Mid Core LABORATORY-SPECIFIC LEADERSHIP SKILLS

Note: The Leadership Level Competency Framework (LLCF) and Mid Core Laboratory-Specific Leadership Skills I are co-requisites. The developing laboratory leader is directed to the LLCF in its entirety as a companion guide for leadership competencies that are not covered in this module.

Definition: Laboratory-specific communication and accountability skills for the developing leader

Level 2: Name communication, procurement, and scientific integrity practices of a laboratory leader

Level 3s:

- **Communication** – Describe rules that govern communication of sensitive information.
- **Leadership** – Identify scientific work principles.
- **Programmatic** – Identify procurement practices.
- **Technical** – Utilize communication tools.

Confidentiality of Laboratory Data **Definition:** Actions surrounding the release of laboratory-related information. **Level 4:** Describe limitations to information distribution. **Level 5s:** 1. Explain confidentiality issues that influence communication. 2. Assess laboratory-specific circumstances when clearance is needed before communicating.	**Brainstorm** • Clearance issues • ISO requirements • Customer communication • Ethics • HIPAA compliance • ADA • 508 requirements • Chain of command • Media awareness • Use of logos • Confidentiality issues • Contract writing

1. Level 5 Competency: Explain confidentiality issues that influence communication.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**

1. The laboratory analyst can determine the source of confidentiality requirements. a. Agency rules b. Customer agreements i. Contracts ii. Grants iii. Cooperative agreements 1. Laboratory Flexible Funding Model 2. Food Emergency Response Network c. Agreements i. 20.88 FDA Information Sharing Agreements ii. Memorandum of Understanding (MOU) iii. FDA credentialing and commissioning program 2. The laboratory analyst can develop guidance on the confidentiality requirements for the laboratory. a. Internal staff i. Human Resources (HR) documents ii. Security protocols iii. Passwords b. External i. Contracts containing sensitive information 1. Testing for bioterrorism or chemical terrorism agents c. Documents containing names of ill persons (outbreak investigation) i. Health Insurance Portability and Accountability Act (HIPAA) d. Documents containing names of firms and test results	1. The laboratory analyst can integrate confidentiality requirements into tools used in the laboratory, such as a Laboratory Information Management System (LIMS), a document control system, or filing system, etc. 2. The laboratory analyst can foster a workplace culture that protects privacy. 3. The laboratory analyst can monitor for compliance to confidentiality requirements. 4. The laboratory analyst can develop a response in case of unintentionally released confidential information.

2. Level 5 Competency: Assess laboratory-specific circumstances when clearance is needed before communicating.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize the requirements for clearance prior to release of information. a. Freedom of Information Act (FOIA) requests b. Customer (firm) requests	1. The laboratory analyst can coordinate clearance for communication that requires it. 2. The laboratory analyst can monitor for compliance to clearance requirements.

c. Contractual requests d. Submission for publication in a journal e. Presentation at a conference 2. The laboratory analyst can evaluate which communications may require clearance prior to release. a. Publications b. Laboratory results i. All ii. Certain results 1. Select Agents 2. Chemical terrorism agents of concern c. Contracts d. Communications with others i. Emails 1. Freedom of Information Act (FOIA) request ii. Documents 1. Laboratory SOPs to a firm that has a violative result 2. Laboratory SOPs involving Select Agents 3. Documents of capabilities of the laboratory provided to Food Emergency Response Network (FERN) 3. The laboratory analyst can assess the need for clearance prior to release of communication. a. Agency rules b. Customer agreements c. Laboratory policy 4. The laboratory analyst can determine the process required to receive clearance before communicating information. a. Chain of command 5. The laboratory analyst can develop instructions for receiving clearance.	3. The laboratory analyst can develop a response in case of unintentionally released communication prior to required clearance.

Communication Tools **Definition:** Use of aids for communication of information. **Level 4:** Apply tools for communication. **Level 5s:** 1. Assess available communication tools. 2. Apply communication tools.	**Brainstorm** • MS Office • Proficient in MS Word • Excel proficiency • Prezi • Create poster • Report templates • Graphical enhancements	• Create flowchart • Memo templates • Topical illustrations • Visual interest • Demonstration • Flipcharts • AV

1. **Level 5 Competency:** Assess available communication tools.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can determine available tools for communication. a. Press release b. Direct mailing c. Email d. Newsletter e. Social media f. News report/blurb g. Presentation h. Software 2. The laboratory analyst can evaluate available communication tools for appropriateness. 3. The laboratory analyst can determine which communication tool(s) are available for communication. 4. The laboratory analyst can utilize the appropriate tool(s) for communication.	1. The laboratory analyst can characterize the audience for the communication. 2. The laboratory analyst can anticipate the reactions to communications. 3. The laboratory analyst can coordinate with others to create quality communications.

2. **Level 5 Competency:** Apply communication tools.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define the focus area/talking points of the communication plan. 2. The laboratory analyst can use templates for laboratory communication.	1. The laboratory analyst can develop a communication plan. 2. The laboratory analyst can implement a communication plan.

a. Report templates b. Form letter c. Data packages d. External partner requirements e. Data programs such as: i. FDA Data Exchange (DX) ii. USDA Agricultural Marketing Service Hemp eManagement Platform (HeMP) iii. FoodSHIELD 3. The laboratory analyst can oversee the completion of required templates.	3. The laboratory analyst can develop effective communication templates. 4. The laboratory analyst can incorporate feedback into communication templates.

Procurement-specific Laboratory Leadership Skills **Definition:** Application of scientific knowledge to laboratory purchasing processes. **Level 4:** Describe laboratory purchasing practices. **Level 5s:** 1. Develop purchasing proposals (goals) 2. Prepare purchasing specifications 3. Justify laboratory purchasing decisions 4. Organize actions for post-purchase instrument setup	**Brainstorm** • Spec writing • Sourcing • Procurement • Instrument setup

1. **Level 5 Competency:** Develop purchasing proposals (goals).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can apply procurement policies to laboratory purchases. 2. The laboratory analyst can estimate the cost of laboratory purchases. 3. The laboratory analyst can correlate supply purchasing needs to existing inventory. 4. The laboratory analyst can track purchasing activity to show compliance with requirements.	1. The laboratory analyst can identify when special procurement requirements apply to laboratory purchases. a. Capital expenditures b. Processing product returns and rebates c. Bidding process d. Annual spending limits per vendor e. Budget f. Tax-exempt status g. Travel policies h. Active purchasing contracts

	i. US General Services Administration (GSA) pricing j. National Association of State Procurement Officials (NASPO) ValuePoint 2. The laboratory analyst can defend a purchasing need to upper management.
2. **Level 5 Competency:** Prepare purchasing specifications	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify the performance criteria of goods and services required to meet testing need(s). 2. The laboratory analyst can research physical needs [e.g., power; heating, ventilation, and air conditioning (HVAC); space] of major equipment purchases prior to writing purchasing specifications. a. Recognize space needs i. bench/floor footprint ii. clearances from walls or heat sources iii. navigation of equipment through doorways and/or elevators to its new location b. Recognize plumbing, electrical, network, HVAC, and other remodeling needs prior to installation 3. The laboratory analyst can survey persons with expert knowledge of equipment selection. a. AgLabs listserv b. APHL CoILABorate community c. Equipment vendors d. Experienced laboratory personnel 4. The laboratory analyst can determine purchasing specifications for laboratory goods and services. 5. The laboratory analyst can trace vendor goods or services to an accreditation or certification document.	1. The laboratory analyst can evaluate performance criteria of goods and services for intended use. 2. The laboratory analyst can facilitate pre-purchasing requirements prior to the delivery date of a major purchase (e.g., equipment, monitoring system software). a. Confirm space needs (bench/floor footprint, ability to move it into space, and the space needed) b. Execute plumbing, electrical, network, HVAC, and other remodeling needs prior to installation 3. The laboratory analyst can formulate equipment testing capabilities and features into purchasing specifications. 4. The laboratory analyst can verify that accreditation or certification claims of vendor goods and services meet laboratory requirements. 5. The laboratory analyst can negotiate economical strategies during a major equipment purchase. a. Volume or other discounts b. Bundling equipment service contracts c. No-cost trial periods for equipment d. Low-cost/free training or starter kit with major equipment purchase
3. **Level 5 Competency:** Justify laboratory purchasing decisions	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**

1. The laboratory analyst can discuss the selection of laboratory goods and services that satisfy quality critical needs. 2. The laboratory analyst can verify that goods or services meet testing requirements. 3. The laboratory analyst can evaluate vendor performance for monitoring purposes. 4. The laboratory analyst can recognize organizational expectations when selecting a vendor. a. Active purchasing contracts b. Preferred vendor c. IT requirements for software	1. The laboratory analyst can identify alternate vendors. a. Discontinued items b. Price differences c. Delivery date d. Supply shortage e. Inadequate vendor performance 2. The laboratory analyst can monitor vendor performance for conformity with laboratory requirements.

4. **Level 5 Competency:** Organize actions for post-purchase instrument setup

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can identify the setup needs for the acquisition of new laboratory equipment. a. Identify potential chemical compatibility, heat load, interferences, and environmental tolerances prior to installation b. Observe equipment delivery date c. Observe new equipment training d. Observe installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) accordingly e. Participate in method performance analysis prior to use on regulatory samples f. Recognize safety needs of new equipment	1. The laboratory analyst ensures fulfillment of equipment acquisition and setup needs such as. a. Resolve potential chemical compatibility, heat load, interferences, and environmental tolerances prior to installation b. Schedule equipment delivery date c. Schedule new equipment training d. Review installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) reports for adequacy e. Ensure method performance needs are met prior to use on regulatory samples f. Teach others on safety needs of new equipment

Scientific Work Principles **Definition:** Applying scientific principles to laboratory work. **Level 4:** Explain scientific principles to laboratory work. **Level 5s:**	**Brainstorm** • Scientific ethos • Integrity • Scientific method

1. Apply scientific theory. 2. Act with scientific integrity. 3. List sources of scientific information.	• Fraud

1. **Level 5 Competency:** Apply scientific theory.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can apply the scientific method. a. Define the problem b. Gather background information c. Form a hypothesis d. Gather data e. Analyze data f. Draw conclusions 2. The laboratory analyst can identify fundamental approaches to scientific processes. a. Testing requirements b. Sampling c. Instrumentation d. Methods e. Accreditation f. Regulatory g. Cross cutting technologies, h. Data requirements.	1. The laboratory analyst can critique the outputs of the scientific method. 2. The laboratory analyst can relate fundamental scientific approaches to laboratory testing activities. a. Testing requirements b. Sampling c. Instrumentation d. Methods e. Accreditation f. Regulatory g. Cross cutting technologies h. Data requirements

2. **Level 5 Competency:** Act with scientific integrity.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can perform job duties with scientific integrity. 2. The laboratory analyst can model scientific integrity. 3. The laboratory analyst can identify fraudulent testing behaviors in a laboratory setting. a. Dry labbing (i.e., recording results without doing the work) b. Falsifying raw data, quality control data, final results, initials, or other testing information	1. The laboratory analyst can instruct others on scientific integrity in a laboratory setting. 2. The laboratory analyst can promote scientific integrity. 3. The laboratory analyst can foster scientific integrity in others. a. Laboratory work environment b. Undue influences c. Having policies in place

c. Intentionally manipulating samples, reagents, equipment to affect results d. Switching reagents without verification, approval, and/or justification e. Intentional omission of data in laboratory records f. Cutting corners, skipping steps in an SOP g. Intentional contamination or tainting of samples 4. The laboratory analyst can identify the four principles of scientific ethos. a. Communality (open communication and sharing) b. Universalism (disallow outside influences to bias results) c. Disinterestedness (pursue truth for the common good rather than for personal or monetary motive) d. Organized skepticism (results are scrutinized before acceptance) 5. The laboratory analyst can conduct testing activities with transparency about data collection, analysis, and reporting.	4. The laboratory analyst can determine ways to detect fraudulent testing behaviors in a laboratory setting. a. Dry labbing (i.e., recording results without doing the work) b. Falsifying raw data, quality control data, final results, initials, or other testing information c. Intentionally manipulating samples, reagents, equipment to affect results d. Switching reagents without verification, approval, and/or justification e. Intentional omission of data in laboratory records f. Cutting corners, skipping steps in an SOP g. Intentional contamination or tainting of samples 5. The laboratory analyst incorporates tools to prevent fraudulent laboratory practices. a. Tracking changes on computers b. Investigate best practices c. Locking down a spreadsheet 6. The laboratory analyst incorporates four principles of scientific ethos into job duties to build credibility. a. Communality (open communication and sharing) b. Universalism (disallow outside influences to bias results) c. Disinterestedness (pursue truth for the common good rather than for personal or monetary motive) d. Organized skepticism (results are scrutinized before acceptance) 7. The laboratory analyst establishes a sense of persuasion through use of their own scientific credibility (ethos).
3. **Level 5 Competency:** List sources of scientific information.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can give examples of scientific information sources: a. academia	1. The laboratory analyst can use multiple scientific information sources: a. academia

b. personnel in other laboratories c. in-person meetings d. continuing education e. technical experts from scientific equipment and supply companies f. professional associations g. records of previous testing activities	b. personnel in other laboratories c. in-person meetings d. continuing education e. technical experts from scientific equipment and supply companies f. professional associations g. records of previous testing activities

Additional Laboratory-specific Leadership Skills **Definition:** Miscellaneous laboratory-specific leadership topics **Level 4:** Apply additional principles for laboratory professionalism. **Level 5s:** 1. Recognize when it is appropriate to implement project management tools. 2. Illustrate dressing for laboratory career success. 3. Justify conference attendance 4. Create harmony in a work environment. 5. Demonstrate resilience.	**Brainstorm** • Project management • Magnitude of effort • High-risk project • Unfamiliar undertaking • Hard deadline • Dress code • What to wear • PPE • First impressions • Professional image • Establish rapport • Crisis preparation • It's who you know • Multi-organization collaboration • Sense of humor • Calming presence • Pleasant • Positive reinforcement • Positive body language • Professional demeanor • Ground rules established • Feedback • Resilience • Post-pandemic

	• Day to day stress (laboratory work is exacting) • Staying positive • Coping • Calm under pressure • Manage priorities • Rebound • Setback

1. **Level 5 Competency:** Recognize when it is appropriate to implement project management tools.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize project management approaches. a. Project Scope b. Scheduling c. Process flow chart d. Cost control e. Deliverables f. Risk management g. Lean Six Sigma/Quality management 2. The laboratory analyst can identify project management tools. a. Gantt chart b. Kanban board c. Risk matrix d. Cost-benefit analysis 3. The laboratory analyst can implement a project management tool. a. Gantt chart b. Kanban board c. Risk matrix d. Cost-benefit analysis	1. The laboratory analyst can incorporate multiple project management tools when appropriate. a. Magnitude of effort involved b. High risk to the organization c. Large uncertainty in the outcome d. Ability of team to complete project on time and within budget e. Project contains many functional parts

2. **Level 5 Competency:** Illustrate dressing for laboratory career success.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst observes the established dress code. a. Dresses for safety b. Correctly dons personal protective equipment where use is required	1. The laboratory analyst models a professional image. 2. The laboratory analyst conveys a professional image by adhering to the dress code. a. Forms a positive impression

c. Dresses for the occasions of the workday	b. Shows professionalism c. Enhances credibility d. Ensures appropriateness
3. **Level 5 Competency:** Justify conference attendance.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst recognizes the benefits of conference attendance. a. Relates conference attendance to professional growth b. Learns new information i. Add to personal knowledge ii. Add to organizational knowledge c. Recognizes the value of networking i. Builds trust ii. Finds a mentor iii. Makes connections	1. The laboratory analyst can use knowledge gained from conferences to further the organizational mission. 2. The laboratory analyst can act on the interrelationships developed from networking. a. Draws on the wisdom of others b. Becomes acquainted with state and federal partners before a crisis occurs 3. The laboratory analyst incorporates the benefits of conference attendance into work activities. 4. The laboratory analyst translates the benefits of conference attendance into professional growth. 5. The laboratory analyst demonstrates the benefits of conference attendance. a. Plants seeds for future collaboration b. Joins extramural task forces c. Participates in multi-laboratory validation studies d. Volunteers on laboratory committees
4. **Level 5 Competency:** Create harmony in a work environment.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can translate the benefits of being a comforting influence to others. a. Workplace productivity b. Workplace harmony c. Defuse situations where emotions run high 2. The lab analyst can describe the roles of team members in a team setting. a. Generalist (Swiss Army knife)	1. The laboratory analyst can create ground rules for team activities. 2. The laboratory analyst can support others through positive reinforcement. a. Positive body language b. Sense of humor c. Calming presence

b. Idea person c. Doer d. Thinker e. Detail-oriented f. High driver g. Overachiever h. Perseverant i. Adaptor j. A.R.E. you there for me? (accessible, responsive, engaged) k. Listener l. Contrarian m. Giver 3. The lab analyst can recognize that group dynamics exist.	d. Pleasant demeanor e. Accolades 3. The laboratory analyst can interpret group dynamics. 4. The laboratory analyst can employ techniques to defuse a tense situation. 5. The laboratory analyst can lead the group to fulfill an expected deliverable. a. Keeps team focused b. Achieves objective despite obstacle(s)
5. **Level 5 Competency:** Demonstrates resilience	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can maintain a positive attitude in the face of adversity. 2. The laboratory analyst can perform job functions for continued laboratory capability and capacity. 3. The laboratory analyst can adapt to changing circumstances. 4. The laboratory analyst can learn lessons from change.	1. The laboratory analyst can manage a crisis. 2. The laboratory analyst can reorganize team priorities. 3. The laboratory analyst can support the needs of others. 4. The laboratory analyst can lead recovery from an adverse situation. 5. The laboratory analyst can create a positive attitude among staff in the face of adversity. 6. The laboratory analyst can construct positive outcomes from change.

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

3. 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
6. 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.

7. 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)	
4. 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.

Advanced Safety

Definition: Workplace practices, conditions, and behaviors that produce a consistent safety outcome and reduce the risk of injury.

Level 2 Competency: Champion laboratory safety.

Level 3 Competencies:

- Promote a safe laboratory environment - Communication
- Educate bench personnel on safe laboratory practices - Leadership
- Model safe practices - Programmatic
- Troubleshoot laboratory safety issues. - Technical

Hazards

BRAINSTORM

- Skin exposure
- Inhalation exposure
- Perchloric acid
- Freezer hazards
- Minus 80 C
- Poisons
- Dry ice
- BSL organisms
- Toxicity
- Solvents
- Vapors
- Hot glass
- Pressure
- Vacuum
- Liquid nitrogen
- Gas cylinder
- Electrical
- Bulk gas supply
- Reagents
- Heat
- Cold
- Pressure
- Petroleum fumes
- Vacuum pumps
- Radioactivity

Definition: Agents, materials, and conditions that may produce harm to people.

Level 4 Competency: Summarize hazards encountered in the laboratory.

Level 5 Competencies:

1. Characterize chemical hazards in the laboratory.
2. Evaluate hazard.

2. Level 5 Competency: Characterize chemical hazards in the laboratory.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can characterize chemical hazards in the laboratory.
    a. categorize or classify chemical hazards in the laboratory, including:
        i. Oxidizers
        ii. Flammables
        iii. Toxins
        iv. Gases
        v. Incompatible with water
        vi. Fumes
        vii. Irritants
        viii. Radioactive
        ix. Reagents
        x. Solvents
5. The laboratory analyst can characterize physical hazards in the laboratory.
    a. categorize or classify physical hazards in the laboratory, including:
        i. Electrical
        ii. Heat/Cold/Minus 80 C
        iii. Pressure
        iv. Hot glass
        v. Dry ice
        vi. Bulk gas
        vii. Liquid nitrogen
6. The laboratory analyst can characterize biological hazards in the laboratory:
    a. categorize or classify biological hazards in the laboratory, including.
        i. Select agents
        ii. Pathogens
        iii. Biosafety level
        iv. Biotoxins

2. Level 5 Competency: Evaluate hazard.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can rank the hazard (high, medium, low). 2. The laboratory analyst can determine the potential outcome (level of harm). a. Skin exposure b. Inhalation c. Mucous membrane 3. The laboratory analyst can identify different hazard symbols. 4. The laboratory analyst can recognize and interpret hazard symbols, including: a. GHS Global Harmonization System b. NFPA National Fire Protection Association c. Explosives d. Biohazard e. Toxicity f. Corrosive g. Poisons h. Flammable i. Oxidizer j. Health hazard 5. The laboratory analyst can evaluate the severity of the hazard.

Assessment and Audit		
BRAINSTORM		
• Risk assessment • Internal audit • Inspections • Corrective action	• Chemical inventory • Incident report • Agencies that perform audits (OSHA, fire marshal, CDC SAP, DEA, FAA, NEC, EPA)	• Hazard identification • Hazard assessment • Safety assessment • Research information

Definition: Evaluating the efficacy of current practices to reduce the risk of harm from hazards in the laboratory.

Level 4 Competency: Evaluate current safety practices.

Level 5 Competencies:

1. Differentiate between agency requirements.
2. Perform a safety audit.
3. Perform a risk assessment.

1. Level 5 Competency: Differentiate between agency requirements.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can list regulatory agencies that perform audits:
    g. OSHA
    h. CDC Select Agent Program
    i. DEA
    j. FAA
    k. NEC Nuclear Energy Commission
    l. EPA
    m. State fire marshal

2. Level 5 Competency: Perform a safety audit.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can evaluate the results of a safety audit.

3. Level 5 Competency: Perform a risk assessment.

Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can evaluate possible exposure. 2. The laboratory analyst can recommend a corrective action. 3. The laboratory analyst can evaluate a chemical/biological inventory. 4. The laboratory analyst can recognize if something is missing. 5. The laboratory analyst can recognize chemicals that shouldn't be stored together. 6. The laboratory analyst can assess what is in the laboratory freezer. 7. The laboratory analyst can prioritize hazards for mitigation. 8. The laboratory analyst can recognize new equipment requirements (electrical, gas, etc.). 9. The laboratory analyst can recognize new analytes/organisms. 10. The laboratory analyst can recognize new analytical methods.

Engineering Controls
BRAINSTORM • Safety barriers • Fume hood • Acid hood • Eye washes • Safety shower • Sinks • Emergency lighting • Communication systems • BSL characteristics • Equipment safety • Facility maintenance • Security • Mitigate hazards • Risk mitigation • Air flow • Alarms • Hood calibration • Hood certification • Snorkel hoods • Lighting • Emergency lights • Biosafety cabinet (BSC)
Definition: Primary and secondary facility barriers that prevent or mitigate exposure to hazards in the laboratory. **Level 4 Competency:** Evaluate engineering controls. **Level 5 Competencies:** 1. Explain the functionality of barriers. 2. Track maintenance.

3. Level 5 Competency: Explain the functionality of barriers.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can explain how specific barriers function/operate, including: a. Security (access control) b. Biosafety cabinet failure c. Eyewashes d. Showers e. Negative pressure f. Fire extinguishers g. Emergency lights h. Temperature controls i. HVAC 2. The laboratory analyst can correlate barrier with hazard. a. explain which hazards specific barriers are meant for, including: b. Biosafety containment c. Fume hood d. Acid hood e. Snorkel hood 3. The laboratory analyst can distinguish between primary and secondary barriers. a. explain the purpose and use of primary barriers, including: i. PPE ii. Centrifuge iii. Biosafety cabinets iv. Hoods b. explain the purpose and use of secondary (facility-related) barriers, including: i. Airflow ii. Security iii. Lighting iv. Alarms v. Safety shower vi. Eyewashes

4. Level 5 Competency: Track maintenance.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can schedule certification. 2. The laboratory analyst can schedule calibration. 3. The laboratory analyst can report failures. 4. The laboratory analyst can perform preventive maintenance. 5. The laboratory analyst can follow the preventive maintenance schedule (daily, per use, quarterly). 6. The laboratory analyst can identify deficiencies/defects. 7. The laboratory analyst can control inventory i.e., make sure you have safety equipment, and justify how many (disposables) are needed. 8. The laboratory analyst can monitor the functionality of safety equipment.

Equipment / PPE		
BRAINSTORM		
• Autoclave • Generator • UV/IR glasses	• Equipment safety • Respirator selection/use • Equipment deficiencies	• Smoke detectors • Narcan (antagonist)
Definition: Equipment that keeps laboratory personnel and others safe. **Level 4 Competency:** Evaluate laboratory equipment/PPE. **Level 5 Competencies:** 1. Verify functionality of safety equipment.		
5. Level 5 Competency: Verify functionality of safety equipment.		
Based on Level 5 competency – Not an all-inclusive list		
BEHAVIORAL ANCHORS Average		
1. The laboratory analyst can check that equipment is working properly. 2. The laboratory analyst can identify a problem. 3. The laboratory analyst can evaluate exposure.		

Safety Practices – Implementation and Improvements

BRAINSTORM

- Radiation safety
- Buddy system
- Safety training
- Power outage
- Fire extinguisher use
- Accident response
- Labeling
- Multiple location
- Instrument use and maintenance
- Suggest improvements
- Emergency response
- Safety tour
- Trainer
- Spill response
- Communication
- Waste disposal
- Fit-testing
- Preparedness
- Exit routes
- Ingress/egress
- First aid
- Ship infectious samples
- Medical emergencies
- Proper use training
- Fire alarm practice
- Active shooter procedures
- Gas cylinder use/training
- Gas supply installation use/training
- Electrical installation use/training
- Chemical inventory
- Safety committee
- Floor warden
- Evacuation routes
- Pest control
- Safety SOPs
- Biosafety officer
- BMBL
- NFPA regs
- PSDS pathogen safety data sheet
- Hazard communication standard
- SDS safety data sheet
- Chemical hygiene plan
- DOT shipping regulations
- Safety officer
- OSHA regs
- Biosafety plan
- Chemical safety officer
- Emergency response plan
- Incident response plan
- Biosecurity plan

Definition: Training, drills, actions, and other safety preparation activities.

Level 4 Competency: Evaluate safety preparation activities.

Level 5 competencies:

1. Promote safety behavior.
2. Serve in a safety leadership position.

1. Level 5 Competency: Promote safety behavior.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst helps promote the following behaviors:
    a. Leading by example.
    b. Accountability
    c. Compliance
    d. Preparedness
    e. Task-oriented

f. Suggesting improvements
g. Reporting incidents related to advanced safety mitigation (incidents pertaining to facility or engineering controls)

2. The laboratory analyst can instruct others on the use of safety equipment.
3. The laboratory analyst can teach other laboratory analysts about safety activities such as:
    a. Buddy system
    b. Accident response
    c. Shipping infectious samples
    d. First aid
    e. Compressed gas use
    f. Fire alarm practice
    g. Active shooter
    h. Waste disposal
4. The laboratory analyst can investigate safety incidents.
    a. Compose a report.
5. The laboratory analyst can recommend improvements to existing safety resources.
6. The laboratory analyst can suggest officer positions.
7. The laboratory analyst can contribute to the development of safety plans.
8. The laboratory analyst can contribute to the development of safety SOPs.
9. The laboratory analyst can contribute to the development of evacuation routes.
10. The laboratory analyst can contribute to the development of shelter-in-place plans.
11. The laboratory analyst can contribute to the development of preparedness plans (social distancing).
12. The laboratory analyst can contribute to the development of safe workflow procedures.
13. The laboratory analyst can prioritize approved analytical methods based on safety.

2. Level 5 Competency: Serve in a safety leadership position.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can formulate safety action responses.
2. The laboratory analyst can create safety action responses related to:
    a. Power outages
    b. Accidents
    c. Emergencies
    d. Active shooter
    e. Medical emergencies
    f. Spill response

g. Safety tour
h. Waste disposal

3. The laboratory analyst can mitigate hazards.
4. The laboratory analyst can address failures.
    a. Recognizes how they can fix something.
    b. Recognizes whether they can continue testing.
    c. Implement a correction.
5. The laboratory analyst can suggest additional barriers.
6. The laboratory analyst can suggest improvements to existing controls (equipment/PPE).
7. The laboratory analyst can interpret various types of safety plans, including:
    a. Biosafety
    b. Chemical hygiene
    c. Incident response
    d. Biosecurity
    e. Hazard communication standard
    f. Emergency response
    g. Integrated pest management
    h. Pathogen safety
    i. Shelter-in-Place
    j. Biomedical (pandemic preparedness and response)
8. The laboratory analyst can interpret safety documents.
9. The laboratory analyst can interpret various safety documents, including:
    a. Safety SOPs
    b. SDS safety data sheets
    c. PSDS pathogen safety data sheet
10. The laboratory analyst can interpret safety regulations.
11. The laboratory analyst can interpret various safety regulations, including:
    a. DOT shipping regulations
    b. OSHA
    c. NFPA regulations
    d. BMBL (Biosafety in Microbiological and Biomedical Laboratories)
12. The laboratory analyst can explain the various safety programs.
13. The laboratory analyst can explain various safety programs, such as:
    a. Radiation safety
    b. Respirator safety

c. Fit-testing
d. Pulmonary fitness (medical exam)
e. Appropriate filters
f. Fire safety
g. First aid
h. Compressed gas handling
i. Gas supply
j. Waste disposal
k. Electrical use

14. The laboratory analyst can conduct a safety tour.
    a. This is where you do your autoclaving
    b. This is where you dispose hazardous waste
    c. Ingress/egress
    d. Exit routes
15. The laboratory analyst can perform a competency safety assessment of other laboratory analysts.
16. The laboratory analyst can assess the competency of other laboratory analysts in relation to:
    a. Spill response
    b. Donning and doffing PPE
    c. Biosafety cabinet use
    d. Chemical fume hood use
    e. Hazardous waste disposal
17. The laboratory analyst can hold various positions such as:
    a. Biosafety officer
    b. Chemical safety officer
    c. Floor warden
    d. Safety committee
18. The laboratory analyst may be able to lead an incident response.

Advanced Waste Management

Definition: Legal responsibilities, regulatory requirements, safety concerns, oversight practices, and destruction methods associated with waste management.

Level 2 Competency: Support laboratory waste management activities.

Level 3 Competencies:

- Teach waste management practices to entry-level laboratory analysts - Communication
- Promote effective waste management practices – Leadership
- Follow laboratory policies related to waste management – Programmatic
- Apply waste management techniques – Technical

Legal Responsibility		
• Documentation • Contractors • Labeling • Shipping • Regulations	• HAZWOPER training • Classifications • Manifest • Regulated waste • Contracting for waste removal	• Compliance • Transportation of hazardous waste • Auditing • Regulatory entities

Description: Legal responsibilities associated with waste management.

Level 4 Competency: Discuss legal responsibilities associated with waste management.

Level 5 Competencies:

1. Describe waste management entities.

2. Describe the regulatory requirements for waste management.

1. Level 5 Competency: Describe waste management entities.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can identify waste management entities, such as:
    a. Federal entities/agencies (EPA - RCRA, Dept of Labor – OSHA, DOT – IATA, CDC - BMBL)
    b. State and local entities/agencies, if applicable.
    c. Contractors

2. Level 5 Competency: Describe the regulatory requirements for waste management.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst has knowledge of the regulatory requirements for various aspects of waste management, such as:
    a. Shipping/transportation
    b. Documentation (SOPs the how and when of recording things,)
    c. Records (shipping manifest, audit records, training records, etc.)
    d. Training (an awareness of HAZWOPER, etc.)
    e. Labeling
    f. Classifications
    g. Safety (fit testing, etc.)
    h. Quantity limits (accumulated waste, storage locations, etc.)
    i. Auditing
    j. Certified contractors (certified for hazardous waste, etc.)

Safety		
• Risk assessment • Hazards • Chemical interactions • Classifications	• Fit testing • Labeling • Compatibility • Sharps handling	• Support experts • PPE • SDS

Description: Safety aspects associated with waste management.

Level 4 Competency: Discuss safety in relation to waste management.

Level 5 Competencies:
1. Contribute to a risk assessment for waste management.
2. Consult resources in matters related to hazardous waste.
3. Assess a hazardous waste-related safety incident.
4. Describe waste-related safety hazards.
5. Identify potential deficiencies in waste handling practices.

1. **Level 5 Competency:** Contribute to a risk assessment for waste management.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst has an awareness of hazards specific to waste management.
2. The laboratory analyst has an awareness of various risk assessment charts/matrices.
3. The laboratory analyst can work with a team on a risk assessment.
    a. Contribute method specific knowledge for the risk assessment.

2. **Level 5 Competency:** Consult resources in matters related to hazardous waste.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can consult the sections of an SDS.
2. The laboratory analyst can consult with human resources (e.g., Safety Officer, industrial hygienist, other experts)

3. **Level 5 Competency:** Assess a hazardous waste-related safety incident.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can determine an appropriate course of action.

2. The laboratory analyst can respond themselves, as appropriate.
3. The laboratory analyst can consult the appropriate people.
4. The laboratory analyst can determine appropriate safety tools (e.g., spill kit, PPE) as appropriate.

4. **Level 5 Competency:** Describe waste-related safety hazards.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst has an awareness of common violations/non-compliances (e.g., lids, leaks, labels, storage locations).

5. **Level 5 Competency:** Identify potential deficiencies in waste handling practices.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can recognize SOP deviations.
    a. Recognize when confidentiality is being breached
        i. Sensitive documents
        ii. Software/hardware
    b. Throwing lithium batteries in the trash
2. The laboratory analyst can recognize errors in an SOP.
3. The laboratory analyst can apply critical thinking skills to the SOP.

Waste Oversight

• Improvements • Sensitive waste • Waste streams • Consolidation • Chemical interactions • Classifications • Characterization • Labeling • Waste prep	• Packaging requirements • Compatibility • Waste minimization/reduction • Waste management plan • Support experts • Recyclable waste • Storage procedures • Regulated medical waste	• Corrective actions • Alternate (support expert) • Inventory • Destruction • Documentation • Disposal procedures • Solvents • Landfill

Description: Supporting waste maintenance procedures and operations.

Level 4 Competency: Describe the oversight of laboratory waste management.

Level 5 Competencies:
1. Support daily operations of waste management.
2. Identify the waste stream process from "cradle to grave."
3. Recognize common violations.
4. Suggest improvements in waste management.
5. Support administrative waste management functions, as applicable. (This would apply to an outstanding mid-level person and may be site-dependent.

1. Level 5 Competency: Support daily operations of waste management.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can monitor waste quantity on hand (including satellite areas, defined as waste stored at or near the site of generation, e.g., fume hood or waste storage container).
2. The laboratory analyst can monitor inventory (e.g., off-spec/expired or almost expired chemicals).
3. The laboratory analyst can check labeling.
4. The laboratory analyst can report issues to the expert (e.g., expired reagents, shortage of satellite containers).
5. The laboratory analyst takes responsibility for their own work area.

2. Level 5 Competency: Identify the waste stream process from "cradle to grave."

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can recognize whether to treat something as hazardous waste.
2. The laboratory analyst can identify the disposition through the waste stream.
3. The laboratory analyst can differentiate waste types in the waste stream (chemical and biological).
    a. Identify incompatible waste streams, such as:
        i. Example from liquid chromatography – where does the acetonitrile go, what do you do with the glass bottle it came, what to do with the spent solvent when the satellite container is full, etc.
    b. Recognize the types and amounts of waste that is generated from their specific operation.
4. The laboratory analyst can recognize that documentation may be required.

3. Level 5 Competency: Recognize common violations.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can describe common violations, such as:

a. lids, leaks, labels, storage locations

4. Level 5 Competency: Suggest improvements in waste management.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can recommend ways to minimize/reduce waste.
2. The laboratory analyst can recommend ways to re-use/recycle.
3. The laboratory analyst can offer potential corrective actions.
4. The laboratory analyst can check labels, packaging, etc.

5. Level 5 Competency: Support administrative waste management functions, as applicable.
(This would apply to an outstanding mid-level person and may be site-dependent.)

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can serve as an alternate for sign-offs/approvals.
2. The laboratory analyst can review disposition procedures. (e.g., can review SOPs for storage, inventory, disposal, labeling).

Final Disposition

• Manifest • Autoclaving	• Disposal coordination • Incineration	• Landfill • Waste prep

Description: Disposal practices in support of waste management.

Level 4 Competency: Discuss the disposal of laboratory waste.

Level 5 Competencies:
1. Describe methods of final disposition based on waste type.
2. Support waste final disposition activities.

1. Level 5 Competency: Describe methods of final disposition based on waste type.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst has knowledge of methods of final disposition based on waste types, such as:
   a. Regulated medical waste

b. Chemical c. Sensitive (protected health information, employee records, test information/results) d. Electronic (LIS, computer hardware and software) e. Radioactive f. Light fixtures g. Batteries
2. Level 5 Competency: Support waste final disposition activities.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can perform reviews of manifest prior to approval by expert. 2. The laboratory analyst can verify the waste listed on the manifest. 3. The laboratory analyst can verify that final disposition records are retained.

Audit

Definition: Techniques and methods of verification in order to assess an operation or facility's compliance with the policies and procedures that cover the scope of the system being reviewed.

Level 2 Competency: Promote the audit process.

Level 3 Competencies:

- Teach others on the importance of audits - Communication
- Support the audit process – Leadership
- Follow laboratory policies in conducting an audit – Programmatic
- Participate in an internal audit – Technical

Scope of the Audit		
• Standard involved • Internal audit • Health and safety regulations • Focused audit	• Purchasing systems • Property/equipment/facility • Requirements (QA, safety, etc.) • Vertical audits • Scope of accreditation	• Role of audit • QMS requirements • External audits (Federal, state, customers, third party, select agents) • Performance standards

Description: Establishing the activities, objectives, and boundaries of the audit.

Level 4 Competency: Describe the scope of an audit.

Level 5 Competencies:

1. Describe types of audits.
2. Identify the standard to which the audit is being conducted.
3. Identify the criteria to which the audit is being conducted.
4. Categorize elements of an audit.

1. Level 5 Competency: Describe types of audits.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can define types of audits, such as:
    a. Safety
    b. QMS

c. Environmental
d. Financial
e. Property
f. Purchasing
g. LIMS
h. Internal
    i. Scope
        1. What records to ask for
        2. Who to interview
        3. What to report
    ii. In-house (self-audit)
i. External
    i. Third party
    ii. Customer
    iii. Accrediting body
    iv. Federal
    v. State
j. Vertical
    i. Follow sample from receipt to disposal
    ii. Follow the procurement of equipment from selection to final disposition
    iii. Follow analyst performance for a specified period of time
k. Horizontal

5. The laboratory analyst can describe an interim audit:
    a. Items can be added to or removed from the scope of accreditation

2. Level 5 Competency: Identify the standard to which the audit is being conducted.

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

BEHAVIORAL ANCHORS Average

2. The laboratory analyst can describe audit standards, such as:
    a. ISO 17025
    b. ISO 35001 (safety)
    c. Internal QMS
    d. Federal/state agency laboratory testing, waste management and safety
    e. CLIA
    f. Drinking water

3. Level 5 Competency: Identify the criteria to which the audit is being conducted.

Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can describe audit criteria, such as: a. Impartiality b. Confidentiality c. Document control d. Documented training e. Management review
4. Level 5 Competency: Categorize elements of an audit.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can explain the purpose of an audit. 2. The laboratory analyst can explain timeframes for activities being audited. 3. The laboratory analyst can define the time allocated to conduct the audit. 4. The laboratory analyst can define the scope of the audit. 5. The laboratory analyst can explain the role of the audit. 6. The laboratory analyst can describe the personnel to be involved in the audit.

Planning for the Audit		
• On-site/remote • Scheduling audit • Number of items or processes • Purpose	• Team selection • Resources • Physical layout • Auditor skills	• Facility controls • Security • Auditor role • Develop written checklist of data needs
Description: Determining who, where, when, and how the audit will be done. **Level 4 Competency:** Participate in planning for an audit. **Level 5 Competencies:** 1. Identify the requirements of the criteria being audited. 2. Identify audit participants. 3. Recognize resources needed for the audit. 4. Support the audit schedule. 5. Assist in the preparation of an audit checklist.		

1. Level 5 Competency: Identify the requirements of the criteria being audited.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
4. The laboratory analyst can discuss the requirements of various standards/criteria being audited: a. ISO 17025 b. FDA c. Internal d. External parties e. Hazardous waste f. Safety regulations g. MFRPS h. AFRPS
2. Level 5 Competency: Identify audit participants.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
3. The laboratory analyst can recognize which staff members may contribute. 4. The laboratory analyst can recognize members of the audit team. 5. The laboratory analyst can describe the role/significance of the quality manager. 6. The laboratory analyst can review analysts' roles. 7. The laboratory analyst can participate in a mock audit.
3. Level 5 Competency: Recognize resources needed for the audit.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
5. The laboratory analyst can describe resources needed for the audit, such as: a. On-site or remote audit b. Physical layout c. Security d. Staff time e. Prior audit report f. Data time range
4. Level 5 Competency: Support the audit schedule.
Based on Level 5 competency – Not an all-inclusive list

BEHAVIORAL ANCHORS Average
2. The laboratory analyst can identify items to consider when creating an audit schedule, such as: a. Frequency b. When to schedule the audit c. Timeframe d. Activities to be audited and timeframe
5. Level 5 Competency: Assist in the preparation of an audit checklist.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can describe items that would be included on an audit checklist, such as: a. Data needs based on scope b. Records c. Testing activities

Preparing for the Audit		
• Roles and responsibilities of staff being audited • Analyst skills • Analyst role • Records • Inventory management • Analyst competency • Corrective actions • Quality control • Audit trail	• Equipment maintenance and calibration • Policies and procedures • Training • Evidence • Non-conforming • SOPs • Pre-analytical • Analytical • Post-analytical • Traceability	• Certified reference materials • Sample tracking • Property inventory • Training records • Laboratory records (temp, repair & maintenance, sample storage, sample receipt storage and disposal)
Description: Actions taken in preparation for an audit. **Level 4 Competency:** Summarize actions taken in preparation for an audit. **Level 5 Competencies:** 1. Collate required materials. 2. Compile data. 3. Review prior audit findings / responses.		

1. Level 5 Competency: Collate required materials.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
6. The laboratory analyst can describe required materials needed for an audit, such as: a. Documents and records. i. Training ii. Laboratory records iii. QMS iv. Equipment v. SOPs vi. Data trails vii. Previous audit reports
2. Level 5 Competency: Compile data.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
5. The laboratory analyst can perform queries.
3. Level 5 Competency: Review prior audit findings / responses.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can examine prior audit findings and responses for information, such as: a. Looking at what findings were found b. Looking at whether a corrective action was taken c. Effectiveness check of corrective action(s)

Conducting an Internal Audit		
• Audit process • Observations • Analyst competency	• Opening and closing meetings • Soft skills • Prior audit findings	• Questioning technique • Consistency in performance • Documentation
Description: Activities related to conducting an internal audit with the audit team. **Level 4 Competency:** Participate in activities related to an internal audit.		

Level 5 Competencies:
1. Examine materials being audited.
2. Document observations using the audit checklist.
3. Conduct interviews.

1. Level 5 Competency: Examine materials being audited.

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

BEHAVIORAL ANCHORS Average

2. The laboratory analyst can describe what materials should be examined, such as:
    a. Training
    b. Laboratory records
    c. QMS
    d. Equipment
    e. SOPs
    f. Data trails
    g. Previous audit reports
    h. LIMS data
    i. Corrective actions/monitoring data/preventative actions
    j. Analyze audit trail

2. Level 5 Competency: Document observations using the audit checklist.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can describe what types of observations should be documented, such as:
    a. Good lab practices/compliance with standard
    b. Deficiencies
    c. Issues/problems
    d. Gaps, missing documents/records
    e. On-the-spot corrections
5. The laboratory analyst can document observations.
6. The laboratory analyst can submit completed audit checklist.

3. Level 5 Competency: Conduct interviews.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can prepare open-ended questions.
2. The laboratory analyst can predict evasive answers.
3. The laboratory analyst can demonstrate soft skills.
4. The laboratory analyst can conduct opening/closing meetings.
5. The laboratory analyst can provide feedback.

Audit Outcomes		
• Audit effectiveness • Corrective actions • Advantages of the audit • Monitoring	• Improvements • Conclusion • Audit report • Implementation	• Preventative actions • Gaps • Reporting non-compliance • Response to the audit

Description: Findings identified, and actions taken following an audit.

Level 4 Competency: Discuss the outcomes of an audit.

Level 5 Competencies:
1. Provide feedback on the audit process.
2. Report internal audit observations.
3. Participate in a close-out meeting / debrief.
4. Participate in a risk assessment of the observed deficiencies/problems.

1. Level 5 Competency: Provide feedback on the audit process.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can discuss feedback on the audit process, such as:
    a. Lessons learned
    b. What went well
    c. What didn't go well
    d. Audit effectiveness (did they find everything?)

2. Level 5 Competency: Report internal audit observations.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can point out potential internal audit observations, such as:
    a. Potential corrective actions
    b. Potential preventive actions
    c. Potential gaps

3. Level 5 Competency: Participate in a close-out meeting / debrief.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can suggest opportunities for improvement, such as:
    a. Preventive actions
2. The laboratory analyst can suggest process improvements (process changes based on the audit).
3. The laboratory analyst can provide insight on what may have gone wrong.

4. Level 5 Competency: Participate in a risk assessment of the observed deficiencies/problems.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can identify how much damage could be done if problem (s) are not resolved, such as:
    a. Samples lost
    b. Time lost
    c. Additional resources needed
    d. How long it would take
    e. Reporting inaccurate data (erroneous decimal point)
    f. Impact on accreditation

Emerging Analytical Challenges Mid-Level Core

Description: Emerging analytical challenges related to methodology, technology, and analysis.

Examples: Whole Genome Sequencing / Melamine / PFAS / Anti-microbial resistance

Problem Identification	**Responding to a Challenge**
Description: Recognizing and describing the impact of emerging challenges to operations. **Competencies:** 1. Recognize potential problems. 2. Describe the problem. 3. Contribute to an impact assessment. • Critical thinking • Threat identification • Identify gaps • Compare • Assess • Analytical • Scientific • Assumptions Challenge ideas (seeking understanding) • Issue recognition	**Description:** Researching and seeking potential solutions to emerging challenges. **Competencies:** 1. Research potential solutions. 2. Formulate potential solutions. 3. Compare potential solutions. 4. Recommend approaches. • Considerations (safety, data handling, etc.) • Assessing facility needs (necessary infrastructure) • Assessing resources needs (cost of implementation) • Innovative • Think outside of the box • Investigate • Research • Seeking • Scientific curiosity • Open minded • Adaptive approach • Research options • Repurpose applications • Discovery • Observant • Problem solving • Impact on regulatory policy (more/fewer violations/recalls, etc.) • Identify resources • Resources • Networking (expertise as a resource)

	• Share information • Participate • Contribute • Continuous learning • Validate understanding • Collaborative • Networking (meetings, trainings, associations) • Community of practice • Data handling • Data sharing • Finding consensus • Growing the knowledge base • Reaching agreement • Throughput • Turn-around-time • Efficiency • Verify • Validate • Collate • Draft • Proven capability • Proven capacity

<table>
<tr><th colspan="4">Problem Identification</th></tr>
<tr>
<td>• Critical thinking
• Threat identification</td>
<td>• Identify gaps
• Compare</td>
<td>• Assess
• Analytical
• Scientific</td>
<td>• Assumptions Challenge ideas (seeking understanding)
• Issue recognition</td>
</tr>
<tr>
<td colspan="2">Description: Recognizing and describing the impact of emerging challenges to operations.

Competencies:
1. Recognize potential problems.
a. Upcoming technologies
b. Public health events
c. Observing trends
2. Describe the problem.
a. Relevance
b. Operational capability/capacity
i. Space
ii. Resources
iii. Workflow
iv. Technology
v. Training
c. Scope (OneHealth/public health)
3. Contribute to an impact assessment of laboratory area immediately impacted.
a. Identify strengths/opportunities
b. Identify limits
c. Identify gaps
d. Communicate (share information) up or across</td>
<td colspan="2"></td>
</tr>
</table>

<table>
<tr><th colspan="4">Responding to a Challenge</th></tr>
<tr>
<td>• Considerations (safety, data handling, etc.)
• Assessing facility needs (necessary infrastructure)
• Assessing resources needs (cost of implementation)
• Innovative
• Think outside of the box
• Investigate
• Research
• Seeking
• Scientific curiosity
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• Adaptive approach</td>
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• Repurpose applications
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• Efficiency
• Verify
• Validate
• Collate
• Draft
• Proven capability
• Proven capacity</td>
</tr>
<tr>
<td colspan="2">Description: Researching and seeking potential solutions to emerging challenges.

Competencies:
1. Research potential solutions.
a. Gather information/grow the knowledge base
i. Literature
ii. Professional networks/community of practice
iii. Seek learning opportunities
iv. Utilize institutional knowledge
v. Existing precedent (other laboratories, agency laboratories, network members)
b. Brainstorming
2. Formulate potential solutions.
a. Processing information
i. Utilize critical thinking
ii. Break the problem down into units
b. Anticipate considerations (e.g., safety, data handling, cost, infrastructure, throughput, feasibility, sustainability)
c. Leverage resources e.g., capability, capacity, software updates, Trainings (APHL, specific agencies
d. Repurpose existing applications if practical</td>
<td colspan="2">3. Compare potential solutions.
a. Weighing the pros and cons e.g., SWOT, GAP
b. Gather data
c. Evaluate data
d. Rank the potential solutions
e. Share information
f. Incorporate feedback
4. Recommend approaches.
a. Provide rationale
b. Draft a proposal with supporting documentation
i. List needed resources
c. Get an objective review
d. Corroborate the approach</td>
</tr>
</table>

Environmental Conditions

Description: Environmental factors that can impact test results in human and animal food safety laboratories.

Level 2 Competency: Support laboratory activities related to environmental conditions.

Level 3 Competencies:

- Teach others about environmental factors that can impact test results - Communication
- Initiate improvements - Leadership
- Organize responses to environmental failures - Programmatic
- Characterize environmental factors - Technical

Facility Design

BRAINSTORM

- "Clean" source of water
- Adequate water supply
- Maintain stable temperature
- Isolating analytical balances
- Humidity control
- Static electricity
- Illumination
- Stable power
- Power backup (uninterruptible)
- Availability of power sources (outlets)
- Bench space
- Storage areas (samples, glassware, reagents, chemicals, gases, separation, incompatibilities, limitations)
- Gasses
- Surfaces (walls, floors, benchtops, cracks)

Description: Considerations for facility design that impact test results.

Level 4 Competency: Discuss facility design considerations that impact test results.

Level 5 Competencies:

1. Characterize facility features that impact test results.

3. **Level 5 Competency:** Characterize facility features that impact test results.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
7. The laboratory analyst can evaluate the laboratory facility for impact on test results, such as: a. Water supply. b. Power supply. (Stability, adequacy for instruments) c. Temperature control. (Stability and adequacy for instruments, chemical storage, sample storage, reactions). d. Humidity control (Stability for instruments, chemical storage, sample storage). i. Low humidity climates 1. Static electricity (material handling such as balances, instruments) ii. High humidity climates e. Instruments f. Sample storage g. Supply storage h. Airflow a. Negative and positive pressure i. Illumination i. Specialized lighting for low illumination areas ii. UV filters for UV sensitive analytes j. Facility surfaces (benches, floor space, walls). i. Adequate (not crowded) ii. Cleanable (surface type dependent on analyte) k. Gas supply (adequacy of use, purity) l. Physical workflow (space, physical movement within the lab) m. Busted pipes/leaky roof n. Safety/security issues	1. The laboratory analyst can suggest improvements to laboratory facility design. 2. The laboratory analyst can evaluate a biosafety cabinet next to an entry way. 3. The laboratory analyst can evaluate non-micro lab areas vs. micro lab areas. 4. The laboratory analyst can evaluate the risks associated with the facility design impacting test results. 5. The laboratory analyst can assess autoclaving vs. oven. 6. The laboratory analyst can assess pre-amplification vs. post-amplification. 7. The laboratory analyst can evaluate anything hazardous in a positive pressure space.

Contaminant Containment

BRAINSTORM

- Laminar flow hoods
- Fume hoods
- Biosafety cabinets
- Avoid contamination (caulking, VOCs)
- Clean room
- Containers/glassware
- Radiological
- Disorganization, clutter
- Bench space Waste storage/disposal
- Incompatibilities
- Hoarding
- Pest control
- Waste management

Description: Control of contaminants impacting test results.

Level 4 Competency: Describe considerations for containment of specific contaminants.

Level 5 Competencies:

1. List analytes that are prone to contamination issues.
2. Assess the risk associated with air flow on test results.
3. Describe the way that containers/labware can impact test results.
4. Evaluate sources of contamination.

1. Level 5 Competency: List analytes that are prone to contamination issues.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can resolve the source of potential contaminants, such as:
    a. Radiological
    b. Select agents
    c. Infectious materials
    d. Toxins
    e. Pesticide
    f. Low level elemental analysis
    g. Pathogens

2. Level 5 Competency: Assess the risk associated with air flow on test results.

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

BEHAVIORAL ANCHORS Average

8. The laboratory analyst assesses the risk associated with airflow on test results, such as:
    a. insufficient air flow
    b. excess air flow

c. proper direction
d. control contamination
    i. Positive pressure areas
    ii. Negative pressure areas
    iii. Appropriate hood type, placement, hood settings
        1. Laminar flow hoods
        2. Fume hoods
        3. Biosafety cabinets
        4. Flexible vents over instruments

3. Level 5 Competency: Describe the way that containers/labware can impact test results.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can investigate ways containers/labware can impact test results:
    a. Leaching of the analyte from the labware
    b. Adsorption of the analyte onto the labware
    c. Insufficient cleaning of labware
    d. Poor seals (cracks)
    e. Sterility

4. Level 5 Competency: Evaluate sources of contamination.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst recognizes housekeeping and office activities may lead to contamination in the laboratory:
    a. Caulking
    b. Painting
        i. VOCs
    c. Pesticide application
    d. Pest control
    e. Cleaning
    f. Sweeping (dust)
    g. Office supplies (pens, copying machines, staplers, computer peripherals)
    h. Plants
    i. Persons (hands, skin, cell phones, glasses, hearing aids, jewelry, hair, clothes, shoes, contaminated PPE (dirty gloves), personal secretions)

2. The laboratory analyst can correct general housekeeping activities that may impact test results:
    a. Organization
    b. Cleanliness
    c. Uncluttered bench space
    d. Appropriate waste storage/disposal
    e. Appropriate chemical/reagent storage
    f. Pest control
3. The laboratory analyst can resolve contamination/degradation events.
    a. Document event
    b. Investigate event
    c. Identify impact
    d. Decontaminate

Monitoring & Prevention

BRAINSTORM

- Monitoring devices (radioactivity, etc.)
- Periodic monitoring
- Hood calibration
- Recordkeeping
- Risk assessment
- Gasses

Description: Controls and practices that support a suitable testing environment.

Level 4 Competency: Explain controls/practices that support the testing environment.

Level 5 Competencies:
1. Monitor activities that impact test results.
2. Detect compromised analytical tools prior to use.

6. Level 5 Competency: Monitor activities that impact test results.

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

BEHAVIORAL ANCHORS Average

4. The laboratory analyst can monitor activities, such as:
    a. Environmental exposure (monitoring devices)
    b. Hood calibration
    c. Gas purity
    d. Gas supply

e. Facility control monitoring (room temperature, room humidity, air flow)

5. The laboratory analysts can assess the monitoring records and identify the risks.
    a. Critique compliance with laboratory practices designed to prevent contamination and degradation.
6. The laboratory analyst can suggest improvements to correct out of compliance events to address risks.
    a. Environmental monitoring (amplicon contamination in pre-analytical molecular space)
    b. Appropriate disinfectants for the work being performed
    c. Systems to prevent errors
    d. How to perform environmental swabbing
    e. Monitoring air contamination using media

7. Level 5 Competency: Detect compromised analytical tools prior to use.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can detect:
    a. Non-sterile supplies (failed autoclave indicator on tools; unsealed/breached consumables)
    b. Non-sterile equipment (media)
    c. Out-of-spec equipment (incubator, refrigerator temperature log, autoclave)

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.

4. 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**
8. The laboratory analyst can define evidentiary integrity. 9. The laboratory analyst can articulate the need for evidentiary integrity to ensure defensible test results. 10. 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
3. 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**
4. 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 5. The laboratory analyst can explain the importance of records relevant to evidentiary integrity. 6. 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.
5. Level 5 Competency: Employ metrological measurement system (SI).	

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
5. The laboratory analyst can define metrological measurement system. 6. The laboratory analyst can describe the importance of metrological measurement system in evidentiary integrity. 7. The laboratory analyst can implement metrological measurement system to support evidentiary integrity. 8. 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.	6. The laboratory analyst can develop procedures for establishing metrological measurement system. 7. 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.

2. 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
5. The laboratory analyst can define traceability. 6. The laboratory analyst can describe the role of laboratory's quality system in traceability. 7. The laboratory analyst can describe the importance of tracing a test result to a decision unit. 8. The laboratory analyst can recognize policies relevant to traceability. 9. 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.

5. 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**
9. The laboratory analyst can define the term "decision unit". 10. The laboratory analyst can explain the importance of unique sample identifiers to support traceability. 11. The laboratory analyst can explain the importance of proper documentation to support traceability. 12. The laboratory analyst can identify gaps in traceability. 13. The laboratory analyst can explain the impact of any deviation from a SOP on traceability. 14. The laboratory analyst can explain the impact of any deviation from chain of custody requirements on traceability. 15. 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.

5. 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
4. The laboratory analyst can define analyte integrity. (e.g., changes to chemical, biological, radiological, or physical characteristics of the analyte) 5. The laboratory analyst can recognize the impact of analyte integrity on evidentiary integrity. 6. The laboratory analyst can list issues that affect analyte integrity, such as: a. Oxidation/reduction b. Absorption c. Volatilization d. Bacterial growth 7. 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.

8. The laboratory analyst can recognize when analyte integrity may be compromised. 9. The laboratory analyst can observe and record conditions related to maintaining analyte integrity. 10. The laboratory analyst can recognize errors that impact analyte integrity.	
6. 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**
5. 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. 6. The laboratory analyst can recognize when analyte integrity procedures have not been followed. 7. The laboratory analyst can explain how quality control activities monitor for loss of analyte integrity.	6. The laboratory analyst can review procedures for effectiveness in maintaining analyte integrity. 7. The laboratory analyst can develop procedures for maintaining analyte integrity. 8. The laboratory analyst can design quality control practices to monitor for loss of analyte integrity.
7. 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.

8. 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
7. The laboratory analyst can recognize the importance of test portions being fit for purpose (fit for decision) with respect to maintaining evidentiary integrity. 8. 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 9. The laboratory analyst can determine whether a test portion mass is fit for purpose.	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.

10. The laboratory analyst can perform representative test portion selection.	
9. 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**
4. 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) 5. 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) 6. The laboratory analyst can describe the importance of minimizing sampling errors to maintaining evidentiary integrity. 7. The laboratory analyst can minimize error in preparing the analytical sample and selecting the test portion. (non-selection & selection processes).	5. The laboratory analyst can troubleshoot/mitigate sampling errors. 6. The laboratory analyst can develop procedures that minimize sampling errors. 7. The laboratory analyst can explain how sampling errors impact test results. 8. The laboratory analyst can identify gaps in laboratory sampling quality control practices.
10. 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**
5. The laboratory analyst can recognize the importance of verification/validation of laboratory sampling protocols as related to maintaining evidentiary integrity. 6. The laboratory analyst can recognize the importance of the sampling protocol to account for and mitigate analyte heterogeneity. 7. The laboratory analyst can identify the need for comprehensive laboratory sampling procedures to support representivity. 8. The laboratory analyst can recognize the importance of laboratory sampling quality control practices.	3. The laboratory analyst can validate a laboratory sampling protocol. 4. The laboratory analyst can calculate error associated with a sampling protocol.

Incident Detection and Response

Definition: Food laboratory activities related to food safety incidents and/or surveillance.

Level 2 Competency: Support laboratory activities related to food safety events and/or surveillance.

Level 3 Competencies:

- Participate in group planning (within laboratory or among laboratories/agencies) for incident detection and response - Communication
- Perform an active role in laboratory activities related to incident detection and response - Leadership
- Explain laboratory responsibilities during incident detection and response - Programmatic
- Apply laboratory services to achieve incident detection and response. - Technical

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
- Needle in a haystack
- Field Information
- Radiation
- Veterinary drugs
- Pesticides
- Unknowns
- Epidemiology
- Toxins
- Pathogens
- Pharmaceuticals
- Chemical Agents
- Definition of a food safety incident (A situation within the food supply chain where there is suspect or confirmed risk associated with consumption of a food that requires rapid response.)

Definition: The elements of a food incident that shape a laboratory response.

Level 4 Competency: Link the elements of a food incident that shape a laboratory response.

Level 5 Competencies:

1. Assist in laboratory planning / response to food incidents.
2. Assist with the evaluation of testing considerations for complex matrices.

5. Level 5 Competency: Assist in laboratory planning / response to food incidents.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can define a food safety incident
2. The laboratory analyst can explain how epidemiology drives sample collection during an incident.
3. The laboratory analyst can participate in table-top exercises. (hypothetical incidents)
4. The laboratory analyst can relate types of incidents to specific laboratory activities.
    a. Chemical
    b. Biological (including zoonotic diseases)
    c. Radiological
    d. Nuclear
    e. Explosive materials
5. The laboratory analyst can relate scale of an incident to laboratory needs.
    a. The laboratory analyst can participate in planning a response to an incident (methods, staff, supplies, equipment)
    b. The laboratory analyst can utilize field investigation information for laboratory planning (e.g., how many samples, duration)
6. The laboratory analyst can prepare for legal implications.
    a. Evidentiary considerations
    b. Enhanced traceability
    c. Chain-of-custody
    d. Performance of controls
    e. Data review
    f. Method verification and any deviations
    g. Training and competency of staff
    h. EUA LDT Emergency Use Authorization Laboratory Developed Test

4. Level 5 Competency: Assist with the evaluation of testing considerations for complex matrices.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can assist in the development of laboratory sampling schemes.
2. The laboratory analyst can assist in identifying appropriate technology.
3. The laboratory analyst can assist in adapting a process for the matrix.
    a. Primary Sampling / Laboratory Sampling/ aliquoting (sharing with other labs)
        i. Extraction, digesting, leeching
        ii. Stomaching, blending, rinsing, grinding
    b. Detection and quantitation (method and instrumental analysis)

c. Expedited reporting
4. The laboratory analyst can suggest new performance controls

Collaborative Communication

BRAINSTORM

- Epidemiological input
- Sample collection
- Cluster detection
- Reporting
- Key partners (FERN, RRTs, LRN, ICLN, etc.)
- Traceback
- Hotwashes
- Risk-based sampling
- Interpretation of results
- NFSDX
- Regulatory program (recalls, import alerts)
- Investigation
- Federal agencies
- Partners

Definition: Laboratory communications related to incident detection and response; this includes before, during, and after an incident response.

Level 4 Competency: Describe collaborative responses to food safety incidents.

Level 5 Competencies:

1. Participate in communications with partners throughout an incident response.
2. Contribute to after-action reviews / debriefings.

3. Level 5 Competency: Participate in communications with partners throughout an incident response.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can participate in planning the response.
    a. Appropriate method
    b. Sample shipment
    c. Preserving sample integrity
    d. Surge capacity
    e. Turn- around- time
    f. Sample disposal
2. The laboratory analyst is familiar with CIFOR guidelines for foodborne disease outbreak response.
3. The laboratory analyst can relay or interpret key findings.
4. The laboratory analyst can correlate epidemiological findings with laboratory data for a comprehensive evaluation.
5. The laboratory analyst can give examples of how key partners utilize laboratory data.

a. Monitoring the safety and quality of the food supply
b. Traceback
c. Recalls
d. Import alerts
e. Detecting outbreaks
f. Helping to solve an outbreak (smoking gun, vehicles)
g. Inform policy
h. Drive programmatic activities
i. Inform risk-based analyses
j. Inform attribution

6. The laboratory analyst can give examples of when engaging the following might be relevant:
    a. Laboratories within your agency's system
    b. Epidemiologists
        i. cluster identification
        ii. reportable finding
        iii. confirmatory result
        iv. atypical finding
    c. Federal Regulatory program staff
        i. any significant findings from an imported product or commodity
        ii. product that crosses state lines
    d. State Regulatory program staff
        i. product that crosses state lines
        ii. any violative sample
    e. FDA Emergency Response Coordinator / RRT Coordinator / FDA CORE (Coordinated Outbreak Response and Evaluation) (for FDA regulated products)
        i. outbreak involving an imported product
        ii. if State lab does not have the capability to conduct the test
        iii. high-profile event
        iv. to confirm State results
        v. coordination for specialized testing (e.g., scombroid, paralytic shellfish poisoning)
        vi. assistance with laboratory testing capacity
    f. USDA FSIS
        i. adulteration of any FSIS-regulated product
    g. FERN /LRN/ICLN/FSAP
        i. if FDA or USDA FSIS requests assistance due to capacity limitations
            1. high-profile events such as Presidential Conventions or Super Bowls
            2. identification of a potential biological or chemical threat

3. large-scale outbreak – melamine
4. identification of select agent or toxin

l. Other partners, based on the incident

6. Level 5 Competency: Contribute to after-action reviews / debriefings.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can identify gaps/areas for increased efficiency/improvement.
    a. Issues with logistics
    b. Issues with resources
    c. Issues with communication
    d. Issues with turnaround times
2. The laboratory analyst can identify what worked.

Laboratory Capacity

BRAINSTORM

- Surge capacity
- Pool/batch sampling detection levels
- Good test portions
- Defensibility
- Throughput scheduling/high throughput

Definition: Sampling and workflow planning strategies in support of laboratory surge activities.

Level 4 Competency: Support laboratory surge activities.

Level 5 Competencies:

1. Contribute to laboratory surge capacity assessment.
2. Assist with high-throughput testing schemes in response to surge capacity needs.

8. Level 5 Competency: Contribute to laboratory surge capacity assessment.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can assist with analyzing workflow efficiencies.
2. The laboratory analyst can identify gaps in workflow efficiencies.
3. The laboratory analyst can predict surge capacity testing needs or resources.
    a. Staffing
    b. Materials/supplies/consumables
    c. Equipment

9. Level 5 Competency: Assist with high-throughput testing schemes in response to surge capacity needs.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can recognize when sample pooling is appropriate.
2. The laboratory analyst can discuss relevant batching scenarios.
3. The laboratory analyst can provide input to management related to:
    a. Physical space
    b. Equipment
    c. Method (EUA, LDT)
    d. Safety
4. The laboratory analyst can incorporate activities to support defensible sample results (refer to Sampling content area)

Laboratory Data Generation

BRAINSTORM

- Troubleshooting
- Critical thinking
- Sources of lab errors
- Performance validation/verification
- Method deviation
- Equipment selection
- Emergency use authorization (EUA)
- Laboratory-developed tests (LDTs)
- Single-lab validation
- Multi-lab validation
- Interpretation of results

Definition: The generation of all data that leads to a test result.

Level 4 Competency: Generate quality data.

Level 5 Competencies:

1. Research appropriate analytical tools.
2. Recognize the impact of laboratory errors on test results.
3. Contribute to a validation/verification proposal.
4. Recognize when a method deviation is warranted.

1. Level 5 Competency: Research appropriate analytical tools.

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

BEHAVIORAL ANCHORS Average

1. The laboratory analyst can recognize both existing and emerging analytical tools.
    a. EUAs, LDTs, NGS, MALDI-TOF, LCMS, LCMSMS, GC/GCMS, TOF/MS
2. The laboratory analyst can recognize the benefits of existing and emerging technologies.
3. The laboratory analyst can recognize the limitations of existing and emerging technologies.
4. The laboratory analyst can use available resources when researching analytical tools:
    a. Colleagues
    b. Peers
    c. SMEs
    d. Method authors

2. Level 5 Competency: Recognize the impact of laboratory errors on test results.

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

BEHAVIORAL ANCHORS Average
1. The laboratory analyst can determine whether the magnitude of a lab error is permissible. 2. The laboratory analyst can determine whether a lab error invalidates a result.
3. Level 5 Competency: Contribute to a validation/verification proposal.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can apply the parameters necessary for the proposal. 2. The laboratory analyst can summarize the data to include in the proposal. 3. The laboratory analyst can analyze the resulting data from the validation/verification. 4. The laboratory analyst can suggest recommendations based on the validation/verification data.
4. Level 5 Competency: Recognize when a method deviation is warranted.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can recognize when performance parameters are not met and warrant a deviation. 2. The laboratory analyst can suggest a substitution for supplies/equipment that are not available during an incident response. 3. The laboratory analyst can recognize that method deviations need approval or authorization.

Surveillance
BRAINSTORM • Fluid nature of surveillance • Virus, bacteria, parasite, prion • GenomeTrakr • PulseNet • CaliciNet • Federal agencies • Interpretation of results • Zero tolerance • Adulterant • Tolerance • Cluster detection
Definition: Monitoring trends and detecting outbreaks. **Level 4 Competency:** Describe how laboratory data is used for surveillance. **Level 5 Competencies:**

1. Describe the role of surveillance in incident detection.
1. Level 5 Competency: Describe the role of surveillance in incident detection.
Based on Level 5 competency – Not an all-inclusive list
BEHAVIORAL ANCHORS Average
1. The laboratory analyst can describe applications of surveillance: a. Regulatory purposes b. Pathogen trends

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.

6. 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
11. The laboratory analyst can list the benefits of professional groups. 12. 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.

5. 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
7. The laboratory analyst can describe the activities of professional groups relevant to their laboratory and discipline. 8. The laboratory analyst can describe the impact on the laboratory by employee participation in a professional group. 9. 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.

6. 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. b. Presentation skills.	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.

c. Contributing to a presentation / poster for a professional event.	4. The laboratory analyst can organize a technical session at a professional meeting.
7. 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.

4. 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
10. The laboratory analyst can list examples of governmental food safety networks. 11. 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) 12. 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.

7. 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**
16. The laboratory analyst can define food safety surveillance. 17. The laboratory analyst can describe a goal and activity of a surveillance network. 18. The laboratory analyst can describe how their laboratory contributes to a surveillance network. 19. 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.
8. 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.
9. 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.
10. 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.

10. 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 • Lab responsibility • Chain of custody • FDA consultation • Accreditation • Standards • Hot topics law • Statutes • 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.

7. 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**
13. The laboratory analyst can recognize the existence of laws or statutes that provide the basis for regulations/rules. 14. The laboratory analyst can name at least one regulation/rule that their laboratory services support. 15. The laboratory analyst can recognize how laboratory testing must meet standards and regulations. 16. The laboratory analyst can identify the compliance requirements for their work. (tolerance)	3. The laboratory analyst can determine if a method is fit-for-purpose for a specific regulation.
6. 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**
10. The laboratory analyst can describe their organization's legal authority. 11. The laboratory analyst can describe who grants their organization's legal authority. 12. The laboratory analyst is familiar with laws affecting their organization, such as: a. Records management b. FOIA 13. 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.

11. 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**
13. The laboratory analyst can define the process of discovery in legal proceedings. 14. 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 15. The laboratory analyst can recognize they may be asked to testify regarding a test result. 16. The laboratory analyst can recognize that they are legally responsible for the defensibility of their test results. 17. The laboratory analyst can describe the difference between a criminal and a civil proceeding. 18. 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)	5. The laboratory analyst can coach other analysts in preparing for legal proceedings. 6. The laboratory analyst can review laboratory procedures for legal defensibility.
7. **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**
20. 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 e. Respectful attitude	1. The laboratory analyst can coach others in appropriate professional conduct.

f. Ethical behavior 21. The laboratory analyst can recognize that conduct outside of work can affect their professional credibility.	
8. **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.
9. **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: a. A fact witness can only verify facts where an expert witness can offer opinions based on experience.	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

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**
8. The laboratory analyst can recognize that accreditation provides credibility and defensibility in court proceedings. 9. The laboratory analyst can recognize the importance of a method falling under the scope of accreditation for defensibility. 10. The laboratory analyst can recognize how the role of accreditation enhances the ability to take regulatory action. 11. 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 12. The laboratory analyst can recognize that laboratory accreditation verifies that the laboratory's quality management system has passed a third-party review process.	9. 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: a. PT results	1. The laboratory analyst can develop legally defensible procedures for demonstrating competence.

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.

11. 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: a. Introducing evidence b. Giving testimony and responding to cross-examination	5. The laboratory analyst can describe the importance of court decorum to credibility. 6. The laboratory analyst can mentor others that have been subpoenaed.

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.	

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.
8. Level 5 Competency: Review method repository.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
17. The laboratory analyst knows where to access the method repository. 18. The laboratory analyst can identify available methods for a particular analyte. 19. The laboratory analyst knows to use only approved methods.	3. The laboratory analyst can suggest new methods not in the existing repository. 4. The laboratory analyst can suggest improvements to the organization of the repository.

7. 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**
14. The laboratory analyst can describe how methods are controlled. 15. The laboratory analyst can describe how to get a method approved. 16. The laboratory analyst can explain why a method needs to be controlled. 17. The laboratory analyst has knowledge of how methods are a part of the laboratory document control. 18. 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.
8. Level 5 Competency: Evaluate methods.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
9. The laboratory analyst can describe the revision process. 10. The laboratory analyst can explain the validation process. 11. The laboratory analyst can identify the reasons for revisions to a method. (new column, reagent, matrix, platform) 12. The laboratory analyst can identify reasons for when method performance should be reviewed. (Proficiency testing (PT), QA, certified reference material) 13. 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.

5. Level 5 Competency: Utilize method selection criteria.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
19. 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) 20. The laboratory analyst can identify internal approved methods that are fit for purpose. 21. The laboratory analyst can identify when there is no approved method fit for purpose. 22. The laboratory analyst can identify external sources of approved methods that are fit for purpose. 23. 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,	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.

GOOD test portions (aafco.org), statistical requirements, regulatory action limits)	
11. Level 5 Competency: Support method safety risk assessment.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
22. The laboratory analyst can assist in completing a method safety risk assessment. (safety of the laboratorian(s) when performing a specific method) 23. 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. 24. The laboratory analyst can identify faulty PPE, general safety materials (transport containers, etc.), and facility safety equipment (eye wash, hoods, etc.) 25. 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)	• SMPR-AOAC Standard Method Performance Requirements	• Follow method validation and verification procedures

• Laboratory developed methods • Validation criteria • Verification criteria • Method performance requirements ((Limit of quantitation (LOQ), Sensitivity, Specificity, etc.)	• Client methods • Statistical evaluation tools • Being aware of the levels of validation • Importance of method validation and verification • What is validation	• 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.

12. Level 5 Competency: Define method performance criteria.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
6. 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.

13. 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
13. The laboratory analyst can perform validation experiments.	1. The laboratory analyst can design validation experiments.

14. The laboratory analyst can implement/incorporate quality control events to monitor ongoing method performance. 15. The laboratory analyst can recognize when method performance has drifted outside performance criteria. 16. The laboratory analyst can demonstrate use of quality control charts. 17. The laboratory analyst can recognize the concept and components of SQC requirements. (analyte integrity, regulatory action limits, inference requirements, etc.)	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
• Instrument/Equipment availability
• Importance of following the exact method/procedure
• Approved deviations
• Quality systems
• Accreditation

▪ 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 • 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.	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.

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.	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.)

QMS II

Definition: Tools and techniques to identify problems and improve processes.

Level 2 Competency: Apply improvement processes.

Level 3 Competencies:

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

Initiating the Improvement Process

BRAINSTORM

- Process improvement
  - Inputs
    - New equipment
    - Audits
    - New technology
    - Non-conforming events
    - Recommendations
    - Customer feedback
    - Management review
    - Benchmarking
    - Service standards
    - Risks & opportunities
    - Analysis of QC data
    - Suggestions
    - Continuous improvement cycle (PDCA)
    - Change management
    - Preventive actions
    - Can identify areas of improvement

Definition: Inputs that start a process improvement cycle.

Level 4 Competency: Describe the initiation of a process improvement cycle.

Level 5 Competencies:

1. Explain the continuous improvement cycle.
2. Describe inputs that would initiate an improvement cycle.
3. Provide input into the evaluation of risks.
4. Provide input into the evaluation of opportunities for improvement.
5. Explain the purpose of management review in process improvement.
6. Compare corrective actions and process improvement.

6. Level 5 Competency: Explain the continuous improvement cycle.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
3. The laboratory analyst can describe the components of the improvement cycle. 4. The laboratory analyst can describe continuous improvement. 5. The laboratory analyst can explain the value of continuous improvement cycles. 6. The laboratory analyst can describe the personnel roles in the continuous improvement cycle.	2. The laboratory analyst exhibits the ability to lead a process improvement cycle. 3. The laboratory analyst can prioritize suggested improvements.
12. Level 5 Competency: Describe inputs that would initiate an improvement cycle.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
26. The laboratory analyst can define the triggers for a process improvement cycle: a. New equipment b. Audits c. New technology d. Non-conforming events e. Recommendations f. Customer feedback g. Management review h. Benchmarking i. Service standards j. Risks & opportunities k. Analysis of QC data 27. The laboratory analyst can explain why each of the following should be considered in a process improvement cycle: a. New equipment b. Audits c. New technology d. Non-conforming events e. Recommendations f. Customer feedback g. Management review	4. The laboratory analyst can establish priorities for a process improvement cycle.

h. Benchmarking i. Service standards j. Risks & opportunities k. Analysis of QC data	
13. Level 5 Competency: Provide input into the evaluation of risks.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
6. The laboratory analyst can identify risks. 7. The laboratory analyst can describe the process of evaluating risks. 8. The laboratory analyst can provide input into risk impact.	1. The laboratory analyst can establish risk levels. 2. The laboratory analyst can evaluate risk based on the various risk levels. 3. The laboratory analyst can guide others in determining risk levels.
14. Level 5 Competency: Provide input into the evaluation of opportunities for improvement.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify opportunities for improvement. 2. The laboratory analyst can describe the process of evaluating opportunities for improvement. 3. The laboratory analyst can provide input into the impact of the opportunity for improvement. 4. The laboratory analyst can implement opportunities for improvement.	1. The laboratory analyst can guide others in determining opportunities for improvement. 2. The laboratory analyst can prioritize opportunities for improvement. 3. The laboratory analyst can implement systemic opportunities for improvement.
15. Level 5 Competency: Explain the purpose of management review in process improvement.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can discuss the importance of management review in the continuous improvement process. 2. The laboratory analyst can describe the management review process. 3. The laboratory analyst contributes to the management review. 4. The laboratory analyst contributes to setting benchmark goals.	1. The laboratory analyst suggests improvements from evaluation of management review data. 2. The laboratory analyst participates in a management review. 3. The laboratory analyst evaluates benchmark goals as part of a management review. 4. The laboratory analyst explains how to achieve benchmark goals.
6. Level 5 Competency: Compare corrective actions and process improvement.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**

1. The laboratory analyst can explain corrective action. 2. The laboratory analyst can differentiate between process improvement and corrective action. 3. The laboratory analyst can identify a non-conformance. 4. The laboratory analyst can use tools to develop the corrective action, such as: a. Root cause analysis b. Evaluates control data	1. The laboratory analyst exhibits ability to lead a team to implement corrective action. 2. The laboratory analyst exhibits ability to lead a team to implement process improvement.

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.

Level 5 Competencies:

1. Recognize events that may affect the quality of test results.
2. Recognize issues that may affect customer confidence.
3. Summarize the event.

9. 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
20. 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 21. The laboratory analyst is aware that the timeliness of reporting an event is important.	
8. 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**
19. The laboratory analyst recognizes the importance of the laboratory's *reputation* in the eyes of customers and the public. 20. 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.
9. Level 5 Competency: Summarize the event.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
14. 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.) 15. The laboratory analyst can describe the process of documenting the event.	8. The laboratory analyst can identify the impact of the failure beyond the immediate sample. (i.e., ramifications) 9. The laboratory analyst can critically analyze the documented event for accuracy and completeness. 10. The laboratory analyst can correlate the event to the quality system.

Investigation		
BRAINSTORM		

• Ask questions
• Compile investigation team
• Solution vs problem
	• Records Review
	  • Documents
	  • Instrument records
		• Investigation tools
		  ○ Five whys
		  ○ Is/is not

• 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
	• 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
		○ Fishbone
		○ Cause mapping
		○ Gap analysis
		○ Interviews
		○ Brainstorm
		○ Change management
		○ Data collection

Definition: Gathering of objective information.

Level 4 Competency: Conduct an unbiased investigation.

Level 5 Competencies:
1. Apply investigation tools.
2. Describe the scope of the investigation.
3. Incorporate the ideas of team members.

1. Level 5 Competency: Apply investigation tools.

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

24. 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
25. The laboratory analyst can list common, appropriate standard investigation tools:
  a. Fishbone
	1. The laboratory analyst can apply critical thinking skills in a root cause investigation.
	4. The laboratory analyst can apply appropriate standard investigation tools.
	3. The laboratory analyst can distinguish between the pros and cons of standard investigation tools.

b. Is/is not c. Gap analysis d. Five whys e. Interviews f. Brainstorm g. Data collection h. Cause mapping 26. The laboratory analyst can describe common, appropriate standard investigation tools.	
2. Level 5 Competency: Describe 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., 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.

Level 5 Competencies:
1. Analyze investigation data.
2. Evaluate trends.

14. Level 5 Competency: Analyze investigation data.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
7. The laboratory analyst can generate a list of contributing factors/findings. 8. 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 9. 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.

15. Level 5 Competency: Evaluate trends.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
18. The laboratory analyst can identify a trend. 19. The laboratory analyst can determine whether something has happened before. (recurring event) 20. The laboratory analyst can evaluate the significant trends/outliers. 21. 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)
- Verification
- Corrections (immediate)

• System improvements • Level of effort • Big picture	• Effectiveness • Retraining documentation • Complaint response	• 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.

Level 5 Competencies:
1. Describe actions that support continual improvement.
2. Monitor the effectiveness of the corrective actions.

12. 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**
11. The laboratory analyst can give examples of corrections: a. Calculation error b. Labeling error c. Perform instrument maintenance d. Reprogram instrument 12. 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.

13. 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**
8. The laboratory analyst documents repeat occurrences or events. 9. The laboratory analyst can evaluate the impact of changes.	9. The laboratory analyst can verify the documentation of repeat occurrences or events. 10. The laboratory analyst can verify the impact of changes for effectiveness.