst can explain the impact of comminution on particle size. The laboratory analyst can explain the impact of maximum particle size on random sampling error. The laboratory analyst can explain the impact of maximum particle size on random error. The laboratory analyst can discuss the importance of maintaining comminution equipment.	The laboratory analyst can explain the impacts of laboratory sampling techniques on compositional and distributional heterogeneity. The laboratory analyst can suggest opportunities for improvements to mitigate compositional and distributional heterogeneity. The laboratory analyst can suggest ways to mitigate sampling errors due to particle size. The laboratory analyst suggests new comminution equipment. The laboratory analyst can explain the impact of maximum particle size on fundamental sampling error. The laboratory analyst can explain the impact of maximum particle size on grouping and segregation error. The laboratory analyst can explain the impact of particle size range on sampling error. Potential for advanced course
Errors	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**

Definition: Imprecision and bias that cause the concentration or characteristic of the test portion to deviate from the true concentration or characteristic of the decision unit.
 	
Level 4 Module TLO: Identify sources of error in laboratory sampling.
 	
Level 5 Module ELOs:
• Describe the types of errors in sampling.
• Give examples of errors from non-selection processes.
• Give examples of systematic errors from selection processes.
• Give examples of random errors from selection processes.
• Give examples of gross errors.
• Describe relationship of error to mass.
• Describe relationship of error to increments.
• Describe relationship of error to sample correctness.
	The laboratory analyst has knowledge of 3 types of errors:
	• Systematic error
	• Random error
	• Gross error (blunders)
	
	The laboratory analyst has knowledge of errors contributing to total sampling error (TSE):
	• Error from selection processes
	• Error from non-selection processes
	
	The laboratory analyst has knowledge of the causes of non-selection errors:
	• Negligence
	• Inattention to detail
	• Lack of understanding of error
	The laboratory analyst has knowledge of categories of systematic error associated with non-selection processes:
	• Extraneous material error (EME)
	• Mass recovery error (MRE)
	• Contamination introduction error (CIE)
	• Analyte recovery error (AIE)
	
	The laboratory analyst has knowledge of categories of systematic error associated with selection processes:
	• Increment delimitation error (IDE)
	• Increment extraction error (IEE)
	  • Contamination introduction error (CIE)
	  • Analyte integrity error (AIE)
	• Increment weighing error (IWE)
		The laboratory analyst can suggest troubleshooting processes to mitigate error.
		
		The laboratory analyst can recognize sources of non-selection errors.
		
		The laboratory analyst can suggest ways to avoid non-selection errors.
		
		The laboratory analyst can suggest ways to modify a process to better control systematic error by mitigating:
		• Extraneous material error (EME)
		• Mass recovery error (MRE)
		• Contamination introduction error (CIE)
		• Analyte recovery error (AIE)
		• Increment delimitation error (IDE)
		• Increment extraction error (IEE)
		• Increment weighing error (IWE)
		
		The laboratory analyst can suggest modifications to a selection process to reduce random error:
		• Increase mass
		• Reduce particle size
		• Increase number of increments
		
		The laboratory analyst can suggest ways to avoid gross errors.
		
		The laboratory analyst can identify components of fundamental sampling error (FSE).

	The laboratory analyst has knowledge of categories of random error associated with selection processes: • Fundamental sampling error • Grouping and segregation error The laboratory analyst has knowledge of several different types of gross errors (blunders): • Spills • Not following instructions • Incorrect weights • Transposing figures • Transposing labels The laboratory analyst has knowledge of the relationship of fundamental sampling error (FSE) to: • Magnitude of the compositional heterogeneity • Mass selected Increasing mass decreases FSE • Particle size Reducing particle size decreases FSE The laboratory analyst can define distributional heterogeneity. The laboratory analyst has knowledge of the relationship of grouping and segregation error (GSE) to: • Magnitude of distributional heterogeneity • Number of increments selected • Greater number of increments decreases GSE	The laboratory analyst can suggest ways to reduce FSE. The laboratory analyst can suggest ways to reduce GSE. The laboratory analyst can explain the concept of equal probability of selection as it relates to sample correctness. The laboratory analyst can suggest improved tools to control error.

	The laboratory analyst has knowledge of the relationship of error to sample correctness:
	• Increment delimitation error is controlled by choice of properly designed tools
	• Increment extraction error is controlled by using proper tools appropriately
	• Tool choice varies with state and dimension of material
	  • Liquids
	  • Without suspended solids
	  • With suspended solids
	  • Slurries
	  • Semi-solids
	  • Solids	

Non-selection Process	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**
Definition: Manipulation of a sample usually performed before a selection process. **Level 4 Module TLO:** Describe the purpose of non-selection processes in laboratory sampling. **Level 5 Module ELOs:** • Describe non-selection processes. • Describe comminution/particle size reduction techniques.	The laboratory analyst can list at least 3 non-selection processes: • Comminution • Removal of extraneous material • Preservation • Conditioning (freezing, removal of water) • Mixing The laboratory analyst can define comminution.	The laboratory analyst can suggest improvements to non-selection processes. The laboratory analyst can contribute to improving a comminution process. The laboratory analyst can recognize factors to consider when incorporating a conditioning technique for a comminution process.

• Explain the effects of mixing techniques. • Describe techniques used to remove extraneous material. • Describe how non-selection processes influences representivity.	The laboratory analyst can recognize appropriate particle size reduction technique for a material: • Liquid • Slurry • Semi-solid • Solid The laboratory analyst can identify comminution equipment: (see Good Test Portions) • Crushing equipment • Cutting/shearing equipment The laboratory analyst can list at least three factors to consider when choosing comminution equipment (see Good Test Portions page 29): a. Initial properties of the material b. Dimension of the material c. Desired particle size characteristics d. Capacity of equipment e. Control of systematic errors f. Design considerations g. Condition of equipmen 5. The laboratory analyst can recognize a conditioning technique for a comminution process: • Cooling • Freezing • Dry ice freezing • Freeze drying • Coarse and fine grind processes The laboratory analyst can identify three or more mixing techniques (see Good Test Portions page 34):	The laboratory analyst can rank choices of comminution equipment for a (specific) material. The laboratory analyst can identify the limitations of two or more types of comminution equipment: (see Good Test Portions) • Crushing equipment • Cutting/shearing equipment The laboratory analyst can identify techniques to evaluate the effectiveness of particle size reduction: • Sieving • Microscopy The laboratory analyst can contribute to developing a comminution process for a particular material they encounter: • Human food • Animal food or pet food • Environmental The laboratory analyst can identify the limitations of mixing techniques: • Stirring • Shaking • Rolling • Vortexing • Blending • Figure 8 motion • Churning The laboratory analyst can identify the impact of mixing techniques: • On distributional heterogeneity • On composition heterogeneity • The need for multiple increments

	• Stirring • Shaking • Rolling • Vortexing • Blending • Figure 8 motion • Churning The laboratory analyst can identify the effectiveness of mixing techniques on materials with: • Similar particle size, shape, density • Dissimilar particle size, shape, density The laboratory analyst can differentiate between extraneous material and the decision unit. The laboratory analyst can identify examples of removal of extraneous material as non-selection processes. The laboratory analyst can identify the impact of removal of extraneous material on: • Representation of the decision unit • Analyte integrity The laboratory analyst can identify examples of how representivity can be impacted by non-selection processes: • Negatively • Positively	The laboratory analyst can suggest improvements to the extraneous material removal process. The laboratory analyst can suggest improvements to the non-selection processes to maintain representivity.

Selection Process	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**
Definition: The act of selecting a smaller mass or volume of	The laboratory analyst can define: • Mass Reduction • Splitting	The laboratory analyst can explain the principles behind the use of

material from a larger mass or volume. **Level 4 Module TLO:** Describe the purpose of selection processes in lab sampling. **Level 5 Module ELOs:** • Differentiate mass reduction and splitting. • Explain the critical factors to control random error in a selection process. • Describe splitting equipment used in selecting a representative test portion. • Contrast one dimensional and two-dimensional sampling. • Explain characteristics of sampling tools. • Describe the effect of selection process on representivity.	• Sample dimensions The laboratory analyst can discuss use of mass reduction techniques. The laboratory analyst can perform multiple increment sampling. The laboratory analyst can explain the importance of sufficient mass in selection of a representative test portion. The laboratory analyst can explain the importance of number of random increments in selection of a representative test portion. The laboratory analyst can discuss the use of splitting techniques such as: • Rotary splitter • Fractional shoveling • Stationary riffle splitter The laboratory analyst can accurately operate splitting equipment if applicable. The laboratory analyst can define sampling dimensions. The laboratory analyst can describe 1-D and 2-D slab cake technique/protocol. The laboratory analyst can give examples of sampling in: • 1-D • 2-D • Three-dimension (3-D) The laboratory analyst can describe various sampling selection tools and their proper use, such as: • Drum thief • Scoops	several mass reduction techniques. The laboratory analyst can suggest improvements to a selection protocol. The laboratory analyst can contribute to developing a selection protocol. The laboratory analyst can maintain a splitter. The laboratory analyst can assist in troubleshooting a splitting protocol. The laboratory analyst can suggest a 1-D or 2-D sampling protocol. The laboratory analyst can suggest a protocol to convert a 3-D material into a 1-D or 2-D material. The laboratory analyst can identify challenges with sampling tools / protocols. The laboratory analyst can suggest improvements to the choice of sampling tools. The laboratory analyst can suggest a representative selection protocol. The laboratory analyst can suggest techniques and tools for equal probability selection.

	• Pipette The laboratory analyst can explain the impact of tool shape on sample correctness. The laboratory analyst can demonstrate the proper use of a sampling tool. The laboratory analyst can demonstrate selection of a representative test portion. The laboratory analyst can demonstrate competency (verify / validate). The laboratory analyst can explain the importance of equal probability of selection.	

Sampling Procedures	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**
Definition: A set of plans used for lab sampling operations. **Level 4 Module TLO:** Articulate lab procedures related to lab sampling. **Level 5 Module ELOs:** • Identify SOP used in laboratory sampling. • Recognize the sampling objective. • Recognize the workflow associated with lab sampling. • Recognize laboratory policy for sample retention.	The laboratory analyst can identify an appropriate laboratory sampling protocol to minimize TSE: • The laboratory analyst can identify an appropriate laboratory sampling equipment/tools to control IDE. • The laboratory analyst can identify the appropriate usage of equipment/tools to control IEE. • The laboratory analyst can recognize a	The laboratory analyst can contribute to the development of laboratory sampling protocols. The laboratory analyst can recognize a need for sampling protocol improvement. The laboratory analyst can identify the impact of regulatory objectives on the sampling protocol. The laboratory analyst can identify improvements to a sampling protocol to meet a regulatory objective.

• Apply safety procedures in lab sampling.	deviation(s) from an existing protocol. (scenario) The laboratory analyst can identify a sampling objective. The laboratory analyst can identify importance of regulatory objectives to the sampling protocol. (e.g. surveillance, compliance, for cause, outbreak, consumer complaint, investigational, import vs domestic) The laboratory analyst can identify components of a laboratory sampling workflow. The laboratory analyst can identify an appropriate sampling workflow. The laboratory analyst can identify elements of a laboratory sample retention policy. The laboratory analyst can give examples of laboratory sampling safety procedures. The laboratory analyst can identify potential risks in laboratory sampling activities. The laboratory analyst can identify why it is important to comply with laboratory sampling safety procedures.	The laboratory analyst can identify an incorrect laboratory sampling workflow. The laboratory analyst can identify improvements to a laboratory sampling workflow. The laboratory analyst can identify improvements to the sample retention policy. The laboratory analyst can give examples of improved laboratory sampling safety procedures. The laboratory analyst can troubleshoot safety issues in a sampling procedure.

QA/QC	**Based Upon Leve 5 Competency – Not an all-inclusive list**	
	BEHAVIORAL ANCHORS Average Performance	**BEHAVIORAL ANCHORS Outstanding Performance**

Definition: Policies and procedures used to assure the representativeness of the test portion. **Level 4 Module TLO:** Explain how QA/QC policies and procedures can be applied to achieve sample representativeness. **Level 5 Module ELOs:** 1. Discuss the importance of validating laboratory sampling processes. 2. Discuss the importance of verifying laboratory sampling processes. 3. Explain the importance of quality control for laboratory sampling processes. 4. Data assessment ???	The laboratory analyst can recognize the importance of validating laboratory sampling protocols. The laboratory analyst can identify approaches for validation of a laboratory sampling protocol: • Whole sample extraction • Materials with a known amount of analyte of interest or surrogate • Tracers The laboratory analyst can recognize the use of replication in estimating random error. The laboratory analyst is aware of their role in validating laboratory sampling protocols. The laboratory analyst can describe the importance of verifying laboratory sampling protocols. The laboratory analyst can identify performance tests for verifying of a laboratory sampling protocol: • Carryover • Final particle size distribution • Contamination procedures • Cleaning procedures The laboratory analyst can identify approaches to verify laboratory sampling protocols. The laboratory analyst can recognize the use of replication in estimating random error. The laboratory analyst can describe the importance of	The laboratory analyst can recognize appropriate validation data. The laboratory analyst can identify the elements of a validation protocol. The laboratory analyst can describe how to train others to perform validation. The laboratory analyst can recognize an approach to validate a non-selection process. The laboratory analyst can identify a protocol to validate a selection process. The laboratory analyst can identify an approach to isolate error for a specific selection process. The laboratory analyst can evaluate verification data. The laboratory analyst can describe the elements of a verification protocol. The laboratory analyst can describe how to train others to perform verification. The laboratory analyst can identify a need for verifying laboratory sampling protocols: • Changes in personnel • Changes in equipment • Changes in protocol The laboratory analyst can recognize trends in sampling QC data.

	incorporating quality control into laboratory sampling protocols. The laboratory analyst can identify quality control tests: • Use replicates to monitor random error • Use blanks to monitor contamination • Measure splits at multiple points in time for analyte integrity • Visual inspection of equipment for mass recovery • Visual check or weight check to verify consistent separation of extraneous material • Compare performance by multiple analysts The laboratory analyst can describe the role of the laboratory in making defensible decisions. The laboratory analyst can recognize elements of evidentiary integrity. The laboratory analyst can identify SQC requirements. The laboratory analyst can recognize QC concerns.	The laboratory analyst can recognize opportunities to better control error. The laboratory analyst can recognize opportunities for additional QC monitoring. The laboratory analyst can state the SQC. The laboratory analyst can recognize QC data that meets SQC requirements. The laboratory analyst can recognize the elements failures in maintaining evidentiary integrity. The laboratory analyst can describe how an inference is made about the decision unit.

E-12 Method Resources

Definition: Sources of analytical methods.

Level 2 Course TLO: Explain why recognized methods are used.

Level 3 Course ELOs:

- Communication
  - Explain where to find recognized methods.
- Leadership
  - Identify fit for purpose analytical methods.
- Programmatic
  - Explain the importance of recognized methods in regulatory analytical work.
- Technical
  - Apply fit for purpose analytical methods.

Foundations	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to analytical testing in the laboratory. **Level 4 Module TLO:** Describe foundational knowledge related to analytical testing. **Level 5 Module ELOs:** • Define recognized methods. • Identify sources of recognized methods. • Discuss the importance of using recognized methods. • Describe the importance of method validation. • Describe the importance of method verification.	The laboratory analyst has knowledge of basic lab techniques and knowledge supporting method applications • Basic math • Basic statistics • Mass, volume, etc. Metrology • Basic supporting chemistry or biology • Basic microbiology • Underlying theoretical basis for equipment • Understanding of supporting technology and tools • How to use a spreadsheet • Basic computer skills The laboratory analyst has knowledge of test methods. • Sources of recognized methods o FDA o USDA o AOAC o Health Canada • Importance of using recognized methods • Sources for references • Regulations and laws The laboratory analyst has an awareness of method suitability.	The laboratory analyst can problem solve. • Troubleshoots equipment, instruments, and methods • Recognizes outliers • Suggestions for improvements The laboratory analyst participates in method management. • Assist with method validation and verification studies • Understand the concept of matrix extension • Integrate QMS principles with analytical testing • Sources of validation guidelines • Assist on method suitability • What constitutes a minor or major change to the method • Knowledge of advanced instrumental techniques The laboratory analyst can assist in training of basic lab techniques.

	• Validation • Verification • Fit for purpose The laboratory analyst adheres to QMS principles.	

Method Selection	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The process by which a laboratory determines suitable analytical methods. **Level 4 Module TLO:** Discuss the process by which a laboratory determines suitable analytical methods. **Level 5 Module ELOs:** • Define QMS terms related to methods. • Describe criteria for methods selection. • Identify fit for purpose method. • Describe the reason for modification to a recognized method.	The laboratory analyst has an awareness of the existence of an established method selection process. The laboratory analyst has an awareness of laboratory QMS. • Define terms o Reference materials o Proficiency testing o Validation o Verification o Fit for purpose The laboratory analyst can discuss the importance of having a method selection process. The laboratory analyst has knowledge of the criteria for selecting a method. • Fit for purpose • Data reporting requirements • Sampling requirements • Regulatory requirements • Analyte levels • Target analyte • LOD and LOQ requirements • Legally defensible results	The laboratory analyst can assist in the method selection process. • Method to determine analytical suitability • Standard Method Performance Requirements (SMPR) The laboratory analyst recognizes resources. • Customer requirements • Availability of equipment • Required capacity • Trained analysts • More generic method availability • Budget The laboratory analyst uses knowledge of criteria for selecting a method. • Elements of method modification • Validation study • Verification where appropriate • Matrix validation The laboratory analyst recognizes QMS requirements. • Proficiency testing • Availability of controls and reference materials

Definition: Foundational information recognizing the interconnections between people, animals, plants and their shared environment and the practices used to detect, prevent, and respond to illness and disease.

Level 2 Course TLO: Describe the role of public health stakeholders.

Level 3 Course ELOs:

- Communication
  - Describe the laboratory role in public health.
- Leadership
  - Discuss the analyst's role in the protection of public health.
- Programmatic
  - Explain the importance of laboratory results to regulatory agencies.
- Technical
  - Produce analytical results for public health use.

Foundations	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to public health principles. **Level 4 Module TLO:** Discuss foundational knowledge related to public health principles. **Level 5 Module ELOs:** • Explain the relationship between the One Health approach and public health. • Define One Health. • Discuss the role of laboratories in public health. • Define the analyst's role in public health. • Illustrate how food safety is part of public health. • Relate how human and animal food laboratories impact public health. • Explain the impact of animal health on human food sources.	The laboratory analyst has knowledge of what public health is. • Why public health exists • The goal of public health • How public health applies to the population • Agencies involved in public health activities • The difference between public health and personal health • Their role • Impact on global health • One Health Approach (impact of environment and animal health on food safety) The laboratory analyst has knowledge of the public health system and the laboratory's role. • Discuss the role of their lab in the public health system (ex. prevent foodborne illness, zoonotic disease detection and prevention) • Knowledge of laboratory role in response (emergency response,	The laboratory analyst recognizes the functions of human and animal food safety laboratories in the public health system. The laboratory analyst can assist others to expand their knowledge of public health principles.

	regulatory actions including recalls) • Part of a team The laboratory analyst recognizes Food Safety as a part of public health. • Link illnesses in different locations to a single source • Human and animal food is a basic need • Outstanding quality human and animal food promotes good health • Animal food impacts animal health which impacts human and animal food sources • Human and animal food can be a disease outbreak vector • Removing contaminated human and animal food reduces public health impact • Foodborne illnesses may lead to secondary illnesses • Unsafe human and animal food is a public health issue • Awareness limits the spread of pathogens The laboratory analyst has knowledge of the impact of human and animal food laboratories on Public Health. • Testing identifies problems and prevents reoccurrences • Decreases the potential for an epidemic or a pandemic • Human and animal food laboratories hold unique expertise in human and animal food safety and human and animal food security	

	• Increased public awareness of human and animal food safety • Human and animal food laboratories are connected to human and animal food regulatory agencies • Human and animal food laboratories are primary responders to foodborne outbreaks	

Laboratory and public health agency interaction	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The relationship of laboratories and regulatory agencies when making public health decisions. **Level 4 Module TLO:** Describe how laboratories interact with regulatory agencies. **Level 5 Module ELOs:** • List the regulatory actions taken based on laboratory results. • List the public health decisions made based on laboratory results. • Recognize the importance of maintaining legal defensibility. • Differentiate between traceforward and traceback. • Define the role of surveillance in public health decisions.	The laboratory analyst can describe regulatory action support. • Foodborne investigation • Provide data for regulatory action • Part of a system for outbreak response, surveillance, compliance, and recalls • Public health lab networks • Actions defined in law • Follow chain of command The laboratory analyst can describe scientific support. • Know that agencies provide technical assistance (interpreting analysis reports of lab results, technical chemistry biology in statutes and rules) • Sources of official methods • Method development The laboratory analyst can describe interactions in public health • Describe the role of epidemiology, lab (regulatory/clinical) and regulatory field staff in addressing public health issues	The laboratory analyst is aware of how FSMA and IFSS encourages collaboration between regulatory agencies • Good communication • Inter-agency relationships The laboratory analyst can describe mechanisms to support resource sharing and integration. • MOUs • Partnership agreements • Funding • Contract labs • Cooperative agreements The laboratory analyst can describe the roles and responsibilities of different agencies in human and animal food safety system • List public health partners • Associations that include regulatory, industry, and academia partners The laboratory analyst can enhance interagency networking. • Interaction with analysts from other agencies

Outbreak	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Multiple cases of illness related to human and animal food contamination. **Level 4 Module TLO:** Give examples of the importance of testing in human and animal food related events. **Level 5 Module ELOs:** • Discuss the different types of outbreaks. • Explain the importance of human and animal testing to prevent outbreaks. • Explain the importance human and animal testing in an outbreak situation.	The laboratory analyst can discuss testing that your laboratory has performed for a human and animal food related event. • Results provide a link to the source of human/animal illness • Faster turn-around time equals fewer illnesses, eg prioritize sample processing • Different types of events that can occur(terrorist, radiological, microbial, chemical) • Prevent additional cases The laboratory analyst can discuss how testing is related to enforcement. • Results provided to support regulatory action eg recall	The laboratory analyst has an awareness of enforcement. • Awareness of the potential for litigation • Analyst may be called upon to testify The laboratory analyst can discuss public health implications. • Surveillance and monitoring • Consult with epidemiologists • Acute and chronic illness • Provide information to medical/veterinary personnel to treat those affected • Give an example of a case of broad public health significance • Routine testing of human and animal food can prevent outbreaks from occurring. • How disease can be introduced from the animals or the environment (i.e., avian flu)

E-14 Quality Management Systems

Definition: The organizational framework that defines the quality policy, objectives, and procedures.

Level 2 Course TLO: Describe how analytical work falls within the parameters of a quality management system.

Level 3 Course ELOs:

- Communication
  - Describe the laboratory's quality management system.
- Leadership
  - Explain quality management principles.
- Programmatic
  - Explain the importance of the quality management system.
- Technical
  - Apply quality management knowledge when performing analytical work.

Foundations	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to the quality management system. **Level 4 Module TLO:** Explain laboratory quality management systems. **Level 5 Module ELOs:** • Explain the importance of a quality management system. • Identify the principles of a quality management system. • Explain the relationship between accreditation and a quality management system.	The laboratory analyst can define quality elements. • Can define a QMS o Say what we do o Do what we say o Prove with records • Can define quality control • Define quality assurance The laboratory analyst can describe how the laboratory integrates quality into their processes. • Can identify the type of quality system that they are working under o Scope of accreditation • Covers from sample receipt to sample disposal • Crucial to the quality of the end product	The laboratory analyst can demonstrate knowledge of other Quality Management Systems • ISO/IEC 17025 • ALACC (AOAC) • AAFCO QA/QC Guidelines • CLIA • NELAC • CLSI The laboratory analyst can compare other quality management systems to the one they are currently working under.

	• Can identify specific components of the quality system they are working under • QMS must be operational for the purpose of laboratory accreditation The laboratory analyst can identify roles and responsibilities. • Quality manager • Supervisor • Staff • Customer The laboratory analyst can describe the importance of QMS. • Data acceptance • Mutual reliance • Legally defensible • Transparency • Consistency • Efficiency	

Elements	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Components of the quality management system. **Level 4 Module TLO:** Describe the components of the quality management system. **Level 5 Module ELOs:** • Identify the importance of technical review. • Apply document control requirements. • Describe the process of reporting non-conforming work a non-conformance. • Locate quality management documents. • Describe training requirements for competency. • Recognize the importance of the quality manual to the laboratory work.	The laboratory analyst can give examples of components of the quality management system. • Quality manual • Non-conformance process • Preventive actions • Training • Improvement process • Documents and records The laboratory analyst can demonstrate compliance with laboratory SOPs. • Ensures reagents are within date • Ensures equipment is calibrated prior to use • Ensures sample integrity • Ensures equipment maintenance is completed • Ensures records are completed properly	The laboratory analyst can identify the elements of their quality system. The laboratory analyst can suggest improvements. • Procedures • Efficiencies • Quality system The laboratory analyst can give at least one example of each element of their quality system. • Documents and records o SOPs o Job aids o Document control o Quality manual o Quality policy • Organizational structure o Quality culture o Resources o Organizational chart

• Describe the corrective action process. • Identify the need for a root cause analysis. • Describe the risk management process. • Describe the importance of quality control. • Describe the internal audit process. • Describe the use of a proficiency sample. • Define traceability. • Explain the importance of using validated methodology. • Explain the importance of using calibrated equipment. • Recognize the need to use only approved supplies.	• Runs methods after completing training The laboratory analyst can report non-conformances. The laboratory analyst can explain the path of sample workflow. • Sample receipt • Sample testing • Reporting	• Personnel o Follow procedures o Training classes o Training requirements o Competency verification documentation o Employee code of conduct training o Ethics training o Staff qualifications • Equipment o Maintenance o Calibration o Acquisition o Qualifications plan • Purchasing o Procurement o Inventory o Evaluation • Information management o Confidentiality o Security o Information integrity • Occurrence management o Non-conformances o Laboratory environmental requirements • Process control o Sample receipt ▪ Understand chain of custody ▪ Sample handling including chain of custody ▪ Sample collection o Sample testing ▪ Traceability ▪ Verification and validation ▪ Measurement of uncertainty

		▪ Quality control o Reporting ▪ o Root cause and corrective action o Participate in root cause discussions • Assessment o External and internal audits o Proficiency testing o Quality indicators o Quality measures • Process improvement o Constant improvement cycle o Change management o Management review o Preventive actions o Can identify areas of improvement • Customer service and satisfaction o Customer feedback o Meeting customer expectations o Service standards • Facilities and Safety o Workplace safety o Waste management o Emergency management o Laboratory design

E-15 Regulatory Programs

Definition: The regulatory framework and activities that ensure safe human and animal food.

Level 2 Course TLO: Describe the regulatory framework and activities that ensure safe human and animal food.

Level 3 Course ELOs:

- Communication
  - Describe the regulatory programs supported by the laboratory.
- Leadership
  - Define regulatory program partners.
- Programmatic
  - Identify laboratory policies and procedures required to meet regulatory program needs.
- Technical
  - Explain how analytical work supports regulatory programs.

Regulatory Participants	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The members of a regulatory system and their roles. **Level 4 Module TLO:** Describe the participants in the regulatory system. **Level 5 Module ELOs:** • Describe federal, state, local regulatory interactions. • Identify regulatory framework stakeholders. • Describe how various laboratories within the framework collaborate with each other.	The laboratory analyst can identify agencies with regulatory jurisdiction. • Federal: FDA and USDA • State • Local • Tribal The laboratory analyst can identify other participants. • CDC • Lab epi environmental health participants • Networks and associations • Industry representatives • Public health agencies • Law enforcement	The laboratory analyst can discuss the interplay between the regulators and other participants. • Clinical versus human and animal food laboratories • Public health and epi in support of regulatory activities • Law enforcement in criminal versus civil cases The laboratory analyst can discuss the interplay between the federal, state, local, and tribal agencies. • Overlapping jurisdictions • Collaborate on investigations

	• Elected officials • Consumer groups The laboratory analyst understands that federal, state, local and tribal laboratory networks collaborate in the interest of public health.	• Collaborate on outbreak response • Sharing of data • Sharing laboratory methods of analysis • Collaborate on developing best practices • Leverage training opportunities

Regulatory Activities	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The primary functions performed by government human and animal food safety regulators. **Level 4 Module TLO:** Discuss key regulatory activities. **Level 5 Module ELOs:** • Identify the components of a regulatory system. • Distinguish between inspection and investigation. • Explain the importance of evidence in enforcement action. • Identify laboratory analyst role in the regulatory structure.	The laboratory analyst has knowledge of regulatory programs. o Retail o Manufactured food o Shellfish o Dairy o Animal food o Produce The laboratory analyst can describe the role of the laboratory in support of regulatory programs. o Identify analytical methods that are applicable to regulatory activities o Method development o Laboratory analysis of human and animal food for key parameters o Reporting o Analytical findings are used as evidence The laboratory analyst has a basic understanding of each of the components found in the regulatory framework. • Surveillance o Monitoring o Evaluate results/risk assessment o Sample collection • Compliance	The laboratory analyst can describe the intrarelationship of the broad components of the regulatory framework • How Surveillance leads to compliance • How Compliance may or may not lead to enforcement • Enforcement activities may include additional surveillance • Response activities may include additional surveillance • Recovery may include the development of additional regulatory requirements

	○ Routine inspection of human and animal food producing establishments ○ Education (compliance assistance) ○ Analytical findings assist in determining compliance • Enforcement ○ Evidence is gathered to build a case ▪ Testifying in court ○ Determine and issue an enforcement action ▪ Legal defensibility • Response ○ Inspections and investigations ○ Traceback and traceforward ○ Recalls ○ Outbreaks ▪ Epidemic versus pandemic ▪ Local versus statewide ▪ Multi-state • ICS • Recovery	

Legal Authorities and Limitations	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The laws and regulations that define agency responsibilities and limitations. **Level 4 Module TLO:** Explain legal authorities. **Level 5 Module ELOs:** • Recognize the difference between interstate and intrastate commerce jurisdictions. • Define the basis of regulatory authority.	The laboratory analyst understands the jurisdiction of regulatory agencies. • Human and animal food is regulated by federal and state agencies • FDA and USDA are the primary federal regulatory agencies for human and animal food ○ Federal agencies have interstate commerce jurisdiction	The laboratory analyst has knowledge that each state can regulate differently. • Model legislation might be created at the Federal level and incorporated in state legislation • States can create their own independent legislation • Laboratories might not have explicit authority in legislation or rules

	• States have unique authority to regulate human and animal food in individual states
	  o State agencies have intrastate commerce jurisdiction
	• Where does the laboratory fit in to a specific program
	
	The laboratory analyst has knowledge of relevant terminology.
	• Civil and criminal
	• Statutes
	• Rules
	• Laws
	• Acts
	• Regulations
	• Guidance
	• Interstate commerce
	• Intrastate commerce
	
	The laboratory analyst has knowledge of how laws and regulations are developed.
	• Legislation is created by elected officials
	  o Legislation defines the agency that is given regulatory jurisdiction
	• To implement legislation, rules are created by regulatory agencies
		The laboratory analyst has knowledge of where to find regulations applicable to a specific program.

Stakeholder Outreach	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**

Definition: The role of laboratory communication with stakeholders.
 	
Level 4 Module TLO: Discuss stakeholder outreach.
 	
Level 5 Module ELOs:
• Explain how laboratory testing contributes to stakeholder decision making.
	The laboratory analyst has an awareness of mechanisms to disseminate information.
	• Public relations
	  o Subject matter experts
	  o Agency spokesperson
	• Town hall meetings
	• Recall notices to consumers
		The laboratory analyst can discuss the value of laboratory networks.
		• Identify Laboratory networks
		• Understand the concept of leveraging
		• Build relationships with regulatory colleagues

	• Information resources
	
	The laboratory analyst has an awareness of collaboration on regulatory issues.
	• Communicate with partners/stakeholders
	  • Between agencies and across jurisdictions
	  o Interagency agreements
	• Regulatory education
	• Changes/additions to laws and rules and fees are disseminated to industry groups
	• Advisory groups
	• Public hearings
		The laboratory analyst has an awareness that laboratory test results and information are used to support regulatory activities.
		
		The laboratory analyst has an awareness that laboratory test results and information are used by regulatory programs in the education of stakeholders.

Laboratory Policies and Procedures	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The authorities and processes that describe how laboratories function. **Level 4 Module TLO:** Discuss laboratory policy and procedures. **Level 5 Module ELOs:** • Explain important aspects of regulatory test methods. • Explain how elements of sample testing support evidence development.	The laboratory analyst has knowledge of method fit for purpose. • Different sample types ▪ Surveillance versus investigation • Method validation for a specific matrix • Documentation of method modification • Use of established methods The laboratory analyst has knowledge of documentation protocols. • Error correction protocol • Procedure to request deviations • Worksheets are subject to FOIA (open records law) The laboratory analyst understands outcome of data. • Importance of quality control • Results are testimony	The laboratory analyst can utilize critical thinking skills to provide feedback on laboratory policies and procedures. • Identify weaknesses in procedures • Ask for clarification of policies and procedures The laboratory analyst has an awareness that human and animal food sample testing may be performed at federal, state, and local levels using the same test methods. The laboratory analyst has an awareness that relevant lab accreditation at the state or local level allows for trust and acceptance of test data by federal agencies such as FDA and USDA.

	• Test results are impartial; the regulated community deserves unbiased treatment • Importance of timeliness The laboratory analyst has knowledge of evidence development. • Samples are evidence • Records are evidence • Standard operating procedures provide legal defensibility • Chain of custody • Authorizations to perform work The laboratory analyst has knowledge of communicating laboratory information. • Protocol for reporting preliminary results • Authorization to give opinions on testing performed • Confidentiality of information is a legal requirement • Social media is verboten • Samples may be proprietary	

E-16 Regulatory Sampling

Definition: The reasons samples are collected in regulatory human and animal food programs.

Level 2 Course TLO: Describe the importance of human and animal food regulatory sampling.

Level 3 Course ELOs:

- Communication
  - Describe the critical components of a sampling process.
- Leadership
  - Articulate condition of laboratory samples during receipt.
- Programmatic
  - Describe the importance of regulatory program quality criteria.
- Technical
  - Determine condition of the laboratory sample.

Sample Planning	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The process regulatory programs use to establish sampling objectives. **Level 4 Module TLO:** Discuss the relationship between the program and the laboratory to meet sampling objectives.	The laboratory analyst has an awareness of sampling program. • Correct lab contacts • Sampling plan The laboratory analyst has an awareness of collection materials. • Sample containers • Supply inventory • Sampling tools	The laboratory analyst has knowledge of the details of sampling program. • Sampling plan • Which lab/lab capability • Sampling requirements, right type • Concept of representative samples, sub-samples, test sample, retain sample

Level 5 Module ELOs: • Differentiate regulatory program requirements. • Discuss laboratory resources required to accommodate a sampling plan. • Discuss the relationship between sampling data quality criteria and fit for purpose decisions. • Identify sample retention requirements.	The laboratory analyst has knowledge of sample documentation. • Concept of chain of custody • Sample submission form The laboratory analyst can generally describe the sample retention requirements.	• Sample size • Labeling requirements • Awareness of time limited samples • Resource costs involved in getting a sample to the lab • Reason for collection (decision unit) • Sample acceptance/rejection criteria The laboratory analyst has knowledge of the documentation process. • Tampering/adulteration • Sample documentation requirements (photos) • Temperature controls The laboratory analyst has an awareness of GOODsamples. The laboratory analyst has an awareness of the concept of data quality objectives as it relates to fit for purpose. The laboratory analyst can describe in detail the sample retention requirements. The laboratory analyst has knowledge of sample retention requirements. • Understand the sample retention schedule • Determine which samples are to be disposed of • Confirm that the compliance process is completed • Sample retention requirements are documented The laboratory analyst has an awareness that sample records are retained according to records retention requirements.

Sample Collection	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Elements of the sample collection process. **Level 4 Module TLO:** Discuss the sample collection process. **Level 5 Module ELOs:** • Discuss the elements of sample collection. • Discuss how to maintain sample integrity from collection to submission.	The laboratory analyst has knowledge of sample integrity. • Aseptic • Prevention of cross-contamination • Tampering The laboratory analyst can describe sampling requirements. • Follow SOPs • By official personnel with specific training • Chain of custody • Awareness of sampling program • Awareness of sampling guidelines • Collected based on sampling plan • Proper size • How many sub-samples need to be collected	The laboratory analyst has an awareness of GOODsamples. The laboratory analyst can suggest improvements. The laboratory analyst can provide advice.

Sample Submission	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: How regulatory samples are provided to the laboratory. **Level 4 Module TLO:** Explain the sample submission process. **Level 5 Module ELOs:** • Discuss the process for assessing sample acceptability. • Relate acceptance criteria to regulatory program quality requirements. • Relate acceptance criteria to sample quality criteria.	The laboratory analyst has an awareness of sample custodian roles and responsibilities. • Adhere to chain of custody • Maintain storage and environmental controls • Verify sample integrity/tampering • Receipt and routing • Follow SOPs The laboratory analyst has an awareness of sample documentation. • Sample submission form • Assignment of unique lab ID • Ensure documentation matches the sample • Labeling	The laboratory analyst can perform troubleshooting. • How to handle broken containers • How to handle submission errors The laboratory analyst can participate in process improvement. • Assist with sample receipt process • Give advice to submitters The laboratory analyst has an awareness of the mechanisms by which the laboratory communicates with customers. • Chain of command

	The laboratory analyst has an awareness of sample requirements. • Accept and reject criteria • Preservation requirements • Temperature check • Sample collection under proper conditions • Packaging requirements • Sterility controls • Prevention of cross contamination • Expedite time limited samples • Inspector submitted The laboratory analyst has an awareness of sample handling. • Aliquot/splitting of samples • Sample plan • Waste The laboratory analyst has an awareness of sample transport. • Shipping • Carrier • Proper shipping coordination • Shipping and transport regulations	• Identifying and documenting corrective action needs for customers • Providing feedback on sample issues • Education/technical assistance of inspection staff

E-17 Safety

Definition: The condition of being free from danger, risk, or injury.

Level 2 Course TLO: Describe safe laboratory practices.

Level 3 Course ELOs:

- Communication
  - Explain safe laboratory practices.
- Leadership
  - Demonstrate safe laboratory practices.
- Programmatic
  - Explain the importance of safe laboratory practices.
- Technical
  - Apply safe laboratory practices.

Laboratory safety	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to laboratory safety. **Level 4 Module TLO:** Discuss laboratory safety. **Level 5 Module ELOs:**	The laboratory analyst can list a number of general safety practices. • Role and responsibility of employees • Safety plans o Inspections • Waste management	The laboratory analyst can explain general safety practices. The laboratory analyst can explain the elements of an emergency response plan.

• Explain general safety practices. • Explain the emergency evacuation plan. • Explain the main principles of a biosafety plan. • Explain the main principles of a chemical hygiene plan. • Explain spill response process.	• Spill clean-up and protocols • Handwashing • Safe work practices • Safety tools • PPE • First aid/CPR/AED training • Security • Maintenance schedules for fire extinguishers, safety equipment, eye wash station, showers • Required training • Documentation • Safety committee The laboratory analyst can list some of the elements of an emergency response plan. • Evacuation • Role and responsibility of employees • Spill clean-up • PPE • Safety tools • First aid • Security • Drills • Active shooter scenario procedures • Required training • Documentation The laboratory analyst can list some of the elements of a biological safety plan. • Role and responsibility of employees • Waste management • Biosafety cabinet operations • Spill clean-up and protocols • Safe work practices • Safety tools • PPE • Security • Required training • Documentation	The laboratory analyst can explain the elements of a biological safety plan. The laboratory analyst can explain the elements of a chemical safety plan. The laboratory analyst can suggest safety process improvements. The laboratory analyst can demonstrate safety leadership. • Assist on safety audits • Participate on safety committee • Conducting safety training • Participate as a floor warden • Take the lead during a safety incident if supervisor is out

	• Safety laws o SDS o Select agent laws o Proper labels and labeling The laboratory analyst can list some of the elements of a chemical safety plan. • Role and responsibility of employees • Waste management • Fume hood operations • Spill clean-up and protocols • Safe work practices • Safety tools • PPE • Gas cylinder safety • Security • Required training • Exposure monitoring • Documentation • Safety laws o Right to know law o SDS o Proper labels and labeling	

Facility	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: The impact of building design on laboratory safety. **Level 4 Module TLO:** Describe how the physical environment impacts safety. **Level 5 Module ELOs:** • Discuss the elements of a safety floor plan. • Describe the impact of utility interruptions. • Discuss laboratory storage measures. • Discuss laboratory security measures	The laboratory analyst can list items in building design that impact safety. • Exits • Specific evacuation routes • Doors • Handicapped accessibility • Blocking aisles and spacing • Fire marshal requirements • Building maintenance • Floods • Fire suppression system • Security • Safety equipment	The laboratory analyst can recognize the impact of building design on workflow. • Specific biosafety requirements • Outstanding security rooms The laboratory analyst can recognize the impact of building design on staff. • Communication between buildings during fire drills or evacuations • Co-location with non-laboratory analysts • Number of floor wardens

	The laboratory analyst can recognize the impact of utility interruptions. • Airflow and air quality • Air monitoring systems • Back-up power generation • Emergency power The laboratory analyst can recognize the purpose of various storage types. • Enough storage space • Chemical storage • Separation of storage • Refrigeration • Explosion-proof storage rooms • Secure sample storage • Waste	The laboratory analyst can identify and report safety issues/risks related to building design. The laboratory analyst can suggest process improvement related to building design. The laboratory understands that when possible, engineering controls to remove a hazard is preferable to the use of PPE to prevent a harm from a hazard.

Personal Protective Equipment (PPE)	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**

Definition: Articles worn to protect laboratory personnel.
 	
Level 4 Module TLO: Describe personal protective equipment.
 	
Level 5 Module ELOs:
• Explain the importance of PPE.
• Select PPE for function.
	The laboratory analyst can explain when to use PPE.
	• To prevent harm from a hazard
	• Job hazard analysis, MSDS/MDS, SOP will identify hazards and appropriate PPE
	• PPE being used properly
	• PPE is available
	
	The laboratory analyst can list types of PPE.
	• Personal Clothing
	  o Long pants
	  o Closed toed shoes
	  o Lab Coats
	  o Lab Aprons
	• Gloves
		The laboratory analyst understands that when possible, re-engineering a process to remove a hazard is preferable to the use of PPE to prevent harm from a hazard.

	o Chemical Resistant ▪ Glove choice depends upon the chemical resistivity of the glove material ▪ Glove choice depends upon allergic sensitivity to glove materials o Heat Resistant o Cut and Puncture Resistant • Eye and Face Protection o Safety Glasses o Goggles • Respirators The laboratory analyst can describe requirements for respirator use. • Respirator choice dependent upon employers assessment of the hazard • May require fit testing • OSHA 1910.134 governs respirator selection and use	

Safety Equipment	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Equipment designed to mitigate the effects of laboratory hazards. **Level 4 Module TLO:** Describe laboratory safety equipment. **Level 5 Module ELOs:** • Explain the importance of safety equipment.	The laboratory analyst can describe the function of required safety equipment. • Fire extinguishers • Eyewash stations • Safety showers • Fire blankets • First aid kits • PPE	The laboratory analyst can assist with improvement to use/location of safety equipment.

• Select safety equipment for function. • Illustrate use of safety equipment.	• Chemical and biosafety hoods • Lifting tools • Safety carts (compressed gas) • Reagent carts • Safety stools • Ladders • Air flow monitor The laboratory analyst can utilize all required safety equipment. • Fire extinguishers • Eyewash stations • Safety showers • Fire blankets • First aid kits • PPE • Chemical and biosafety hoods	

E-18 Waste Management

Definition: The collection, transport, processing, disposal, and monitoring of laboratory waste materials.

Level 2 Course TLO: Explain laboratory waste management.

Level 3 Course ELOs:

- Communication
  - Describe laboratory waste management procedures.
- Leadership
  - Report waste management concerns.
- Programmatic
  - Describe laboratory waste management requirements.
- Technical
  - Apply laboratory waste management procedures.

Foundations	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Foundational knowledge related to the storage, treatment, transport, and disposal of biological and chemical waste. **Level 4 Module TLO:** Describe waste management in a laboratory. **Level 5 Module ELOs:** • Discuss the importance of waste management. • Describe biological waste management procedures. • Describe chemical waste management procedures. • Identify types of waste.	The laboratory analyst of what waste is. • SDS • Source of waste The laboratory analyst can list types of waste. • Chemical • Biological • Radiological • Recycling • Trash The laboratory analyst has knowledge of hazardous waste storage. • Roles and responsibilities • Segregate waste • Labeling waste • Determine if it needs to be treated or decontaminated • Awareness of storage limits • Place waste in collection locations in the lab • Inventory • Waste containers The laboratory analyst has knowledge of disposal process. • Documentation	The laboratory analyst can perform hazardous waste consolidation. • Assist in maintaining storage limits The laboratory analyst can assist with documentation. • Complete manifest • Assist in maintaining inventory The laboratory analyst can solve problems. • Responding to a spill • Recognition of deviations The laboratory analyst can assist with risk assessment.

Laws/Regulations	Based Upon Level 4 Competency – Not an all-inclusive list	
	BA Average Performance	**BA Outstanding Performance**
Definition: Legal and regulatory requirements related to waste management. **Level 4 Module TLO:** Describe legal/regulatory requirements related to waste management. **Level 5 Module ELOs:**	The laboratory analyst can follow SOPs. • Location of SOPs • Labeling requirements • PPE • Training • Compliance with laws and regulations • Track volume and disposition	The laboratory analyst understands the importance of following laws, regulatory requirements, and procedures. • Identify state and local requirements • Identify federal requirements • Identify regulatory requirements (ISO)

• Explain the main waste management regulatory requirements.	The laboratory analyst can access and interpret SDS. The laboratory analyst has knowledge of roles and responsibilities. • Knows identity of hazardous waste custodian • PPE • Training • Labeling • Support others in following the policies The laboratory analyst can report observed deficiencies. The laboratory analyst can follow exposure monitoring plan. Recognize the necessity of authorized waste management contractors.	• Violations risk losing certifications • Know legal requirements for appropriate waste streams • Help implement changes with new regulations The laboratory analyst can suggest improvements to the system. The laboratory analyst can guide others in following the policies. The laboratory analyst can assist in audits. • Assist with risk assessments

Transportation/Storage	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Moving and holding biological and chemical waste. **Level 4 Module TLO:** Describe the management of biological/chemical waste. **Level 5 Module ELOs:** • Describe transportation of waste. • Describe waste handling. • Describe the importance of labeling waste. • Differentiate among waste streams. • Recognize waste storage limits.	The laboratory analyst can follow SOPs. • Autoclaving procedures • Labeling • Decontamination • Treatment/neutralization • Spill response The laboratory analyst has knowledge of waste handling. • Where to put the waste • Differentiate types of waste • Differentiate waste stream • Storage • Disposal • Isolation • Inventory • Documentation and tracking	The laboratory analyst can assist with SOP development. • Articulate the basis of procedures and policies • Assist in writing or modifying SOPs • Describe the system of SOPs The laboratory analyst can assist with waste management. • Assist with inventory documentation • Be proactive so that capacities are not exceeded • Troubleshoot The laboratory analyst can assist with continuous improvement. • Suggest improvements

	The laboratory analyst has knowledge of waste handling compliance. • Roles and responsibilities • Training • Awareness of laws and requirements • Report deviations or non-conformance	• Improvement of the workflow • Assist in resolution of deviations or non-conformance • Assist with audits

Equipment/Supplies	**Based Upon Level 4 Competency – Not an all-inclusive list**	
	BA Average Performance	**BA Outstanding Performance**
Definition: Items and tools used in waste management. **Level 4 Module TLO:** Give examples of items and tools used in waste management. **Level 5 Module ELOs:** • Match the proper container to the type of waste. • Identify PPE used in waste management. • Describe disposal of contaminated PPE. • Identify equipment used in waste management.	The laboratory analyst has knowledge of disposal tools. • Charts with location of waste containers • Material pickup charts/schedules • Waste inventory • Shipping containers • Tracking logs • Documentation The laboratory analyst has knowledge of SOPs. • Safety procedures • Preventive maintenance schedule for autoclaves, cabinets, and hoods The laboratory analyst has knowledge of safety tools. • PPE • Spill kits • Handling materials • Signs and labels • Waste containers • Neutralization materials • Decontaminate agents • Explosion proof containers • Area wipes of benches • MSDS/SDS The laboratory analyst has knowledge of safety equipment. • Autoclaves • Chemical fume hood • Biosafety cabinet • Chemical storage cabinets	The laboratory analyst can suggest improvements. • Preventive actions • Suggest new tools or equipment • Critique tools and equipment • Assist in modifying SOPs