Advanced Quality Techniques

Note: Pre-requisite required.

Definition: Applying quality control and quality assurance tools to determine data fitness for purpose.

Level 2 Competency: Facilitate the use of advanced quality techniques.

Level 3 Competencies:

- Articulate the importance of advanced quality techniques - Communication
- Instruct others on advanced quality techniques - Leadership
- Explain the laboratory's use of advanced quality techniques - Programmatic
- Apply advanced quality techniques - Technical

Statistical Applications

BRAINSTORM

- Knowledge / Definitions of Calculations/Formulas (examples below)
  - Z-Scores
  - Percent Recovery
  - Standard deviation
  - Relative standard deviation
  - Average/mean
  - CV (Coefficient of variation)
- Random error
- Systematic error/bias
- Uncertainty/Total Analytical Error (TAE)
- Horowitz
- Rounding Rules
- Significant Figures
- Charting and Associated Rules
- Total sampling error
  - AIE (Analytical Integrity Error)
  - CIE (Contamination Introduction Error)
  - EME (Extraneous Material Error)
  - FSE (Fundamental Sampling Error)
  - GSE (Grouping and Segregation Error)
  - IDE (Increment Delimitation Error)
  - IEE (Increment Extraction Error

	○ IWE (Increment Weighting Error) ○ MRE (Mass Recovery Error) • Uniformity and stability studies
Definition: Statistical applications in relation to advanced quality techniques. **Level 4 Competency:** Apply statistics.	
1. Level 5 Competency: Perform data reduction.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can explain data reduction strategies, such as: a. Rounding b. Using averages c. Standard deviation d. Significant figures e. Dilution factors f. Correcting for recovery g. Apply conversion factor 2. The laboratory analyst can evaluate data reduction. 3. The laboratory analyst can properly input data.	1. The laboratory analyst can determine which reduction strategy applies. 2. The laboratory analyst can articulate the strengths and weaknesses of different strategies.
2. Level 5 Competency: Evaluate control charts.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can apply the appropriate tools for control charting. 2. The laboratory analyst can detect trends, such as: a. Detect when a process is in questionable control. b. Detect when a process is out of control. 3. The laboratory analyst can apply control chart rules. a. Westgard	1. The laboratory analyst can interpret control chart information, such as: a. Data deviations / deviation points b. Trends / tracking 2. The laboratory analyst can investigate the reasons for trends. ** Note: From ISO 2017 - resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.*

3. Level 5 Competency: Estimate measurement uncertainty.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can apply appropriate calculations to estimate measurement uncertainty. 2. The laboratory analyst recognizes the steps taken to determine the measurement uncertainty. 3. The laboratory analyst recognizes the role of standard deviation in measurement uncertainty. 4. The laboratory analyst can identify parameters impacting uncertainty budget.	1. The laboratory analyst can interpret the utility of the measurement uncertainty. 2. The laboratory analyst can communicate the value of the measurement uncertainty to the customer. 3. The laboratory analyst can calculate measurement uncertainty. 4. The laboratory analyst can evaluate measurement uncertainty for subsequent testing or calibration. 5. The laboratory analyst can assist in risk assessment using measurement uncertainty.
4. Level 5 Competency: Discuss the relationship between total sampling error and total analytical error.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize how total sampling error and total analytical error relate to global estimation error. 2. The laboratory analyst can recognize the impact of total sampling error. 3. The laboratory analyst can recognize the impact of total analytical error. 4. The laboratory analyst can recognize how the key components of Good Test Portions relate to measurement quality.	1. The laboratory analyst can communicate the impact of total sampling error to the customer. 2. The laboratory analyst can communicate the impact of total analytical error to the customer. 3. The laboratory analyst can explain global estimation error. 4. The laboratory analyst can describe sources of fundamental sampling error. 5. The laboratory analyst can describe the sources of grouping and segregation error.

** Note: Definition of total sampling error from Good Test Portions - Error from all non-selection and selection processes that causes the concentration or characteristic of the test portion to deviate from the true concentration or characteristic of the decision unit. The major components of total sampling error are AIE, CIE, EME, FSE, GSE, IDE, IEE, IWE, and MRE.*

Customer Requirements

BRAINSTORM

- Method selection
- Assessment criteria
- Grants/contract
- Standards
  - Manufactured Foods/Manufactured Food Regulatory Program Standards (MFRPS)
  - Retail Foods/Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)
  - Dairy
  - United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS)
  - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Animal Feed Regulatory Program Standards (AFRPS)
  - National Environmental Laboratory Accreditation Conference (NELAC)
  - Clinical Laboratory Improvement Amendments (CLIA)
  - International Organization for Standardization (ISO)
- Methods reporting requirements
  - Methods for determining Reporting Limits (e.g. Limit of Quantitation (LOQ), Method Detection Limit (MDL)) – Different techniques between the three regulatory agencies (and within programs) above
  - Significant figures
  - Reporting units
  - Formatting
  - Differences between Environmental Protection Agency (EPA)/Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) Rounding Rules (Round even versus Round up)
  - Method reference
  - Quality Control (QC) results
  - Uncertainty
  - Disposition

Definition: Requirements related to reporting.

Level 4 Competency: Administer customer requirements.

1. Level 5 Competency: Demonstrate knowledge of quality standards/regulations appropriate for the customer.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
Note: Please define in the context of the following BAs as review only or as a lead-in 1. The laboratory analyst can define quality standards/regulations. 2. The laboratory analyst can employ the appropriate customer quality requirements, such as: a. Regulatory i. FDA ii. USDA iii. EPA iv. Dairy v. FIFRA b. Non-regulatory i. Pesticide Data Program (PDP) or other customers c. ISO Standard 3. The laboratory analyst can identify which quality standard/regulations are appropriate for the customer, such as: a. Code of Federal Regulations (CFR) b. Federal Register c. ISO	1. The laboratory analyst can facilitate the use of appropriate customer quality requirements. 2. The laboratory analyst can interpret customer quality requirements. 3. The laboratory analyst can verify that customer quality requirements are met. 4. The laboratory analyst can identify which sections of the quality standard/regulations are appropriate for the customer. a. CFR b. Federal Register c. ISO

2. Level 5 Competency: Determine methods for use based on customer requirements.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can employ the appropriate methods that meet customer requirements. a. Validated method b. Verified method c. Fit for purpose	1. The laboratory analyst can select appropriate methods or procedures that are capable of meeting the customers' requirements (extracted from ISO/IEC 17025:2017). 2. The laboratory analyst can recommend appropriate methods to the customer.

2. The laboratory analyst can confirm that the correct methods are used. a. Validated method b. Verified method c. Fit for purpose i. e.g., reporting limits (different commodities have different regulatory limits – ppm)	
3. Level 5 Competency: Report results based on customer requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can select the appropriate reporting language, such as: a. Methods for determining reporting limits (LOQ, MDL, etc.) b. Significant figures c. Reporting units d. Formatting e. Differences between EPA/FDA and USDA rounding rules (round even versus round up) f. Method reference g. QC results h. Uncertainty 2. The laboratory analyst can provide the results in a report: a. Accurately b. Clearly c. Unambiguously d. Objectively e. Based on the information agreed with the customer. 3. The laboratory analyst can review reports for: a. Completeness b. Accuracy	1. The laboratory analyst can select appropriate disclaimers or qualifiers. 2. The laboratory analyst can identify in a data package the need for a disclaimer/qualifier: a. Exceptions to sampling b. Deviations from the method c. Background contamination d. Reduced recovery e. Matrix interference 3. The laboratory analyst can interpret data, such as: a. Significance of compliance levels b. Regulatory limits c. Health advisory limits

Quality Tools

BRAINSTORM

- National Institute of Standards and Technology (NIST)
- Charting referenced in (Critical Thinking M5)
  - Histograms
  - Pareto chart
  - Gantt chart
  - Cause and effect diagram
    - fishbone diagram
    - Ishikawa diagram
- Blanks
- Replicates
- Spikes
- Swipes/swab
- Control samples
- Reference cultures
- Risk assessment tools
- Media controls
- Data loggers
- Certified Reference Materials (CRMs)
- Competency
- Traceability
- Environmental monitoring
- Internal audits
- Validation
- Verification
- Platform/matrix extension
- Proficiency Testing (PT)
- Application
  - Statistics Software
  - Excel
  - Laboratory Information Management System (LIMS) - Basic Stat Package imbedded in program
- Choice of statistical treatment

Definition: Use of quality tools to monitor the accuracy and quality of processes.

Level 4 Competency: Identify quality control tools.

1. Level 5 Competency: Apply statistical software applications.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can list commonly used software applications, such as: a. Statistical software (e.g., SAS, Stata, R, Northwest Analytical, Graphpad Prism, etc.) b. Excel c. LIMS d. Control charting 2. The laboratory analyst can choose an appropriate application for the data set. 3. The laboratory analyst can apply the appropriate statistical techniques to evaluate data.	1. The laboratory analyst can recommend QC application acquisitions. 2. The laboratory analyst can develop the laboratory quality control tool specifications. 3. The laboratory analyst can recognize the strengths and limitations of the statistical applications.

2. Level 5 Competency: Incorporate quality assurance processes.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can explain the impact of the following on quality assurance, such as: a. Expired reagents b. Calibration standards c. Internal standards d. Surrogate compounds e. Storage conditions 2. The laboratory analyst can determine appropriate controls: a. Reference b. Replicates c. Blanks d. Spikes e. Control samples 3. The laboratory analyst can assess the impact of quality control deviations. 4. The laboratory analyst can contribute to an internal audit.	1. The laboratory analyst can assist with an assessment of the laboratory's quality assurance plan. a. Identify gaps in the laboratory's quality assurance plan b. Monitor the effectiveness of laboratory's quality assurance plan c. Plan for an internal audit 2. The laboratory analyst can identify and correct problems. 3. The laboratory analyst can perform an internal audit. 4. The laboratory analyst can assure quality test results: a. Accurate b. Reliable c. Timely reporting d. Consistent 5. The laboratory analyst can develop tools for quality assurance: a. Quality checklist b. Quality-specific forms for the analysis

Quality Management

BRAINSTORM

- Interpretation
  - Trend analysis
  - "Out-of-Control" and steps to correct (Move to Failure investigation, tools)
  - Proficiency Testing (PT) Reports
  - Interpretation
- Investigation
  - AAFCO PTP /QRM Failure Investigation
    - Clerical
    - Calculations
    - Calibration
    - QC
    - Method/Procedures
    - Sample Handling
  - Root cause analysis (cause mapping)
  - Assessment of QC failure or trend
  - Assess deviation/non-conformance
- Assessment criteria
- Correction
- Corrective action
- Improvement

Definition: Processes for managing quality objectives.

Level 4 Competency: Monitor ongoing quality data.

1. Level 5 Competency: Evaluate quality data.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can detect key indicators from quality data, such as: a. Trends b. Outliers c. Extrapolate relevant data points 2. The laboratory analyst can determine the impact on quality data of: a. Traceability b. Environmental monitoring c. Validation d. Verification e. Proficiency testing	1. The laboratory analyst can analyze key indicators from quality data, such as: a. Trends b. Outliers 2. The laboratory analyst can interpret quality data: a. Outside warning limits b. Outside control limits c. Risk d. Relevant data points 3. The laboratory analyst can recommend corrections. 4. The laboratory analyst can recommend corrective actions.

f. Instrument variation g. Deviations 3. The laboratory analyst can classify quality data based on key indicators: a. Risk b. Relevant data c. Irrelevant data	5. The laboratory analyst can perform root cause analysis.
2. Level 5 Competency: Evaluate feedback from proficiency testing (PT) results.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can explain Z-scores. 2. The laboratory analyst can identify trends in proficiency testing results: a. Individual b. Laboratory-wide 3. The laboratory analyst can explain the impact of PT: a. Laboratory quality management system b. Accreditation c. Certification d. Analytical system e. Demonstrating competency	1. The laboratory analyst can calculate a Z-score. 2. The laboratory analyst can describe the use of PT results in improving/monitoring the laboratory's performance. 3. The laboratory analyst can explain follow-up actions of failing a PT, such as: a. initiate a PT failure investigation. b. Recommend corrective action 4. The laboratory analyst can interpret differences in PT provider reports, such as: a. AAFCO b. AOCS c. FAPAS d. FDA
3. Level 5 Competency: Report results of quality control events.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can communicate the cause and effect of a non-conformance. 2. The laboratory analyst can explain the importance of documenting a QC event. 3. The laboratory analyst can identify the key information critical in documenting QC events. 4. The laboratory analyst can recognize how a quality event impacts the report of analysis.	1. The laboratory analyst can recommend action based on data in the report of analysis. 2. The laboratory analyst can identify how a quality event needs to be reported: a. Qualifiers b. Disclaimer

4. Level 5 Competency: Recommend actions.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can contribute to an investigation. a. Identify contributing causes b. Identify trends 2. The laboratory analyst can contribute to a root cause analysis.	1. The laboratory analyst can recognize when a root cause analysis needs to be conducted. 2. The laboratory analyst can lead an investigation. 3. The laboratory analyst can recognize when to close an event. 4. The laboratory analyst can contribute suggestions for improvement.

Evidentiary Integrity

Definition: Application of policies and procedures to ensure the authenticity and identity of evidence.

Level 2 Competency: Ensure evidentiary integrity.

Level 3 Competencies:

- Articulate the importance of evidentiary integrity - Communication
- Support the implementation of practices for maintaining evidentiary integrity - Leadership
- Explain the organization's need to maintain evidentiary integrity - Programmatic
- Apply evidentiary integrity processes - Technical

Evidence
BRAINSTORM • Sample Quality Criteria (SQC) • Policies • Procedures • Decision unit • Not one size fits all!! • Training records • Records management framework • Defensibility • Legal case • Evidence • Personnel training on evidence management • Standardized evidence management forms • Defined staff roles in evidence management • Audits of evidence management activities • Evidence anomalies-how to record • Subject Matter Experts (SMEs)
Definition: Testimony, documents, records, objects, etc., which may be presented as evidence to support a decision. **Level 4 Competency:** Characterize the connection between laboratory activities and legal evidence.

1. Level 5 Competency: Articulate the relevance of laboratory activities on evidentiary integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define evidentiary integrity. 2. The laboratory analyst can articulate the need for evidentiary integrity to ensure defensible test results. 3. The laboratory analyst can articulate that the evidentiary integrity lifecycle ("cradle to grave") starts with primary sample collection and continues through reporting results and disposal.	1. The laboratory analyst can compose portions of SOPs to enhance evidentiary integrity. 2. The laboratory analyst can articulate the components of evidentiary integrity from primary sample collection, through all laboratory processes, ending with reporting of results and final disposition of sample and records. 3. The laboratory analyst can describe the differences in evidentiary integrity processes for samples collected for different purposes, such as: a. Compliance b. Surveillance c. Monitoring
2. Level 5 Competency: Explain the laboratory analyst's role in maintaining evidentiary integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe records in their laboratory that may be used as evidence, such as: a. Document control b. Chain of custody records c. Laboratory analyst competency/training records d. Quality control records e. Calibration records f. Raw data 2. The laboratory analyst can explain the importance of records relevant to evidentiary integrity. 3. The laboratory analyst can identify issues that might impact evidentiary integrity, such as: a. Lack of information b. Records not being maintained c. Analyte integrity is compromised d. Representivity is compromised	1. The laboratory analyst can remediate evidentiary integrity non-conformities and other issues observed during the testing process. 2. The laboratory analyst can suggest improvements to evidentiary integrity processes.

3. Level 5 Competency: Employ metrological measurement system (SI).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define metrological measurement system. 2. The laboratory analyst can describe the importance of metrological measurement system in evidentiary integrity. 3. The laboratory analyst can implement metrological measurement system to support evidentiary integrity. 4. The laboratory analyst can maintain metrological measurement system: a. Document unbroken chain of calibrations b. Link calibration types to an appropriate reference i. NIST ii. International Bureau of Weights and Measures ***Note:*** We need to make sure that metrological traceability and reference materials are covered appropriately elsewhere.	1. The laboratory analyst can develop procedures for establishing metrological measurement system. 2. The laboratory analyst can identify challenges in implementing metrological measurement system.

Traceability

BRAINSTORM

- SQC
- Policies
- Procedures
- Decision unit
- Not one size fits all!!
- Training records
- Records management framework
- Traceability
- Chain of custody
- Containers/packaging
- Sealing/resealing of the container
- Condition upon receipt
- Sample ID
- Data and time collected
- Data storage and security
- Mishandling
- Tampering
- Intentional & unintentional
- When and how disposed
- Personnel involved
- Trace back
- Identity of evidence
- Shipping
- Shipping records
- Transfer records
- Forms
- Documentation
- Procedures
- Identity of evidence
- Unique sample identifiers—cross reference
- Recreate sample storage trail from the records
- Recreate sample ownership trail from the records
- Traceability of records—retrieving evidentiary records

Definition: Ability to trace test results (through all laboratory and sampling processes) to a sampled decision unit.

Level 4 Competency: Reconstruct the pathway from primary sampling to test results including disposition based on records.

1. Level 5 Competency: Describe activities to ensure traceability of the sample through its lifecycle.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can define traceability. 2. The laboratory analyst can describe the role of laboratory's quality system in traceability. 3. The laboratory analyst can describe the importance of tracing a test result to a decision unit. 4. The laboratory analyst can recognize policies relevant to traceability. 5. To establish evidentiary traceability, the laboratory analyst can describe the interdependent activities among various entities, such as: a. Collection b. Laboratory c. Compliance d. Management	1. The laboratory analyst can differentiate chain of custody, document traceability, metrological traceability, and traceback. 2. The laboratory analyst can assist in training on traceability processes. 3. The laboratory analyst can recommend activities to ensure evidentiary traceability.

2. Level 5 Competency: Perform procedures (SOPs) to support traceability of test results to the decision unit.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define the term "decision unit". 2. The laboratory analyst can explain the importance of unique sample identifiers to support traceability. 3. The laboratory analyst can explain the importance of proper documentation to support traceability. 4. The laboratory analyst can identify gaps in traceability. 5. The laboratory analyst can explain the impact of any deviation from a SOP on traceability. 6. The laboratory analyst can explain the impact of any deviation from chain of custody requirements on traceability. 7. The laboratory analyst can verify that documentation supports traceability.	1. The laboratory analyst can create or develop documents/forms to support traceability. 2. The laboratory analyst can review existing SOPs for traceability components. 3. The laboratory analyst can correct gaps in documentation. 4. The laboratory analyst can verify that the laboratory sample and analytical sample are consistent with the decision unit.

Analyte Integrity		
BRAINSTORM		
• Symptoms • Timeframe • Recognize what happened	• Cause and effect • Similar events • System failure	• Human error • Assumptions • When and where • Environmental factors

Definition: The characteristic or concentration of the analyte is maintained from collection of the primary sample through selection of the test portion, testing and disposal.

Level 4 Competency: Characterize processes for maintaining analyte integrity.

1. Level 5 Competency: Describe conditions critical for the integrity of a target analyte.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can define analyte integrity. (e.g., changes to chemical, biological, radiological, or physical characteristics of the analyte) 2. The laboratory analyst can recognize the impact of analyte integrity on evidentiary integrity. 3. The laboratory analyst can list issues that affect analyte integrity, such as: a. Oxidation/reduction b. Absorption c. Volatilization d. Bacterial growth 4. The laboratory analyst can explain how conditions are critical to maintaining analyte integrity, such as: a. Controlling temperatures b. pH c. Container compatibility d. Aseptic techniques e. Equipment compatibility f. UV g. Storage / holding times h. Aerobic / anaerobic	1. The laboratory analyst can troubleshoot instances where analyte integrity has been compromised. 2. The laboratory analyst can recommend activities to preserve analyte integrity. 3. The laboratory analyst can develop mechanisms to detect occurrences that may compromise analyte integrity. 4. The laboratory analyst can resolve errors that impact analyte integrity.

5. The laboratory analyst can recognize when analyte integrity may be compromised. 6. The laboratory analyst can observe and record conditions related to maintaining analyte integrity. 7. The laboratory analyst can recognize errors that impact analyte integrity.	
2. Level 5 Competency: Evaluate procedures (SOPs) to ensure analyte integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can evaluate procedures for processes which may affect the integrity of analytes, such as: a. Degradation products of a specific analyte. b. Stability of their biological agents. 2. The laboratory analyst can recognize when analyte integrity procedures have not been followed. 3. The laboratory analyst can explain how quality control activities monitor for loss of analyte integrity.	1. The laboratory analyst can review procedures for effectiveness in maintaining analyte integrity. 2. The laboratory analyst can develop procedures for maintaining analyte integrity. 3. The laboratory analyst can design quality control practices to monitor for loss of analyte integrity.
3. Level 5 Competency: Evaluate risk of contamination.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize potential sources of contamination that compromise evidentiary integrity. 2. The laboratory analyst is familiar with processes used to prevent cross-contamination of the analyte, such as: a. Aseptic techniques b. Storage c. Environmental d. Containers 3. The laboratory analyst can explain the different points at which contamination might occur. 4. The laboratory analyst can detect that a contamination may have occurred, such as: a. Contamination from a control b. Sample to sample contamination c. Blanks (reagent, container, environmental, matrix, etc.)	1. The laboratory analyst can troubleshoot instances where contamination has been introduced. 2. The laboratory analyst can develop procedures to prevent contamination. 3. The laboratory analyst can design quality control practices to monitor for contamination.

Representivity

BRAINSTORM

- SQC
- Policies
- Procedures
- Equipment use (E5)
- Equipment maintenance (E5)
- Decision unit (all buckets)
- Not one size fits all!!
- Training records
- Records management framework
- Representivity
- Analyte of interest
- Sampling tools used
- Final mass of sample
- Validation of selection processes
- Validation of non-selection processes
- Validation of laboratory sampling processes
- Equipment used
- Inference
- Total sampling error
- Global sampling error
- Sample correctness
- Sufficient mass
- Sufficient increments
- Random increments
- Authenticity of evidence
- Control of random error
- Quality control
- Control of systematic error (bias)
- Relate sampling error to selection of sufficient mass.
- Relate sampling error to selection of sufficient number of increments.
- Relate sampling error to sample correctness

Definition: The test portion provides confidence that the systematic error is controlled throughout all sampling processes (sample correctness is maintained) and that the random error meets the requirements of the sample quality criteria.

Level 4 Competency: Confirm test results are representative of the decision unit.

1. **Level 5 Competency:** Evaluate procedures (SOPs) to ensure test portion is representative of the decision unit.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can recognize the importance of test portions being fit for purpose (fit for decision) with respect to maintaining evidentiary integrity. 2. The laboratory analyst can explain the importance of practices consistent with the selection of a representative test portion. a. Processing the entire laboratory sample b. Representative splitting procedures c. Sufficient mass d. Sufficient increments e. Adequate particle size	1. The laboratory analyst can develop validation to determine whether the test portion mass is fit for purpose. 2. The laboratory analyst can develop a validation to demonstrate representative test portion selection. 3. The laboratory analyst can recommend ways to obtain a representative test portion from novel or challenging matrices.

3. The laboratory analyst can determine whether a test portion mass is fit for purpose. 4. The laboratory analyst can perform representative test portion selection.	
2. Level 5 Competency: Describe how sampling errors impact evidentiary integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list errors contributing to total sampling error, such as: a. Fundamental Sampling Error (FSE) b. Grouping and Segregation Error (GSE) c. Increment Delimitation Error (IDE) d. Increment Extraction Error (IEE) e. Increment Weighting Error (IWE) 2. The laboratory analyst can provide examples of errors, such as: a. Fundamental Sampling Error (FSE) b. Grouping and Segregation Error (GSE) c. Increment Delimitation Error (IDE) d. Increment Extraction Error (IEE) e. Increment Weighting Error (IWE) 3. The laboratory analyst can describe the importance of minimizing sampling errors to maintaining evidentiary integrity. 4. The laboratory analyst can minimize error in preparing the analytical sample and selecting the test portion. (non-selection & selection processes).	1. The laboratory analyst can troubleshoot/mitigate sampling errors. 2. The laboratory analyst can develop procedures that minimize sampling errors. 3. The laboratory analyst can explain how sampling errors impact test results. 4. The laboratory analyst can identify gaps in laboratory sampling quality control practices.
3. Level 5 Competency: Relate the importance of laboratory sampling to evidentiary integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize the importance of verification/validation of laboratory sampling protocols as related to maintaining evidentiary integrity. 2. The laboratory analyst can recognize the importance of the sampling protocol to account for and mitigate analyte heterogeneity.	1. The laboratory analyst can validate a laboratory sampling protocol. 2. The laboratory analyst can calculate error associated with a sampling protocol.

3. The laboratory analyst can identify the need for comprehensive laboratory sampling procedures to support representivity. 4. The laboratory analyst can recognize the importance of laboratory sampling quality control practices.	

Human and Animal Food Incident Response

Definition: Laboratory practices for responding to public or animal health related events.

Level 2 Competency: Describe the framework of incident response.

Level 3 Competencies:

- Describe the flow of information in an incident response - Communication
- Describe how the laboratory responds to an incident - Leadership
- Explain how regulatory jurisdiction impacts planning - Programmatic
- Propose a testing plan - Technical

Causative Agents		
BRAINSTORM		
• Toxins • Pathogens • Pharmaceuticals • Chemical Agents	• Pesticides • Unknowns • Epidemiology	• Needle in a haystack • Field Information • Radiation • Veterinary drugs

Definition: Analytes of interest, known and unknown, that have the potential to cause a human or animal food incident.

Level 4 Competency: Determine approach to identify analytes of interest.

1. Level 5 Competency: Give examples of analytes of interest.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can name approx. 5 common analytes of interest in the context of an event: a. Salmonella b. Listeria c. Melamine d. Norovirus e. Heavy metals	1. The laboratory analyst can go more in depth about the analytes they have named. 2. The laboratory analyst can list approx. 5 more above and beyond the average level. 3. The laboratory analyst can explain relationships between outbreak types and analytes of interest.

f. Toxins g. Polycyclic aromatic hydrocarbons (PAH) h. Pentobarbital (dog food) i. Dioxins j. Enterohemorrhagic E. coli (EHEC) k. Pesticides l. Mycotoxins m. Antibiotics (feed and milk) 2. The laboratory analyst can associate typical analytes of interest with a specific food.	
2. Level 5 Competency: Recognize the complexity of the matrix.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify common inhibitors (interfering characteristics): a. Fat content b. pH c. Color d. Polymerase chain reaction (PCR) inhibitors (humic acid) 2. The laboratory analyst can explain various processing mechanisms for different food types: a. Stomaching (fish bones, piercing bags) 3. The laboratory analyst can identify 3 typical separation techniques used for matrices: a. Water extraction vs. soil b. Digestion c. Mixing (peanut butter) 4. The laboratory analyst can choose the appropriate methods.	1. The laboratory analyst knows how to overcome inhibitors: a. Dilution b. Adjusting the pH 2. The laboratory analyst can identify which mechanism is best. 3. The laboratory analyst knows when interfering characteristics cannot be overcome (hence, test results may be suspect). 4. The laboratory analyst can explain how types of matrices may be directly involved in an outbreak. 5. The laboratory analyst can contribute to the modification of methods to meet the need of the matrix. 6. The laboratory analyst can describe the sampling requirements that meet testing criteria.
3. Level 5 Competency: Identify technology needed to test for analytes.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe rapid screening platforms: a. PCR machines b. Enzyme-linked immunosorbent assay (ELISA)	1. The laboratory analyst can give the pros and cons of the various platforms.

c. Test Equipment Calibration Readiness Assessment (TECRA) d. Liquid Chromatography Mass Spectrometry (LCMS)/ Gas Chromatograph Mass Spectrometer (GCMS) e. Screening kits: i. Lateral flow device ii. Latex agglutination f. Test kit (allergen testing, pesticides) 2. The laboratory analyst can choose the correct approved methods. 3. The laboratory analyst can use the technology or method to confirm the presence of the analyte. (e.g., Bacteriological Analytical Manual (BAM), Pesticide Analytical Manual (PAM), Association of Official Analytical Chemists (AOAC), Microbiology Laboratory Guidebook (MLG), etc.)	2. The laboratory analyst can suggest alternate (non-standard) methods.
4. Level 5 Competency: Describe expertise needed to test for various analytes.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify sources of expertise: a. Experts within the lab (SMEs) b. References (Codex, BAM, (AOAC) c. Authors of methods 2. The laboratory analyst can identify sources of expertise related to instruments. (e.g., manufacturer rep)	1. The laboratory analyst can identify external sources of expertise: a. SMEs from laboratory networks Food Emergency Response Network (FERN) b. Authors of methods c. Listservs, including Ag Labs 2. The laboratory analyst can begin to troubleshoot. (is beginning to become an expert) 3. The laboratory analyst contributes to a published study.

Testing Protocols

BRAINSTORM

- Chain of Custody
- Evidence
- Fit for Purpose Test Methods
- Minimal Verification
- Emergency
- Field Information
- Inspection Reports
- Multi Analyte Methods
- FERN Methods
- Unknown
- Ad hoc method development
- Prioritization/triage
- Epidemiology
- Chemistry Know-How
- Attributes and Skills versus Standard test methods
- Identity versus numerical value
- Methods
- Follow-Up testing
- Needle in a haystack
- Regulatory Action Limits
- Procedures
- Imperfect Samples

Definition: Standard and non-standard testing protocols used to identify analytes of interest that have the potential to cause a human or animal food incident.

Level 4 Competency: Discuss testing approaches in response to an event.

1. Level 5 Competency: Describe the flow of testing.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can help with creating a testing scheme for a stated number of samples: a. Assisting in designing surge capacity testing/capabilities 2. The laboratory analyst can prioritize (triage) samples. 3. The laboratory analyst can differentiate between presumptive and confirmatory tests: a. Continue processing samples b. Requirements before reporting 4. The laboratory analyst knows when to notify management of any preliminary findings.	1. The laboratory analyst can explain the turnaround time for testing in relation to the number of samples. 2. The laboratory analyst can capitalize on downtime (incubation periods, digestions) to increase efficiency. (i.e., catch up on paperwork) 3. The laboratory analyst is aware of post-analysis data review. 4. The laboratory analyst can independently design surge capacity workflow. 5. The laboratory analyst can prioritize or triage non-standard samples.

2. Level 5 Competency: Identify the limitations of approved test methods.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize false positive or false negative results. 2. The laboratory analyst can recognize the type of data that has resulted from a test. (e.g., DNA detected does not mean viable organism present) 3. The laboratory analyst recognizes the differences between approved methods for an analyte. (e.g., atrazine in water vs. atrazine in produce)	1. The laboratory analyst can troubleshoot false positive or false negative results. 2. The laboratory analyst can verify an approved test method on an alternate matrix. 3. The laboratory analyst can verify an alternate method for the test sample matrix.
3. Level 5 Competency: Differentiate between standard and non-standard testing protocols.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify a standard testing protocol. 2. The laboratory analyst can identify a non-standard testing protocol. 3. The laboratory analyst can identify an "on the fly" testing protocol (when nothing else exists): a. Different extraction solvent b. Different technology for digestion c. No approved technologies or standards	1. The laboratory analyst knows when a particular testing protocol may be appropriate 2. The laboratory analyst can design a non-standard protocol 3. The laboratory analyst can suggest a non-standard protocol for approval.
4. Level 5 Competency: Explain the relevance of test data.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can explain test confidence limits. 2. The laboratory analyst can identify stakeholders. 3. The laboratory analyst can recognize the implications of reporting erroneous data. 4. The laboratory analyst can recognize the importance of accuracy, quality, and turnaround time in reporting test results. (better to be right than first)	1. The laboratory analyst can identify how stakeholders use data to assure a safe food supply. 2. The laboratory analyst can suggest ideas to streamline results. 3. The laboratory analyst can suggest ideas to make result reporting clearer and more concise. 4. The laboratory analyst can rule in or rule out data related to the incident.

Lab Operational Considerations		
BRAINSTORM		
• Time of the Essence • Work Long Hours • All hands on deck • HR rules • Overtime • Fair Labor Standards Act (FLSA)	• Capacity Limitations • Back-Up Capacity • Emergency • Types of incidents/level of intensity may vary • Networks (FERN), Laboratory Response Network (LRN), Pulsed-field gel electrophoresis (PFGE), Veterinary Laboratory Investigation and Response Network (Vet-LIRN), etc.)	• Needle in a haystack • Follow-Up testing • Identity versus numerical value • Resources • Prioritization/triage • Continuity of operation planning (COOP)

Definition: Recognition of how an incident may impact operations within the laboratory, and contributing information related to resources, capacity, and personnel to assist with operational planning.

Level 4 Competency: Recognize the importance of a resource utilization plan.

1. Level 5 Competency: Relate resources to response capacity.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can prepare the resources needed to test a stated number of samples: a. Reagents b. Materials c. Supplies d. Space e. Personnel (lab staff, staggered hours) f. Instruments and equipment (pipettes, balances, calibrated, standardized) 2. The laboratory analyst can calculate the reagents needed for a particular instrument. (e.g., 10 samples at a time vs. 30 samples at a time) 3. The laboratory analyst can identify staff training competencies: a. Consult training/personnel records	1. The laboratory analyst can estimate resources for *new or modified tests.* 2. The laboratory analyst can *create a timeline* in preparation for the arrival of samples. 3. The laboratory analyst can prepare the resources needed during *surge capacity (high throughput).* 4. The laboratory analyst can determine whether high throughput instrumentation is needed to meet turnaround time. 5. The laboratory analyst can prepare for surveillance/follow-up testing to provide data to monitor incident recovery. 6. The laboratory analyst can provide necessary training. 7. The laboratory analyst can inform what training is needed.

4. The laboratory analyst can recognize competency gaps related to staff. 5. The laboratory analyst can identify the number of staff needed for the current event. 6. The laboratory analyst can determine the appropriate instruments that can test for the number of samples. (high throughput vs. regular) 7. The laboratory analyst can identify other assays that can use that platform. 8. The laboratory analyst can keep the instrument(s) running or can find someone to keep the instrument(s) running. 9. The laboratory analyst can determine order points and cost estimates. 10. The laboratory analyst can identify/locate alternate sources: a. Vendors b. Other laboratories (universities, state labs) c. FERN 11. The laboratory analyst can conduct an inventory of supplies. 12. The laboratory analyst can prepare reagents.	8. The laboratory analyst can identify the number of staff needed for long-term planning. (sprint vs. marathon, avoiding burnout) 9. The laboratory analyst can explain their role during a COOP activation. 10. The laboratory analyst can identify alternate instrumentation that can be used in support of the incident. 11. The laboratory analyst recognizes when instrument maintenance falls under warranty or outside maintenance agreement. 12. The laboratory analyst can anticipate scheduled (annual, monthly, etc.) instrument maintenance with an outside vendor. 13. The laboratory analyst can identify external sources for equipment. (loaners, rentals, etc.) 14. The laboratory analyst can verify alternative products. 15. The laboratory analyst can ensure the quality of in-house prepared reagents. (MacGyver) 16. The laboratory analyst can prepare for surge capacity inventory. (pipette tips/class A glassware)
2. Level 5 Competency: Recognize the impact of time-is-of-the-essence testing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can communicate the impact to other ongoing lab functions. 2. The laboratory analyst can explain the impact of testing delays. (instrument not working, lack of consumables/supplies) 3. The laboratory analyst can proactively prepare in anticipation of sample arrival.	1. The laboratory analyst can come up with an alternate schedule/solution. (extend turnaround time, contact customers) 2. The laboratory analyst can propose alternative work schedules. (10-hr days, Mon-Fri, Tue-Sat, shifting work schedules)

Incident Characteristics		
BRAINSTORM		
• Not animal diseases • Human Food • Animal Food • Animal health impacts human food supply • Types of incidents/level of intensity may vary • Intentional	• Accidental • Field Information • Inspection Reports • Imperfect Samples • Chain of Custody • Evidence	• Procedures • Collaboration • Epidemiology • Identity versus numerical value (qualitative vs. quantitative) • Concentrations • Geo spatial
Definition: The elements to be considered when planning for a laboratory response. **Level 4 Competency:** Characterize the elements of a human or animal food incident that shape a laboratory response.		
1. Level 5 Competency: Describe laboratory planning / response to adverse incidents.		
Based on Level 5 competency – Not an all-inclusive list		
BEHAVIORAL ANCHORS Average		**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe a small-scale event. 2. The laboratory analyst can describe a large-scale event. 3. The laboratory analyst can relate types of incidents/outbreaks to specific lab requirements: a. Chemical, biological, radiological, nuclear, explosive materials (CBRNE + P) b. Testing requirements c. Staffing d. Supplies e. Reporting 4. The laboratory analyst recognizes how intentional and accidental events may differ in planning and response: a. Intentional b. Unintentional c. Economic impact 5. The laboratory analyst can describe zoonotic diseases: a. Impact on animals b. Impact on humans 6. The laboratory analyst recognizes when a COOP may be activated.		1. The laboratory analyst can relate a disease event that occurs from a small-scale event. 2. The laboratory analyst can relate a disease event that occurs from a large-scale event. 3. The laboratory analyst can assist with contingency plans for various types of incidents: a. Intentional b. Unintentional

7. The laboratory analyst recognizes their role during a COOP activation.	
2. Level 5 Competency: Explain the importance of field investigation information.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst recognizes the field investigation information that is needed for or relevant to their analysis. 2. The laboratory analyst recognizes that data from the field impacts their activities. 3. The laboratory analyst can capture and document all relevant data. 4. The laboratory analyst can identify the field investigation information that might be important. 5. The laboratory analyst can describe evidentiary considerations** related to field investigation information: a. Chain of custody b. Sample forms c. Traceability 6. The laboratory analyst can discuss legal implications: ** a. Findings could result in legal proceedings b. Freedom of Information Act (FOIA) (documentation – emails, etc.) c. Confidential information d. Proprietary information ** Evidentiary Integrity and Legal Proceedings are Mid-Level content areas – may be a prerequisite – or there may a sequencing issue among Evidentiary Integrity, Legal Proceedings, Incident Response	1. The laboratory analyst can apply field data to identify linkages to other cases.
3. Level 5 Competency: Describe the role of the laboratory in the epidemiological system.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe the role of an epidemiologist in an incident. 2. The laboratory analyst can explain how epidemiology drives sample collection during an incident. 3. The laboratory analyst can interpret the meaning of epidemiological data. 4. The laboratory analyst can define basic epidemiological terms:	1. The laboratory analyst can suggest sampling strategies within their purview.

a. Attack rate b. Risk c. Positive predictive values d. Morbidity e. Mortality 5. The laboratory analyst can describe the collaboration between the laboratory and epidemiology. a. The linkage between a positive sample and a genetic match / distinctive cluster markers.	

Regulatory Responsibilities		
BRAINSTORM		
• Cross Jurisdictional • Multi State • Emergency • Tribal • Territorial • Centers for Disease Control and Prevention (CDC) • Food and Drug Administration (FDA) • Environmental Protection Agency (EPA)	• United States Department of Agriculture (USDA) • Rapid Response Team (RRT) • Networks (FERN, LRN, FDA GenomeTrakr, VetLIRN, National Food Safety Data Exchange (NFSDX), Environmental Response Laboratory Network (ERLN), Department of Defense (DoD), etc.) • Incident command (Incident Command System (ICS), National Incident Management System (NIMS)) • Collaboration	• FERN Methods • Response and Recovery • Epidemiology • Follow-Up testing • State or Local • Primary agency

Definition: The regulatory authority associated with any human or animal food incident response.

Level 4 Competency: Describe how regulatory authorities interact with laboratories during an event.

1. Level 5 Competency: Relate the interaction of governmental agencies with the laboratory during an event..

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can name Federal agencies that may be involved: a. USDA b. FDA c. CDC d. DoD e. EPA f. United States Department of Commerce (USDC) g. Customs and Border Protection (CBP) h. Federal Emergency Management Agency (FEMA) i. Coast Guard	1. The laboratory analyst is aware of how Federal agency involvement might impact laboratory operations. 2. The laboratory analyst is aware of how Federal agencies may help laboratories during an event: a. Resources b. Training c. Supplies d. Laboratory networks (NFSDX, etc.) 3. The laboratory analyst is aware of how other entities may be involved. a. Manufacturers

2. The laboratory analyst can recognize how a multi-agency response might occur: a. Intrastate b. Interstate c. Federal d. Local e. Tribal f. Territorial	b. Producers

Laboratory Networks, Collaborations, and Interagency Programs

Definition: The laboratory's participation in governmental collaborations, interagency programs, and professional networks.

Level 2 Competency: Explain why laboratories participate in professional organizations.

Level 3 Competencies:

- Give examples of how professional organizations enhance information sharing - Communication
- Describe how participation in professional organizations promotes professional development - Leadership
- Explain how participation in professional organizations improves laboratory competency - Programmatic
- Identify resources available through participation in networks - Technical

Professional Networks

BRAINSTORM

- Scientific organizations
  - American Chemical Society (ACS)
  - AOAC International
  - International Association for Food Protection (IAFP)
  - Institute for Food Technology (IFT)
  - North American Chemical Residue Workshop (NARCW)
  - American Society for Microbiology (ASM)
- Professionalism
- Opportunities for growth by being an active member of an organization
- Networking
- Regulatory associations, meetings, committees and workgroups
  - Association of American Feed Control Officials (AAFCO)
  - Association of Public Health Laboratories (APHL)
  - Association of Food and Drug Officials (AFDO)
- Succession planning
- Access to training
- AgLabs Listserve
- Exposure to cutting edge technology, research and methods
- Resources
- Active participation

- Technology Advancement-
  Knowledge Transfer

Definition: Professional organizations, societies, and associations(groups) for professional development and networking that lead to enhanced laboratory operations.

Level 4 Competency: Discuss the benefits of professional groups.

1. Level 5 Competency: Identify professional groups that support food and feed safety.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list the benefits of professional groups. 2. The laboratory analyst can list professional groups relevant to their laboratory and discipline.	1. The laboratory analyst promotes participation in professional groups. 2. The laboratory analyst actively participates in professional groups.

2. Level 5 Competency: Describe the activities of professional groups.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe the activities of professional groups relevant to their laboratory and discipline. 2. The laboratory analyst can describe the impact on the laboratory by employee participation in a professional group. 3. The laboratory analyst can discuss how professional groups enhance awareness of national issues: a. List one or more national issues addressed by a professional group.	1. The laboratory analyst participates in a professional group activity. 2. The laboratory analyst serves on a professional committee or working group.

3. Level 5 Competency: Discuss learning opportunities provided by professional groups.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list training opportunities provided by a professional group. 2. The laboratory analyst requests training provided by professional groups. 3. The laboratory analyst can improve interpersonal skills: a. Communication skills through networking.	1. The laboratory analyst assists in presenting training through a professional group. 2. The laboratory analyst can give a presentation / poster at a professional event. 3. The laboratory analyst can be an active participant on a committee or workgroup.

b. Presentation skills. c. Contributing to a presentation / poster for a professional event.	4. The laboratory analyst can organize a technical session at a professional meeting.
4. Level 5 Competency: Discuss how professional groups are a resource to enhance laboratory capabilities / capacity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list resources (methods, guidelines, discussion forums, communication platforms, standards, technical information, informal data sharing, grants, etc.) provided by professional groups. 2. The laboratory analyst utilizes resources from a professional group.	1. The laboratory analyst contributes to professional groups: a. By participating in committees. b. Workgroups. c. Participate in a collaborative study.

Governmental Food Safety Collaborations

BRAINSTORM

Data Information Sharing
- Animal Feed Network - SampleNet
- National Food Safety Data Exchange (NFSDX)

Surveillance Networks
- Antibiotic Resistance Laboratory Network (ARLN)
- PulseNET
- National Norovirus Outbreak Network (CalciNet)
- Cholera and other vibrio illness surveillance (COVIS)
- The Foodborne Diseases Active Surveillance Network (FoodNet)
- National Antimicrobial Resistance Monitoring System (NARMS) for Enteric Bacteria
- Cryptosporidiosis Transmission (CryptoNet)
  Norovirus Sentinel Testing and Tracking (NoroSTAT) Network

Response Networks
- Food Emergency Response Network (FERN)
  - Laboratory Response Network (LRN)
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
- National Animal Health Laboratory Network (NAHLN)
- National Plant Diagnostic Network (NPDN)
- Environmental Response Laboratory Network (ERLN)
- Department of Defense (DoD) Laboratory Network (DLN)
- GenomeTrakr

Collaboration
- Integrated Consortium of Laboratory Networks (ICLN)
- Integrated Food Safety System (IFSS)
- Partnership for Food Protection (PFP)
- World Health Organization (WHO)
- CODEX
- State Agency Specific Expertise
- Interagency data sharing
- Technology Advancement-Knowledge Transfer
- Building capability and capacity
- Funding opportunities

Definition: Governmental food safety networks for surveillance, response, capacity building, data exchange, and collaboration.

Level 4 Competency: Articulate the importance of food safety networks.

1. Level 5 Competency: Describe the role of the analyst in contributing to food safety networks.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can list examples of governmental food safety networks. 2. The laboratory analyst can list ways in which their data impacts the effectiveness of governmental food safety networks. (capabilities and capacity are expanded, e.g., more methods, more data, more expertise) 3. The laboratory analyst can list specific examples where the analyst's data contributed to food safety responses (recalls, import alerts, identifying the contamination source, identifying outbreaks, and resolving outbreaks)	1. The laboratory analyst can describe the impact of animal food testing on food safety. a. Melamine b. Aquaculture- contaminated fish feed c. Pig ears 2. The laboratory analyst can describe how an individual laboratory's testing can play a role in global food safety.

2. Level 5 Competency: Describe the purpose of food safety surveillance networks.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
4. The laboratory analyst can define food safety surveillance. 5. The laboratory analyst can describe a goal and activity of a surveillance network. 6. The laboratory analyst can describe how their laboratory contributes to a surveillance network. 7. The laboratory analyst can list the networks their laboratory belongs to.	1. The laboratory analyst can describe how surveillance data can identify a food safety hazard or an outbreak. 2. The laboratory analyst can participate in developing a surveillance workplan.
3. Level 5 Competency: Describe the purpose of foodborne emergency response networks.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define a foodborne emergency response. 2. The laboratory analyst can describe a goal and activity of a response network. 3. The laboratory analyst can describe how their laboratory contributes to a response network. 4. The laboratory analyst can list one or more examples of a foodborne emergency response: a. Fukushima b. Gulf oil spill PAHs and dispersant c. Melamine and Cyanuric acid d. E.coli in Romaine e. Blue Bell ice cream f. Jack in the Box g. Salmonella in peanut products 5. The laboratory analyst can describe how method development may be part of a response: a. Polonium 210 b. Gulf oil spill PAHs and dispersant c. Melamine and Cyanuric acid	1. The laboratory analyst can describe how response data contributed to the control of a food safety hazard or outbreak. 2. The laboratory analyst can assist in modifying a workplan to address a response. 3. The laboratory analyst can contribute to the development of a method to respond to a food safety emergency.

4. Level 5 Competency: Describe the importance of data sharing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can explain the purpose of data sharing. 2. The laboratory analyst can list some limitations to data sharing. 3. The laboratory analyst can list data shared in their laboratory. 4. The laboratory analyst can identify who receives shared data. 5. The laboratory analyst can explain how data is shared. 6. The laboratory analyst can participate in data sharing. 7. The laboratory analyst can describe the One Health concept.	1. The laboratory analyst can improve data sharing. 2. The laboratory analyst can verify the accuracy of the transfer of data. 3. The laboratory analyst can provide interpretation of shared data. 4. The laboratory analyst can describe how method performance impacts shared data. 5. The laboratory analyst can describe when it is appropriate to share data and how widely it can be shared.
5. Level 5 Competency: Describe the importance of collaboration among laboratories.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe the benefits of laboratory collaboration. (resource sharing, e.g. instruments, expertise, methods) 2. The laboratory analyst can list examples of collaboration directly between laboratories. (training, supplies, reagents, data confirmation)	1. The laboratory analyst can explain the value of memorandum of understanding (MOU) and contracts. 2. The laboratory analyst can identify contacts who are resources in other laboratories. (e.g. AgLabs Listserve)

Interagency Programs

BRAINSTORM
• Food Defense
• Laboratory capacity
• Emergency Response
• Economy of scale
• Surge capacity
• Interstate Agency Partnerships
• Contracts
• Within State-Agency Jurisdiction
• Within State-Multi Agency Cooperation
• Partnerships not Hierarchy
• Memorandum of Understanding (MOU)
• Program standards
  ○ Manufactured Food
  ○ Retail Food
  ○ Animal Food
• Cooperative agreements
  ○ Milk
  ○ Shellfish
  ○ Retail
• State Agency Specific Expertise
• ISO 17025 Accreditation
• Integrated Food Safety System

Definition: The influence of interagency programs (cooperative agreements, program standards, partnerships, accreditation, etc.) on laboratory operations. **Level 4 Competency:** Explain how interagency programs affect laboratory operations.
1. Level 5 Competency: Discuss how interagency programs impact laboratory operations.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**

1. The laboratory analyst can identify the interagency programs in their laboratory.
2. The laboratory analyst can describe the impact of participating in an interagency program.
3. The laboratory analyst can describe how participation in programs benefits capacity and capabilities.
4. The laboratory analyst can describe the program requirements of a program.
5. The laboratory analyst can discuss how interagency programs impact laboratory quality systems.
  a. How program requirements affect method selection.
  b. How program requirements affect reporting requirements.
	1. The laboratory analyst can recommend participation in a program.
	2. The laboratory analyst can assist in complying with program requirements.
	3. The laboratory analyst can assist in development of quality procedures to meet program standards.

Legal Proceedings

Definition: The laboratory analyst's role as an active participant in court hearings, depositions, and other court actions.

Level 2 Competency: Apply best practices for legal proceedings.

Level 3 Competencies:

- Articulate the importance of preparation for legal proceedings - Communication
- Support the laboratory's preparation for legal proceedings - Leadership
- Explain the organization's role in legal proceedings - Programmatic
- Participate in preparation for legal proceedings - Technical

Authority
BRAINSTORM • Regulatory requirements • FDA consultation • Hot topics law • Lab responsibility • Accreditation • Statutes • Chain of custody • Standards • Chain of command
Definition: The basis for the laboratory analyst's involvement in legal proceedings. **Level 4 Competency:** Explain why a laboratory analyst interacts with the court.

1. Level 5 Competency: Describe how regulatory standards/regulations are important in legal proceedings.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize the existence of laws or statutes that provide the basis for regulations/rules. 2. The laboratory analyst can name at least one regulation/rule that their laboratory services support. 3. The laboratory analyst can recognize how laboratory testing must meet standards and regulations. 4. The laboratory analyst can identify the compliance requirements for their work. (tolerance)	1. The laboratory analyst can determine if a method is fit-for-purpose for a specific regulation.
2. Level 5 Competency: Describe how legal authority is determined.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe their organization's legal authority. 2. The laboratory analyst can describe who grants their organization's legal authority. 3. The laboratory analyst is familiar with laws affecting their organization, such as: a. Records management b. FOIA 4. The laboratory analyst recognizes that there are laws and statutes that provide legal authority.	1. The laboratory analyst can cite statutes pertaining to their organization's legal authority. 2. The laboratory analyst can describe their organization's legal authority for methods outside of their own responsibility. 3. The laboratory analyst can give examples of regulations that establish authority.

Preparation for Legal Proceedings.

BRAINSTORM

- Ethics
- Competency
- Use of plain language
- Professional appearance
- Under oath
- Technical experience
- Neutrality
- Clear communication
- Truth
- Stay in your lane
- Expert witness
- Fact witness
- Listen
- Supportable facts
- Supportable professional opinion
- Stick to work performed
- Presumption of innocence
- Anticipate
- Ask for clarification
- Legal counsel preparation
- Expert training
- Preparation

Definition: The process of preparing to give legal testimony.

Level 4 Competency: Discuss the importance of preparing for legal proceedings.

1. Level 5 Competency: Give examples of evidence that might be used in court.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can recognize that laboratory records and documents may be used as evidence in court. 2. The laboratory analyst can describe the importance of maintaining records for defensibility. 3. The laboratory analyst can recognize that they may be asked to defend test results in court. 4. The laboratory analyst can describe how quality control acceptance limits relate to data defensibility. 5. The laboratory analyst can recognize that external documents can be used in court, such as: a. Reference material reports b. Certificates of analysis c. Calibration d. Method sources	1. The laboratory analyst can develop methods that are defensible in court. 2. The laboratory analyst can explain the legal criteria for data acceptance in court, such as: a. Official method b. Method accepted by scientific peers c. Method has been validated d. Method has been used in prior evidentiary proceedings (precedent)

2. Level 5 Competency: Describe activities related to legal proceedings.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define the process of discovery in legal proceedings. 2. The laboratory analyst can list some of the information that might be requested during the process of discovery, such as: a. Test results b. Emails c. Sampling records d. Chain of custody records e. Report of analysis f. Possible redaction of information 3. The laboratory analyst can recognize they may be asked to testify regarding a test result. 4. The laboratory analyst can recognize that they are legally responsible for the defensibility of their test results. 5. The laboratory analyst can describe the difference between a criminal and a civil proceeding. 6. The laboratory analyst can describe the process for providing information to persons outside of the department, such as: a. Designated / authorized individual b. Sunshine laws (open records laws) c. Information required via Freedom of Information Act (FOIA)	1. The laboratory analyst can coach other analysts in preparing for legal proceedings. 2. The laboratory analyst can review laboratory procedures for legal defensibility.
3. Level 5 Competency: Describe how professional conduct impacts credibility.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize that professional conduct is critical to credibility, such as: a. Good communication skills b. Being prepared c. Being informed d. Clear, accurate, and detailed reporting	1. The laboratory analyst can coach others in appropriate professional conduct.

e. Respectful attitude f. Ethical behavior 2. The laboratory analyst can recognize that conduct outside of work can affect their professional credibility.	
4. Level 5 Competency: Demonstrate the use of plain language in describing work performed.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize the importance of using language that can be understood by a non-scientist. 2. The laboratory analyst can clearly and succinctly summarize the testing highlighting critical details without elaboration. 3. The laboratory analyst can provide analogies to everyday concepts.	1. The laboratory analyst can assist others with language.
5. Level 5 Competency: Identify procedures used to prepare a witness to testify.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst is aware of the information needed to prepare as a witness, such as: a. Knowing the relevant regulation b. Knowing the specification limits c. Having the pertinent records available d. Having the relevant documents available e. Having materials well-organized 2. The laboratory analyst can recognize the importance of a thorough document review in preparation to testify. 3. The laboratory analyst can recognize the importance of practicing before testifying, such as: a. Moot court (mock trial) b. Practice giving a deposition 4. The laboratory analyst can identify possible gaps in the data being provided. 5. The laboratory analyst can describe the difference between a fact witness and an expert witness:	1. The laboratory analyst can assist with rehearsing possible questions in preparation for testifying. 2. The laboratory analyst can recognize the *voir dire* process used to qualify an expert witness: a. Examination b. Cross-examination questions

a. A fact witness can only verify facts where an expert witness can offer opinions based on experience. 6. The laboratory analyst can describe the process of providing testimony via a deposition: a. Recognize that during a deposition they will be asked a series of questions related to work they have conducted: i. Answer only the questions asked ii. Stay calm iii. Do not be defensive iv. Be objective v. Be consistent vi. Be truthful b. Recognize there are different purposes for a deposition, such as: i. Learn what the witness knows ii. Allow both parties to know the facts before trial	

Evidence Defensibility		
BRAINSTORM		
• Evidence • Records • Test results • Quality control	• Methods • Accreditation • Scope • Corrective actions	• Training/competency • Document control • Record keeping

Definition: Elements that contribute to the credibility of facts and data introduced into legal proceeding.

Level 4 Competency: Identify criteria that provides evidence defensibility.

1. Level 5 Competency: Recognize the significance of laboratory accreditation.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize that accreditation provides credibility and defensibility in court proceedings. 2. The laboratory analyst can recognize the importance of a method falling under the scope of accreditation for defensibility. 3. The laboratory analyst can recognize how the role of accreditation enhances the ability to take regulatory action. 4. The laboratory analyst can list accreditation processes that enhance test result defensibility, such as: a. Corrective action process b. Training/Competency c. Document control d. Record keeping 5. The laboratory analyst can recognize that laboratory accreditation verifies that the laboratory's quality management system has passed a third-party review process.	1. The laboratory analyst can participate in the process to add a method to the laboratory's scope of accreditation.

2. Level 5 Competency: Explain the relationship between analyst competence and evidence defensibility.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize that a record of analyst competence is critical to legal defensibility, such as:	1. The laboratory analyst can develop legally defensible procedures for demonstrating competence.

a. PT results b. Training records c. Competency records 2. The laboratory analyst can recognize how documented competency supports their credibility in legal proceedings.	

3. Level 5 Competency: Describe how adhering to laboratory procedures enhances defensibility.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize that adhering to laboratory procedures is critical to legal defensibility. 2. The laboratory analyst can recognize how documented procedures support their credibility in legal proceedings.	1. The laboratory analyst can develop legally defensible procedures.

Court Process

BRAINSTORM

- Testimony
- Evidence
- Stipulation
- Testifying
- Records
- Discovery
- Examination
- Deposition
- Subpoena
- Court room time
- Defense witness
- Cross-examination
- Criminal proceeding
- Civil proceeding
- Administrative proceeding
- Professional demeanor
- Defendant
- Prosecution
- Ask for clarification
- Only answer the question asked

Definition: The process of introducing evidence and giving testimony.

Level 4 Competency: Describe the steps that occur in legal proceedings.

1. Level 5 Competency: Describe the laboratory analyst's role in providing testimony.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list actions expected of them during a court proceeding, such as:	1. The laboratory analyst can describe the importance of court decorum to credibility.

a. Introducing evidence b. Giving testimony and responding to cross-examination c. Providing opinion (if an expert witness) d. Answering only the question asked e. Being objective (present the facts) 2. The laboratory analyst can recognize that they may be sequestered while others are giving testimony. 3. The laboratory analyst can describe court decorum, such as: a. Be on time. b. Speak only when asked. c. Stay calm. d. Speak to the judge or jury, not to the lawyer. e. Wear professional attire. f. Follow judge and court instructions. g. Turn off phone or leave it outside the courtroom. 4. The laboratory analyst can describe what occurs during cross-examination, such as: a. Answer only the questions asked. b. Stay calm. c. Do not be defensive. d. Be objective. e. Be consistent. f. Be truthful.	2. The laboratory analyst can mentor others that have been subpoenaed.

Method Evaluation and Selection

Definition: Techniques applied to method management, method selection, resource management, and meeting performance requirements.

Level 2 Competency: Justify method selection.

Level 3 Competencies:

- Explain the characteristics of a fit for purpose method - Communication
- Determine method selection - Leadership
- Ensure laboratory readiness - Programmatic
- Evaluate needs to perform testing - Technical

Method Management

BRAINSTORM

- External document (online & hardcopy)
- Document control management
  - Method changes
  - Method display (i.e. flow charts, etc.)
  - Method review
  - Detect non-official method copies

Definition: Control, review, and revision of methods used to generate reportable results.

Level 4 Competency: Verify the use of current methods.

1. Level 5 Competency: Review method repository.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst knows where to access the method repository. 2. The laboratory analyst can identify available methods for a particular analyte. 3. The laboratory analyst knows to use only approved methods.	1. The laboratory analyst can suggest new methods not in the existing repository. 2. The laboratory analyst can suggest improvements to the organization of the repository.

2. Level 5 Competency: Outline the process for method control.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe how methods are controlled. 2. The laboratory analyst can describe how to get a method approved. 3. The laboratory analyst can explain why a method needs to be controlled. 4. The laboratory analyst has knowledge of how methods are a part of the laboratory document control. 5. The laboratory analyst can explain the importance of version control.	1. The laboratory analyst can suggest a method for approval. 2. The laboratory analyst can implement the process for getting a method approved or modified. 3. The laboratory analyst can suggest improvements to the process of method control.
3. Level 5 Competency: Evaluate methods.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can describe the revision process. 2. The laboratory analyst can explain the validation process. 3. The laboratory analyst can identify the reasons for revisions to a method. (new column, reagent, matrix, platform) 4. The laboratory analyst can identify reasons for when method performance should be reviewed. (Proficiency testing (PT), QA, certified reference material) 5. The laboratory analyst can specify the frequency in which approved method SOPs should be reviewed.	1. The laboratory analyst can contrast conditions that would require verification vs re-validation of an existing method. 2. The laboratory analyst can conduct an evaluation of method SOPs. 3. The laboratory analyst can compare a currently approved method to an improved/revised method.

Method Selection

BRAINSTORM

- Selection of an approved method
- Fit for purpose
- How to find approved methods
- What is an approved method?
- The importance of using an approved method
- Relationship of recognized methods and regulatory work
- Client methods
- Sources of approved methods (FDA, USDA, Association of Official Analytical Chemists (AOAC) International, Canadian Food Inspection Agency (CFIA), CDC, PulseNet, FERN, LRN, VetLIRN, Verterinary methods, dairy methods, American Public Health Association (APHA) Standard methods, Compendium, etc.)
- Safety evaluation/need
- Waste generation/management E18

Definition: Selecting an appropriate method that is fit for purpose.

Level 4 Competency: Select methods for use in analysis.

1. Level 5 Competency: Utilize method selection criteria.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can list method selection criteria to assure fit for purpose. (matrix, analyte, level of concern, repeatability, platform, cost/expenses, available expertise, safety concerns, customer requirements, regulatory action limits) 2. The laboratory analyst can identify internal approved methods that are fit for purpose. 3. The laboratory analyst can identify when there is no approved method fit for purpose. 4. The laboratory analyst can identify external sources of approved methods that are fit for purpose.	1. The laboratory analyst can recommend an unapproved method that may be fit for purpose. 2. The laboratory analyst can identify the steps needed to evaluate and obtain method approval. 3. The laboratory analyst can evaluate a method to demonstrate it meets customer requirements. 4. The laboratory analyst can recommend a method that meets the sample quality criteria.

5. The laboratory analyst can identify that the method meets all sample quality criteria elements. (removal of extraneous material, LOD/LOQ requirements, analyte integrity requirements, inference requirements, *GOOD* test portions (aafco.org), statistical requirements, regulatory action limits)	
2. Level 5 Competency: Support method safety risk assessment.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can assist in completing a method safety risk assessment. (safety of the laboratorian(s) when performing a specific method) 2. The laboratory analyst can assist in completing a method safety risk assessment for the handling of laboratory samples, materials, or products arriving at the laboratory. 3. The laboratory analyst can identify faulty PPE, general safety materials (transport containers, etc.), and facility safety equipment (eye wash, hoods, etc.) 4. The laboratory analyst can review method safety instructions for adequacy.	1. The laboratory analyst can suggest procedures and improved PPE to mitigate risk. 2. The laboratory analyst can identify an unexpected risk with a method and laboratory sample. 3. The laboratory analyst can be a resource for developing safety instructions in the laboratory.

Method Performance Requirements

BRAINSTORM

- Validation levels
- Validation methods (FDA, AOAC)
- Laboratory developed methods
- Validation criteria
- Verification criteria
- Method performance requirements ((Limit of quantitation (LOQ), Sensitivity, Specificity, etc.)
- SMPR-AOAC Standard Method Performance Requirements
- Client methods
- Statistical evaluation tools
- Being aware of the levels of validation
- Importance of method validation and verification
- What is validation
- Follow method validation and verification procedures
- What is verification
- Deviations
- Use of data
- Troubleshooting
- Sampling
- QC considerations
- Accreditation standard(s) requirements for methods

Definition: Confirming that a method is fit for purpose.

Level 4 Competency: Characterize method performance for intended use.

1. Level 5 Competency: Define method performance criteria.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can list method performance criteria. a. Limit of Quantitation (LOQ), Limit of Detection (LOD) b. Consistent with regulatory action limits c. Sensitivity d. Specificity e. Selectivity f. Repeatability (precision) g. Dose response (calibration, residuals) h. Applicability (analyte, matrix, concentration, range) i. Flexibility j. Platform k. Robustness l. Bias (accuracy) m. Recovery n. Probability of Detection (POD) o. Measurement uncertainty p. Etc.	1. The laboratory analyst can recommend procedures to measure performance. 2. The laboratory analyst can establish performance criteria for a method.

2. Level 5 Competency: Verify performance against sample quality criteria (SQC) requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can perform validation experiments. 2. The laboratory analyst can implement/incorporate quality control events to monitor ongoing method performance. 3. The laboratory analyst can recognize when method performance has drifted outside performance criteria. 4. The laboratory analyst can demonstrate use of quality control charts. 5. The laboratory analyst can recognize the concept and components of SQC requirements. (analyte integrity, regulatory action limits, inference requirements, etc.)	1. The laboratory analyst can design validation experiments. 2. The laboratory analyst can evaluate validation data to determine if the method meets performance criteria requirements. 3. The laboratory analyst can improve method performance to meet stricter SQC requirements.
3. Level 5 Competency: Evaluate method limitations.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst recognizes that method usage is limited by the scope of validation. 2. The laboratory analyst can describe the impact of method performance limitations. 3. The laboratory analyst can describe how a method could be limited to a particular platform/instrument. 4. The laboratory analyst can describe the limitations of a method relative to regulatory action limits. 5. The laboratory analyst can recognize the possible consequences of detection limit when there are no regulatory action limits.	1. The laboratory analyst can explain to a customer the limitations of a method. 2. The laboratory analyst can recommend modifications to overcome method limitations.
4. Level 5 Competency: Resolve method performance issues (troubleshoot).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize that a method performance problem exists. 2. The laboratory analyst can isolate the method performance problem. 3. The laboratory analyst can correct the method performance problem. 4. The laboratory analyst can suggest an update to a method to prevent future problems.	1. The laboratory analyst can evaluate quality control data to predict possible method performance issues. 2. The laboratory analyst can recommend updates to a method to make it more robust. 3. The laboratory analyst can work with an instrument vendor to assess and troubleshoot to correct a problem.

	4. The laboratory analyst can assist a co-worker with resolving a method performance issue.

Laboratory Resources

BRAINSTORM

- Analyst competency
  - PT costs
  - Training
  - Certification costs
  - Authorizations
  - Expertise
  - Critical thinking
- Readiness
  - Contracts
    - Equipment
    - Waste generation
  - Facility needs
    - Storage
    - Health and safety
    - Security/evidentiary integrity
    - Space
  - Instruments
  - Standards and chemicals
  - Certified Reference Materials (CRMs)
  - Staff capacity
  - GAP analysis
  - Funding
    - Set-up costs
    - Factor non-method staff time (leave, meetings, etc.) into resource quantitation.
    - Consumables
  - Procurement availability/limitations
- Instrument/Equipment availability
- Importance of following the exact method/procedure
- Approved deviations
- Quality systems
- Accreditation
- Approved supplier

Definition: Supporting the readiness of laboratory resources.

Level 4 Competency: Evaluate resources that affect laboratory capacity.

1. Level 5 Competency: Support cost estimates.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list the consumable supplies that go into a method cost estimate. 2. The laboratory analyst can list capital expenses that go into method cost estimate. (equipment/instruments) 3. The laboratory analyst can list ongoing equipment maintenance costs. 4. The laboratory analyst can prepare cost estimates for the development, validation, and implementation of new methods. (supplies and reagents) 5. The laboratory analyst can identify the approved suppliers.	1. The laboratory analyst can prepare const estimates for the development, validation, and implementation of new methods. (supplies and reagents) 2. The laboratory analyst can revise a methods consumable cost estimate. 3. The laboratory analyst can prepare cost estimates for equipment, quality requirements. (including, QC, proficiency testing (PT), training, equipment maintenance, equipment calibration, etc.). 4. The laboratory analyst can suggest savings in equipment maintenance costs. 5. The laboratory analyst can compare costs and suggest savings in supply costs. 6. The laboratory analyst can verify performance of supplies from alternate suppliers.
2. Level 5 Competency: Anticipate supply consumption.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can monitor and conduct inventory of supplies. 2. The laboratory analyst can predict usage of supplies. 3. The laboratory analyst can maintain supply stock so that method analysis is not interrupted. 4. The laboratory analyst can describe the procedure for ordering supplies.	1. The laboratory analyst can predict supplies needed to provide surge capacity. 2. The laboratory analyst can address supply shortages: a. identify an alternate method b. suggest an alternate supplier 3. The laboratory analyst can describe the overall laboratory needs. (same supplies used by multiple methods, anticipated needs for method development, consumables for new instrumentation, more staff, implementing new compliance programs, etc.)

3. Level 5 Competency: Anticipate required analyst resources.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can manage their time to assure completion of assigned methods. 2. The laboratory analyst can estimate when additional analyst resources are needed.	1. The laboratory analyst can recommend staff resources (time and expertise) needed to perform a method. 2. The laboratory analyst can recommend training. 3. The laboratory analyst can suggest an improved time management schedule.
4. Level 5 Competency: Estimate equipment capacity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can manage equipment to assure completion of assigned tasks. 2. The laboratory analyst can estimate when additional equipment resources are needed. 3. The laboratory analyst can inform management when there is a shortage of trained analysts.	1. The laboratory analyst can recommend equipment resources needed to perform a method. 2. The laboratory analyst can recommend equipment training. 3. The laboratory analyst can suggest improved management of multi-user equipment. 4. The laboratory analyst can suggest additional equipment to improve capacity.
5. Level 5 Competency: Determine testing capacity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can estimate testing capacity. (through evaluation of human resources and equipment resources) 2. The laboratory analyst can predict needed testing capacity.	1. The laboratory analyst can suggest collaboration or outreach with other laboratories. 2. The laboratory analyst can suggest improvements to expand testing capacity. 3. The laboratory analyst can estimate the overall needs of the laboratory when testing demands are changed. (human resources, equipment resources, laboratory space, storage, available safety equipment, consumables, supplies, etc.)

6. Level 5 Competency: Report facility issues.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize problems with facility resources. (clean water source, hoods, environment, hazardous waste, lab space, autoclaves, gases, engineering controls, etc.) 2. The laboratory analyst can describe the procedures for reporting problems with the facility. 3. The laboratory analyst can determine when an immediate health hazard requires evacuation prior to reporting.	1. The laboratory analyst can assist in addressing facility breakdown. (power outages, unstable power, flooding, etc.)

Root Cause Analysis

Definition: Tools and techniques to discover, investigate, and solve the cause of a problem.

Level 2 Competency: Utilize Root Cause Analysis process.

Level 3 Competencies:

- Explain the steps of root cause analysis - Communication
- Recommend system improvements - Leadership
- Participate in continual improvement - Programmatic
- Implement root cause tools - Technical

Initiating Event

BRAINSTORM

- Non-conformance
- Customer complaints
- QC failure (including trend analysis)
- Events
- Proficiency testing (PT) failure
- System failure
- Audit findings
- Aha moment

Definition: An event that triggers or prompts an investigation.

Level 4 Competency: Evaluate event.

1. Level 5 Competency: Recognize events that may affect the quality of test results.

Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can describe how QC events can affect the quality of test results: a. System failure (e.g., laboratory accident) b. Process deviations (e.g., sample irregularities, expired standards i. Changes in temperature ii. Humidity	1. The laboratory analyst can distinguish between incident events and human error. 2. The laboratory analyst can anticipate potential events/deviations/irregularities. 3. The laboratory analyst can propose the initiation of a root cause analysis.

c. QC failure d. Audit finding e. PT failure f. Customer complaint 2. The laboratory analyst is aware that the timeliness of reporting an event is important.	
2. Level 5 Competency: Recognize issues that may affect customer confidence.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst recognizes the importance of the laboratory's *reputation* in the eyes of customers and the public. 2. The laboratory analyst can distinguish between an inquiry and a complaint or can distinguish between feedback and a complaint.	1. The laboratory analyst can re-instill confidence by explaining the measures taken to prevent reoccurrence. 2. The laboratory analyst can assist in responding to issues related to data that is being requested.
3. Level 5 Competency: Summarize the event.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can provide a timeline from the identification of the event: a. Documentation b. Personnel involved c. Volume of samples involved d. Investigation e. Records (QC, preventive maintenance, etc.) 2. The laboratory analyst can describe the process of documenting the event.	1. The laboratory analyst can identify the impact of the failure beyond the immediate sample. (i.e., ramifications) 2. The laboratory analyst can critically analyze the documented event for accuracy and completeness. 3. The laboratory analyst can correlate the event to the quality system.

Investigation		

BRAINSTORM
• Ask questions
• Compile investigation team
• Solution vs problem
• Who's involved
• Scope of investigation
• Unbiased Guiding Principles
  ○ Proficiency vs performance
  ○ Don't make it personal
  ○ Avoid names
  ○ Don't use for disciplinary actions
  ○ Objectivity
  ○ Do not judge
  ○ Facilitate change
  ○ Open ended questions
	• Records Review
	  • Documents
	  • Instrument records
	  • Monitoring systems
	  • Contract scope
	  • Analyst competency
	  • Method
	  • Procedures
	  • Analysis of data
	  • Illustrations and charts
	  • User manual
	  • Maintenance requirements
	  • Quality control records
	  • Inventory of chemicals and supplies
	  • Data results records
		• Investigation tools
		  ○ Five whys
		  ○ Is/is not
		  ○ Fishbone
		  ○ Cause mapping
		  ○ Gap analysis
		  ○ Interviews
		  ○ Brainstorm
		  ○ Change management
		  ○ Data collection

Definition: Gathering of objective information.

Level 4 Competency: Conduct an unbiased investigation.

1. Level 5 Competency: Apply investigation tools.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**

1. The laboratory analyst can describe the use of critical thinking skills in a root cause investigation:
  a. Logical fallacies
  b. Think outside of the box
  c. Unbiased
  d. Problem solving
  e. Open mindedness
2. The laboratory analyst can list common, appropriate standard investigation tools:
	1. The laboratory analyst can apply critical thinking skills in a root cause investigation.
	2. The laboratory analyst can apply appropriate standard investigation tools.
	3. The laboratory analyst can distinguish between the pros and cons of standard investigation tools.

a. Fishbone b. Is/is not c. Gap analysis d. Five whys e. Interviews f. Brainstorm g. Data collection h. Cause mapping 3. The laboratory analyst can describe common, appropriate standard investigation tools.	
2. Level 5 Competency: Consider the scope of the investigation.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define the initial scope of the investigation. 2. The laboratory analyst recognizes that the initial scope of the investigation might need to change.	1. The laboratory analyst recognizes how the scope of the investigation needs to change: a. Expand/enlarge b. Contract c. Focus the issue d. Narrow the scope
3. Level 5 Competency: Incorporate the ideas of team members.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst recognizes the importance of team member input (i.e., he/she is not doing it alone): a. Positive/negative comments b. Constructive criticism c. Feedback 2. The laboratory analyst recognizes the need for continuous process improvement.	1. The laboratory analyst incorporates team member input into a report. 2. The laboratory analyst diplomatically facilitates dialogue among team members during the investigation.

Causal Factors		
BRAINSTORM		
• Symptoms • Timeframe • Recognize what happened	• Cause and effect • Similar events • System failure	• Human error • Assumptions • When and where • Environmental factors

Definition: Identification of factors contributing to an event.

Level 4 Competency: Determine causation.

1. Level 5 Competency: Analyze investigation data.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can generate a list of contributing factors/findings. 2. The laboratory analyst can determine which of the findings apply to their section: a. Reagents stored out of temp b. Equipment failure (e.g., auto-pipettor, etc.) c. Reagents out of date d. Calculation error 3. The laboratory analyst can determine which of the findings are external to their processes: a. Laboratory Information Management System (LIMS) b. Reagents stored out of temp due to AC failure	1. The laboratory analyst can validate the findings within their processes. 2. The laboratory analyst can validate external findings.

2. Level 5 Competency: Evaluate trends.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify a trend. 2. The laboratory analyst can determine whether something has happened before. (recurring event) 3. The laboratory analyst can evaluate the significant trends/outliers. 4. The laboratory analyst can determine whether the trends are relevant to the initiating event.	1. The laboratory analyst can devise ideas as to what is causing the trend. 2. The laboratory analyst can discuss sampling and evaluative statistics. 3. The laboratory analyst can make recommendations.

Improvements		
BRAINSTORM		
• Corrective actions (immediate, long term) • System improvements • Level of effort • Big picture	• Verification • Effectiveness • Retraining documentation • Complaint response	• Corrections (immediate) • End goal impacted • Risk assessment • Prepare feedback

Definition: Actions, risks, and opportunities to address the event and prevent reoccurrence.

Level 4 Competency: Support continual improvement.

1. Level 5 Competency: Describe actions that support continual improvement.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can give examples of corrections: a. Calculation error b. Labeling error c. Perform instrument maintenance d. Reprogram instrument 2. The laboratory analyst can give examples of corrective actions: a. Use spreadsheet for peer-reviewed calculations b. Peer review of labels c. Redesigning forms d. Rewrites or edits to SOPs e. Verify program before use	1. The laboratory analyst can identify opportunities for improvement (OFI): a. Calculations for all assays moved to locked, verified spreadsheets 2. The laboratory analyst can apply corrective actions to prevent future non-conforming events.

2. Level 5 Competency: Monitor the effectiveness of the corrective actions.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst documents repeat occurrences or events. 2. The laboratory analyst can evaluate the impact of changes.	1. The laboratory analyst can verify the documentation of repeat occurrences or events. 2. The laboratory analyst can verify the impact of changes for effectiveness.