Animal Food

Definition: Basic theory and chemical testing related to animal food.

Level 2 Competency: Indicate how animal food testing safeguards human and animal health.

Level 3 Competencies:

- Describe the role of the laboratory in animal food sample testing. - Communication
- Explain how animal food test results are used. - Leadership
- Describe how regulatory requirements impact animal food testing. - Programmatic
- Perform animal food testing. - Technical

Regulatory

BRAINSTORM

- Regulatory action level
- Statutes
- Import/export certifications
- AV analytical variation
- Tolerances
- Association of American Feed Control Officials (AAFCO)-function
- AAFCO membership
- AAFCO website
- AAFCO Laboratory Methods and Services website (https://www.aafco.org/Laboratory)
- AAFCO Official Publication (AAFCO OP)
- AAFCO Sampling Resources
- Disposition
- Violations
- Misbranded
- Adulterated
- Follow-up inspection
- Industry education State driven requirements
- Legal requirements
- Recall
- Emergency response
- Food Emergency Response Network (FERN)
- Reporting systems (ELexnet, AnimalFeedNetwork.net, other Federal databases)
- Data acceptance
- Data assessment
- Label guarantees
- Species dependent labeling
- Acceptance criteria
- NRC Nutrient Requirement Collection

Definition: The analytical basis for regulatory actions.

Level 4 Competency:
Discuss the relationship of testing to regulatory actions.

1. **Level 5 Competency:** Discuss the value of AAFCO for feed laboratories.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian has an awareness of the Association of American feed Control Officials (AAFCO). 2. The laboratorian has an awareness of the AAFCO Official Publication (AAFCO OP). 3. The laboratorian has an awareness of AAFCO website (aafco.org/) 4. The laboratorian has an awareness of AAFCO Laboratory Methods and Services. (https://www.aafco.org/Laboratory) 5. The laboratorian can discuss AAFCO best practice guidelines. 6. The laboratorian has an awareness of AAFCO Animal Feed Labeling Guide (https://www.aafco.org/Portals/0/SiteContent/Publications/Feed_Labeling_Guide_web_complete.pdf) 7. The laboratorian has an awareness of the AAFCO Pet Food Labeling Guide.	1. The laboratorian can mentor others in the value of AAFCO. 2. The laboratorian can mentor others on resources available from AAFCO. 3. The laboratorian can discuss the importance of National Research Council Nutrient Requirements of Animals Collection.
2. **Level 5 Competency:** Discuss how label guarantees influence laboratory testing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can recognize regulatory significance of analyte guarantees found on animal feed label: a. Laboratory determines analyte concentrations for adherence to label guarantees 2. The laboratorian can recognize whether guarantee is expressed as a minimum, maximum or both. 3. The laboratorian can relate a guarantee to an analyte that may be expressed differently than the guarantee: a. Crude protein (measured as N x 6.25) b. Equivalent crude protein (measured as Non-Protein Nitrogen x 6.25)	

c. Calories (calculated from crude protein, crude fat, ash, moisture, crude fiber) d. Unit differences between label concentration and method calibration	
3. **Level 5 Competency:** Calculate analyte concentration from a custom mix formula.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can perform calculations to obtain analyte concentrations when presented with a custom mix formula. **NOTE:** For training, present trainee with a custom mix formula and ask them to select the correct answers from a listing. Trainee will have to correctly perform calculations.	1. The laboratorian can mentor others who have questions when performing the calculations.
4. **Level 5 Competency:** List possible regulatory actions to be taken in response to test results.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can recognize regulatory actions that are taken in response to violative test results: a. Stop sale b. Product recall c. Product destruction d. Product reformulation e. Fines 2. The laboratorian can recognize implications to regulatory actions taken in response to violative test results: a. Financial b. Market confidence c. Agency confidence d. Public perception	1. The laboratorian can describe the process of inspection, investigation and enforcement of products determined to have a violative disposition.

Laboratory Procedures

• Association of Official Analytical Chemists (AOAC) methods • American Oil Chemists Society (AOCS) methods	• In-house Standard Operating Procedures (SOPs) • Test kits • Gravimetric testing	• Chromatography • Mass spectrometry • Atomic emission • Atomic absorption	

• Single Lab Validations published in peer review journals • AAFCO LM&S Document Library • AAFCO LM&S Best Practices Documents • AAFCO LM&S Laboratory Sampling Resources	• Method selection • Consensus methods • Titrimetric testing • Microscopy • Dry or wet weight Combustion • Auto analyzer	• Other techniques • Standardized methods • Non-standardized • Fit for purpose • Polymerase chain reaction (PCR)	

Definition: Animal food testing procedures used in the laboratory.

Level 4 Competency: Describe animal food testing procedures used in the laboratory**.**

1. **Level 5 Competency:** Identify resources for Animal Feed Regulatory Laboratories.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can list method resources published by recognized organizations: a. Association of Official Analytical Chemists International (AOACI) b. American Oil Chemists Society (AOCS) c. National Forage Testing Association (NFTA) 2. Association of American Feed Control Officials (AAFCO) The laboratorian can list the role of the organizations which publish method resources. The laboratorian can list various documents published by AAFCO: a. Best Practices Document b. Guidelines for Preparing Laboratory Samples c. Quality Assurance/Quality Control Guidelines for Feed Laboratories	1. The laboratorian can describe the roles of recognized organizations. 2. The laboratorian can describe the purpose of documents published by AAFCO.

2. **Level 5 Competency:** Explain how to select a test method.

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

1. The laboratorian has an awareness of a method selection process. The laboratorian has knowledge of the criteria for selecting a method: a. Fit for purpose b. Data reporting requirements c. Sampling requirements d. Regulatory requirements e. Analyte levels f. Target analyte g. LOD and LOQ requirements 2. Legally defensible results The laboratorian can list the sources of test procedures used in the laboratory: a. Standard Methods b. Consensus methods published by a recognized organization c. Multi-Lab validated procedures a. In house test methods 3. The laboratorian can describe the reasons for using a single analyte method versus a multi-analyte method.	1. The laboratorian can discuss the importance of having a method selection process. 2. The laboratorian can describe differences between the sources of test procedures used in the laboratory: a. Standard Methods b. Consensus methods published by a recognized organization c. Multi-Lab validated procedures d. In house test methods
3. **Level 5 Competency:** Describe the analytical techniques used to test animal food.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can list non-instrumental analytical techniques: a. Titrimetric Testing b. Gravimetric Testing c. Reporting as dry-weight or wet-weight d. Microscopy 2. The laboratorian can list analytical techniques used in the testing of nutritional components. 3. The laboratorian can list instrumental functionality used for animal food testing. a. Combustion b. Auto Analyzer c. Atomic Absorption d. Atomic Emission	1. The laboratorian can describe the basic science of non-instrumental techniques. 2. The laboratorian can describe the basic science of instrumental techniques.

e. Mass Spectrometry f. Chromatography	
4. **Level 5 Competency:** Describe the use of test kits for animal food testing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can list analytes commonly targeted by test kits. The laboratorian can describe advantages of using test kits: a. Reagents all in one b. Throughput c. Screening a large number of negatives d. Timeliness 2. The laboratorian can describe disadvantages of using test kits: a. Regulatory requirements may not be met b. Not typically multi-analyte c. False positive and false negative rates must be considered	1. The laboratorian can describe the basic science of test kits used for animal feed testing.

Quality Considerations

• AAFCO Proficiency Testing Program (https://www.aafco.org/Laboratory/Proficiency-Testing-Program) • Reference Materials • AAFCO LM&S ISO 17025 Accreditation • EPTIS • AFRPS • Control samples, replicates, blanks, spikes • Confirmation	• Legally defensible results • Validation/verification • AAFCO QA/QC Guidelines Document • Data review • Uncertainty	• Control charts • Relationship of error to action limit (e.g., label guarantee or level of regulatory action) • In-house animal food quality documents • AAFCO Quality Reference Materials (QRMs)	

Definition: Quality considerations related to Animal Food Programs.

Level 4 Competency: Discuss quality considerations for an Animal Food Program.

Level 5 Competency: Identify quality resources for animal feed testing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**

1. The laboratorian has an awareness of the purpose of the AAFCO QA/QC Guidelines document. 2. The laboratorian has an awareness of the content of the AAFCO QA/QC Guidelines. 3. The laboratorian can choose appropriate method specific options for quality control. 4. The laboratorian can describe the content of in-house animal food quality documents.	1. The laboratorian can describe the content of animal food quality resource documents. 2. The laboratorian can apply options to develop quality control as described in the AAFCO QA/QC Guidelines.

Level 5 Competency: Explain the importance of proficiency testing to quality system.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can explain how the AAFCO Proficiency Testing Program enhances the quality of animal food testing. 2. The laboratorian can assess performance against a Z score. 3. The laboratorian can explain that AAFCO Quality Reference Materials are a source of control samples.	1. The laboratorian can explain how the AAFCO Proficiency Testing Program relates to legal defensibility of results.

1. **Level 5 Competency:** Recognize the relationship of statistical error to action limits.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can explain different types of action limits: a. Label guarantees b. Regulatory actions limits c. Toxic dose 2. The laboratorian can describe the concept of statistical error: a. Analytical uncertainty b. Total sampling error c. Global estimation error	1. The laboratorian can relate a test result including statistical error to a specification limit a. Interpret the disposition e.g. violative, pass/not pass

Matrices

• Pet treats • Pet food • Medicated animal food	• Nutritional ingredients • Ingredients	• Complete feed vs feed supplements	

• Non-medicated animal food • Inorganic vs organic	• Food pyramid (triangle)/diversity of matrices • Mineral mix	• Animal species • Raw pet food • Dry pet food vs Wet pet food • AOAC Nine Sector Food Triangle	

Definition: Diversity in types of animal/pet food matrices.

Level 4 Competency: Describe the diversity in matrices.

Level 5 Competency: Give examples of animal/pet food matrices.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratorian can list the animal species: a. Bovine b. Ovine c. Porcine d. Equine e. Poultry 2. The laboratorian can list the examples of animal feed matrices. 3. The laboratorian can list major pet species: a. Dog b. Cat 4. The laboratorian can list the examples of pet food matrices: a. Dry b. Wet c. Raw d. Treats	1. The laboratorian can list obscure pet food categories: a. Iguana b. Rabbit c. Chinchilla d. Supplements

Level 5 Competency: Recognize the differences between a supplement/premix and a complete feed.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratorian can recognize that there are different analytical methods for supplements and complete feeds.	1. The laboratorian can discuss the methodology difference between a supplement and a complete feed: a. Mineral supplements-more vigorous digestion

2. The laboratorian can recognize that there are analyte concentration differences. 3. The laboratorian can recognize that there are matrix differences.	b. Sample prep techniques

Nutritional Analytes

• Label - guaranteed analysis (analyte and concentration estimates) • Label – product name • Label – ingredient statement • Label – species • Label – feeding directions • Label – guarantor (manufacturer)	• Amino acids • Proximates • Fat soluble vitamins • Macro minerals • Micro minerals • Carbohydrates (fibers, sugars, starch)	• Fatty acids • Water soluble vitamins • Formulated drug levels • Calories	

Definition: Nutritional analytes for animal food.

Level 4 Competency: Characterize nutritional analytes for animal food.

1. **Level 5 Competency:** Explain how the animal food label relates to laboratory testing.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratorian can identify the guaranteed concentration of analytes on a product label. 2. The laboratorian can identify the ingredients on the product label. 3. The laboratorian can identify the applicability of the animal food for the intended species. 4. The laboratorian can explain how the label is used to select test methods. 5. The laboratorian can choose the correct method based on the label guarantee and sample matrix.	1. The laboratorian can describe the implications for testing based on information provided on an animal food label. 2. The laboratorian can describe dilution schemes based on animal label concentrations. 3. The laboratorian can relate concentration found on a label to method calibration. 4. The laboratorian can perform a unit conversion of the label guarantee to the lab unit of measure. 5. The laboratorian can perform the correct sample extraction for an analytical method based on the sample matrix.

Level 5 Competency: Give examples of non-label nutritional components for which an analysis is performed.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratorian can list non-label nutritional components for which an analysis can be performed: • Moisture • Ash • Dietary fibers • Copper • Selenium • Amino acids • Sugars • Fatty acids • Dietary starch	1. The laboratorian can understand how to utilize moisture and ash values as a part of calculating carbohydrates. 2. The laboratorian can apply limits for non-label nutritional components.

Contaminants, Toxicants, and Anti-nutritional Factors

• Drug residues • Prions • Antibiotic residues • Toxic metals • Environmental contaminants • Pathogens • Cross-species sensitivities	• Pesticides • Mycotoxins • Allergens • Dioxins • Trypsin inhibitor • Microbes	• Melamine • Nutrient toxicity and deficiencies • Nitrates • Prussic acid • Microscopy • Noxious weed seed screen	

Definition: Contaminants, toxicants and anti-nutritional factors in animal food.

Level 4 Competency: Describe how contaminants, toxicants and anti-nutritional factors relate to laboratory testing.

Level 5 Competency: Give examples of contaminants found in animal food.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratorian can describe the most commonly found contaminants: a. Mycotoxins b. Toxic metals c. Antibiotics	1. The laboratorian can describe additional contaminants of animal food: a. Prions b. Melamine

d. Pathogenic microorganisms e. Filth and foreign material o Insects o Rodent hair	c. Naturally occurring toxins o Trypsin inhibitor o Nitrates o Prussic acid o Glycoalkaloids d. Environmental contaminants o Pesticides o Dioxins o Polychlorinated biphenyls (PCB's) o Perfluoroalkyl compounds (PFOA) e. Nutrient excess o Vitamin D o Copper
Level 5 Competency: Give examples of toxicants found in animal food.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can describe the categories of the most commonly found toxicants: a. Mycotoxins b. Toxic metals c. Pathogenic microorganisms	1. The laboratorian can describe additional categories and examples of toxicants found in animal food: a. Mycotoxins o Aflatoxins o Deoxynivalenol o Ochratoxins b. Toxic metals o Lead o Cadmium o Arsenic o Mercury c. Pathogenic microorganisms o Listeria o Salmonella d. Melamine e. Naturally occurring toxins o Trypsin inhibitor o Nitrates o Prussic acid

	o Glycoalkaloids ▪ Solanine ▪ Chaconine o Pesticides ▪ Cypermethrin ▪ Imidacloprid ▪ Glyphosate
Level 5 Competency: Give examples of anti-nutritional factors found in animal food.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can give some examples of anti-nutritional factors: a. Trypsin inhibitor b. Tannins c. Phytic acid d. Protease inhibitor e. Saponins f. Lectins	1. The laboratorian can describe some specific mechanisms of anti-nutritional factors.

Emergency Response

• Toxicity • Excess nutrient (ex. Vitamin D, Selenium) • Animal mortality • Human food impacts	• Food chain • Animal illness related to feed or pet food • Cross-species sensitivities • Pathogens	• Raid response • Clinical links • Element ratios	

Definition: Animal food emergency response impacts.

Level 4 Competency: Discuss quality considerations for an Animal Food Program.

Level 5 Competency: Discuss the impact of an animal food incident on the human food chain.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**

1. The laboratorian can recognize that contaminants in animal food can also affect humans. 2. The laboratorian can list the impact of specific animal food contaminants on the human food chain: a. Mycotoxins in dairy cow food b. Heavy metals c. Pesticides d. Antibiotics e. Bovine spongiform encephalopathy (BSE) f. Natural toxins g. Melamine h. Pathogens 3. The laboratorian can give examples of contaminants that could cause human illness.	1. The laboratorian can describe route of exposure from animal food to human food: a. Mycotoxins in dairy cow food b. Heavy metals c. Pesticides d. Antibiotics e. Bovine spongiform encephalopathy (BSE) f. Natural toxins g. Melamine 2. The laboratorian can discuss ways to mitigate these types of scenarios.
Level 5 Competency: Discuss the linkage between an animal food incident and animal mortality.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can list animal food incidents that can lead to animal mortality: a. Mycotoxins b. Lasalocid/Monensin c. Melamine d. Hormones e. Nutritional deficiencies f. Heavy metals g. Pesticides	1. The laboratorian can discuss how exposure to contaminants can cause animal mortality: a. Mycotoxins b. Lasalocid/Monensin c. Melamine d. Hormones e. Nutritional deficiencies f. Heavy metals g. Pesticides
Level 5 Competency: Discuss the process of responding to an animal food incident involving pet food.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratorian can recognize that there are concerned partners in a pet food recall. 2. The laboratorian can list components involved in responding to an animal food incident: a. Notification b. Identification of potential lots	1. The laboratorian can discuss which entities and organizations would be involved in the components listed: a. Notification b. Identification of potential lots c. Communication d. Investigation

c. Communication d. Investigation e. Evaluation of findings f. Recalls (early voluntary/outreach) g. Press releases h. Enforcement Actions/Prevention 3. The laboratorian can identify the organizations that may become involved in a pet food recall: a. Regulatory agencies b. Manufacturers c. Retail d. Consumers/Consumer groups	e. Evaluation of findings f. Recalls (early voluntary/outreach) g. Press releases h. Enforcement Actions/Prevention 2. The laboratorian can recognize the difficulties involved with properly responding to an animal food incident involving pet food.

Select Agents

Definition: Designated toxins and biological agents that have the potential to pose a severe threat to both human and animal health.

Level 2 Competency: Explain the purpose of select agent testing.

Level 3 Competencies:

- Discuss reporting requirements when working with select agents. - Communication
- Identify the roles of organizations that support select agent testing. - Leadership
- Describe programs designed to support select agent testing. - Programmatic
- Perform select agent testing. - Technical

Overview		
BRAINSTORM • Bioterrorism • FERN • Public health laboratories • LRN • USDA • CDC • The select agent list	• Intentional and unintentional contamination • Agroterrorism • History • Naturally occurring • Chemical/biological agents • Toxins	• Humans, animals, and plants • Testing • Screening techniques • Confirmation techniques • Inspections • Quantity limits • Registration • Tiers
Definition: Introduction to the Federal Select Agent Program (FSAP). **Level 4 Competency:** Explain the purpose of the FSAP.		
2. **Level 5 Competency:** List the Federal agencies responsible for overseeing the Federal Select Agent Program (FSAP).		
Based on Level 5 competency – Not an all-inclusive list		
BEHAVIORAL ANCHORS Average		**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can name the two federal agencies: a. CDC b. APHIS		1. The laboratory analyst can explain how the FSAP came about (history).

	2. The laboratory analyst has an awareness that CDC regulates agents that cause disease in humans. 3. The laboratory analyst has an awareness that APHIS regulates agents that cause disease in plants and animals.
3. **Level 5 Competency:** Define bioterrorism.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
3. The laboratory analyst can offer an understandable definition or can paraphrase the "official" definition, which is: a. The deliberate release of viruses, bacteria, or other biological agents used to cause illness or death in people, animals, or plants.	1. The laboratory analyst can give a historical example of bioterrorism.
4. **Level 5 Competency:** Define agroterrorism.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can state that the purpose of agroterrorism is economically motivated: a. Intended to damage a country's agriculture. b. Intended to damage a country's food supply.	1. The laboratory analyst can give one historical example.
5. **Level 5 Competency:** List the laboratory networks that support the FSAP.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst has an awareness of two of these networks: a. Laboratory Response Network (LRN) b. Food Emergency Response Network (FERN) c. National Animal Health Laboratory Network (NAHLN) d. Environmental Response Laboratory Network (ERLN) e. National Plant Diagnostic Network (NPDN)	1. The laboratory analyst has an awareness of more than two of these networks: a. Laboratory Response Network (LRN) b. Food Emergency Response Network (FERN) c. National Animal Health Laboratory Network (NAHLN) d. Environmental Response Laboratory Network (ERLN) e. National Plant Diagnostic Network (NPDN)

6. **Level 5 Competency:** Explain the purpose of the Food Emergency Response Network (FERN).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can define FERN: a. A network of government labs. i. Federal ii. State iii. Local iv. Land-grant universities 2. The laboratory analyst is aware that the purpose comprises four major activities related to both intentional and unintentional contamination of food: a. Prevention b. Detection c. Response d. Recovery	1. The laboratory analyst can describe the benefits of being a member of FERN: a. Training b. Standardized protocols c. Resources d. Supplies e. Methods development
7. **Level 5 Competency:** List the different agents that can be used in BT.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst has an awareness of the different types of select agents that can be used in BT: a. Chemical b. Biological c. Radiological d. Toxins	1. The laboratory analyst can give a historical example. 2. The laboratory analyst can give specific examples: a. Chemical (ricin) b. Biological (Bacillus anthracis, Yersinia pestis, Brucella melitensis) c. Radiological (polonium 210, uranium 235) d. Toxins (marine toxin, aflatoxin, Botulinum toxin)

Program Requirements

BRAINSTORM

- Biosecurity
  - Security plans
  - Forms for reporting
  - Incident response plan
  - Exercises
  - Inventory requirements
  - Restricted access
  - Sample handling requirements
  - Accountability
  - Select agent transfers
  - Select agent release
  - Reporting requirements
  - Training requirements
- BMBL
- Biosafety plans
- Forms for reporting
- Incident response plan
- Exercises
- Reporting requirements
- Training requirements
- Decon procedures
- Responsible official
- Biosafety officer
- Authorized laboratory analyst
- Personnel requirements
- Federal security clearance

Definition: Requirements related to the Federal Select Agent Program.

Level 4 Competency: Describe requirements related to the FSAP.

2. **Level 5 Competency:** Recognize biosecurity elements required for the Federal Select Agent Program (FSAP).

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
1. The laboratory analyst can list at least three essential biosecurity elements: a. Biosecurity plan b. Incident response plan c. Training plan d. (Information) security plan e. Reporting requirements	1. The laboratory analyst can explain the purpose of any of these essential elements.

3. **Level 5 Competency:** Recognize biosafety elements required for the Federal Select Agent Program (FSAP).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can list at least three essential biosafety elements: a. Biosafety plan b. Incident response plan c. Training plan d. Reporting requirements	1. The laboratory analyst can explain the purpose of any of these elements.

3. Level 5 Competency: Recognize the utility of the Biosafety in Microbiological and Biomedical Laboratories (BMBL).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst knows where to access the BMBL. 2. The laboratory analyst is aware that it is the best resource for biosafety.	1. The laboratory analyst is aware of which part of the BMBL applies to them. 2. The laboratory analyst has an awareness of the purpose of the BMBL. 3. The laboratory analyst has an awareness of various sections of the BMBL.

4. Level 5 Competency: Identify key personnel associated with the Federal Select Agent Program.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can name two key personnel: a. Biosafety officer b. Responsible official (and alternate responsible official, if applicable) c. Principle investigator d. Authorized laboratory analyst	1. The laboratory analyst can describe what a biosafety officer does. 2. The laboratory analyst can explain the roles of the key personnel.

5. Level 5 Competency: Give examples of personnel requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst has an awareness that personnel must be: a. Trained b. Have federal security clearance	1. The laboratory analyst can explain why a person must be authorized to work with select agents and toxins.

Biosafety Level 3

Definition: The purpose and function of a Biosafety Level - 3 laboratory, a specialized laboratory where work is performed with infectious agents and toxins that may cause serious or potentially lethal disease through inhalation.

Level 2 Competency: Describe the importance of a Biosafety Level - 3 laboratory.

Level 3 Competencies:

- Describe ways to communicate safety information in a Biosafety Level – 3 laboratory. - Communication
- Identify the roles of organizations supporting safe work practices in Biosafety Level – 3 laboratories. - Leadership
- Describe programmatic requirements for Biosafety Level - 3 activities. - Programmatic
- Use the safety measures required for a Biosafety Level - 3 laboratory. - Technical

Overview		
BRAINSTORM		
• Purpose of BSL3 facility • Training plan • Incident response plan	• Evacuation plan • Security plan • Safety plan	• Incident plan • Principle Investigators • Record requirements
Definition: Administrative requirements that support BSL3 facilities. **Level 4 Competency:** Describe the administrative requirements that support BSL3 facilities.		
3. **Level 5 Competency:** Describe the purpose of a BSL3 facility.		
Based on Level 5 competency – Not an all-inclusive list		
BEHAVIORAL ANCHORS Average		**BEHAVIORAL ANCHORS Outstanding**
2. The laboratory analyst can explain that a BSL3 facility is designed to contain infectious agents.		1. The laboratory analyst can describe specific construction/engineering systems and features of a BSL3 facility: a. Showers b. Autoclaves c. Airflow (dedicated air supply and exhaust)

	d. unidirectional 2. The laboratory analyst can define the four BSL level facilities based on BMBL.
4. **Level 5 Competency:** List plans that meet the administrative requirements of BSL3 facilities.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
2. The laboratory analyst can identify 3 types of plans related to BSL3 facilities: a. Training b. Incident response c. Evacuation d. Security e. Safety f. Incident	1. The laboratory analyst can explain where plans are typically located.
8. **Level 5 Competency:** Identify the contact for issues related to the BSL3 facility.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
2. The laboratory analyst can recognize that BSL3s have various contacts.	2. The laboratory analyst can correlate specific contact persons with BSL3 issues.

Security		
BRAINSTORM		
• Restricted access requirements • Clearance • Controlled and registered microbes and toxins	• Inventory requirements • Visitor instructions • Sign-in/sign-out • Potentially lethal	• Criminal purposes • Legal ramifications • Funding loss
Definition: Monitoring systems and controls to prevent unauthorized access.		

Level 4 Competency: Describe security measures to prevent unauthorized access.

3. **Level 5 Competency:** List controls to prevent unauthorized access to a BSL3 facility.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
4. The laboratory analyst can identify 3 controls that prevent unauthorized access to a BSL3 facility: a. Restricted access b. Cameras c. Locks d. Key card access e. Biometric access f. Sign-in/sign-out g. escort h. Security clearance for select agents i. Inventory requirements for registered microbes and toxins	2.

4. **Level 5 Competency:** Explain the importance of controlling microbes and toxins contained in a BSL3 facility.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
4. The laboratory analyst can give 3 reasons why controlling microbes and toxins in a BSL3 facility is important: a. Potentially lethal b. Can be used for criminal purposes c. Laws related to select agents (violations could result in fines or jail) d. Facility can lose its federal funding e. Facility can lose its ability to work with these agents	2. The laboratory analyst can give 3 reasons why controlling microbes and toxins in a BSL3 facility is important.

Safety

BRAINSTORM

- Special practices
  - Buddy system
  - Double bagging
  - Biosafety carriers
  - Carts
  - Waterproof furniture/walls
  - Clean-to-dirty
- First aid kit
- Spill response
- Facility systems
  - Continuous power (emergency generators)
  - Air flow
  - Emergency showers
  - Eye wash stations
  - Dedicated systems
  - HEPA filtration
  - PSDA
  - Signage
- Monitoring of air flow
  - Alarms
  - Detection of air flow
  - Smoke test
- Safety Equipment
  - Secondary barriers
  - Biosafety cabinets
  - Hand free sink and eyewash
  - Self-closing doors
  - Seals
  - Furniture
  - PPE
    - Powered Air Purifying Respirator (PAPR)

Definition: Equipment and monitoring systems utilized by BSL3 to assure personnel safety.

Level 4 Competency: Describe safety measures implemented in BSL3 facilities.

1. Level 5 Competency: Describe equipment utilized by BSL3 personnel.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS Outstanding
5. The laboratory analyst can identify 3 types of safety equipment used by BSL3 personnel: a. Secondary barriers b. Biosafety cabinets c. Autoclave d. Hands free sink and eyewash e. Disposable PPE f. Booties g. Double gloving h. Sleeves	3. The laboratory analyst can explain why these types of safety equipment are used. 4. The laboratory analyst can explain how these types of safety equipment are used.

i. Respirator j. Lab coats k. Self-closing doors l. Seals m. Impervious furniture n. Non-porous surfaces	
2. Level 5 Competency: Discuss monitoring systems in BSL3 facilities.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify monitoring systems found in BSL3 facilities: a. Alarms b. Detection of air flow c. Smoke tests d. Air pressure monitor	1. The laboratory analyst can explain how these systems work. 2. The laboratory analyst can explain why these systems are important.
3. Level 5 Competency: List special practices in BSL3 facilities.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can recognize 3 types of special practices in in BSL3 facilities: a. Buddy system b. Double bagging c. Using dedicated equipment and supplies d. Biosafety carriers e. Biosafety cabinet f. Clean-to-dirty g. Zones h. Remote video monitoring	1. The laboratory analyst can explain how these practices are put in place. 2. The laboratory analyst can explain the purpose behind these practices.

4. Level 5 Competency: Describe facility systems to support BSL3 laboratories.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS Outstanding**
1. The laboratory analyst can identify 3 facility systems that support BSL3 laboratories: a. Continual power b. Air flow c. Emergency showers d. Eye wash stations e. Dedicated air and exhaust systems f. HEPA filtration g. PSDS h. Signage	1. The laboratory analyst can explain how these systems are put in place. 2. The laboratory analyst can explain the purpose behind these systems.

Shellfish Regulatory Programs

Definition:

Laboratory testing performed in support of the National Shellfish Sanitation Program.

Level 2 Competency: Apply the requirements of a regulatory shellfish program.

Level 3 Competencies:

- - Communication – Articulate laboratory requirements to perform testing under the NSSP.
- - Leadership – Apply knowledge of laboratory testing to optimize efficiency.
- - Programmatic – Follow the requirements of the NSSP.
- - Technical – Perform laboratory testing under the NSSP.

NSSP		
Partnerships Cooperative programs ISSC NSSP checklist Checklist interpretation	Approved methods/applications Purpose/mission Regulatory documents Program requirements Shellfish control authorities	Compliance New technology New methods Model ordinance Control plan

Definition: The National Shellfish Sanitation Program and the cooperative efforts the support the Program.

Level 4 Competency: Summarize the significance of the laboratory within the NSSP.

1. **Level 5 Competency:** Describe the role of the ISSC in the NSSP.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst … • Can define ISSC • Can define NSSP • Can talk about what the ISSC does within the NSSP (cooperative relationship) • Can find the ISSC website • Understand the relationships of the agencies within the program	The laboratory analyst … • Can explain the purpose of the ISSC • Can explain how the conference works o Task forces o Committees o Assembly • Can explain the proposal process

5. **Level 5 Competency:** Locate the NSSP checklists in the guide for the control of molluscan shellfish.

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

• Can find the checklists on the ISSC website • Can find the checklists in the model ordinance • Use the correct (current) version	• Can point out that links do not work or are outdated or incorrect

9. **Level 5 Competency:** Explain the importance of the NSSP checklist.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• They can relate the checklist to their day-to-day work • They recognize that there are consequences if the checklist is not used • Can read a single line item on the checklist and determine if they are compliant	• Can perform an internal audit using the entire checklist • Can compare the checklist with an SOP • Can use the checklist to review and/or develop SOPs

4. **Level 5 Competency:** List the cooperative partners involved in the NSSP.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Know where they (as a lab person) fit within the program • Know why the program is relevant to them • Can list federal, state, private industry, tribal entities, academia	• Can name individual federal partners (FDA) • Can explain the role of FDA (MOU with ISSC) • Are aware that there is an international component • Are aware of regional groups and their importance • Understand how the states administer the program
5. **Level 5 Competency:** Determine whether a method is approved under the NSSP.	
Based on Level 5 competency – Not an all-inclusive list	

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
• Can locate approved methods within the model ordinance • Can interpret the approved methods table	• Can identify the need for a new approved method • Can suggest improvements of existing methods • Are aware that there is a process for method changes
6. **Level 5 Competency:** Explain how the checklist is used to determine laboratory status.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• They recognize that there are consequences if the checklist is not used • Understand the criticality codes and their weight	• Can perform an internal audit using the entire checklist • Understand the impact of different statuses
7. **Level 5 Competency:** Differentiate between the three status levels of laboratory conformance.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can name the three status levels (conforming, provisionally conforming, non-conforming) • Are aware of consequences related to laboratory status (e.g., a non-conforming lab cannot produce data to support the NSSP)	• Can provide details about each status (timelines, deadlines, submission of corrective actions, etc.) • Can locate applicable laboratory sections within the MO

Quality System	
Basic QA QC SOPs Training requirements Corrective action Compliance Method implementation	Calibration/verification Method validation Proficiency testing Audits LEO Competencies

Definition: The processes in place to ensure that a laboratory has a system to generate legally defensible data.

Level 4 Competency: Explain the importance of a quality system within an NSSP laboratory.

1. **Level 5 Competency:** Describe the difference between instrument calibration and verification.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can define both terms (calibration and verification). • Understand when calibration is needed versus when verification is needed. •	• Are aware of the documentation needed for calibration. • Aware of calibration and verification frequency requirements.

2. **Level 5 Competency:** Give examples of incidents that would necessitate corrective actions.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can recognize when something has gone wrong. • Understand the corrective action process. • Can recognize when something requires a corrective action. • Awareness that if something impacts data, it will warrant a corrective action (as a general rule).	• Can actually initiate the corrective action process and documentation. • Can work through a corrective action process (e.g., root cause analysis, write the statements, documentation, etc.).

3. **Level 5 Competency:** Differentiate between quality assurance and quality control.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can define the two terms (QA & QC). • Can give examples of each.	• Can recognize possible areas for improvement (problem areas) within the quality system.
4. **Level 5 Competency:** Describe the role of SOPs in the laboratory.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can define an SOP. • Can read and perform a method under an SOP.	• Can propose changes/updates to SOPs. • Can explain the different sections of an SOP.
5. **Level 5 Competency:** Outline the NSSP laboratory evaluation process.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can explain the role of LEOs in the NSSP. • Can find the appropriate section in the guide. • Can explain what functions LEOs perform within an NSSP lab. • Can locate the current or last lab evaluation and all supporting documents.	• Are aware of who their particular LEO is. • Can help prepare for upcoming evaluation. • Aware of all timelines associated with lab evaluations.
6. **Level 5 Competency:** Describe the difference between method validation and method verification/implementation.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can define both terms. • Can find the appropriate sections in the guide. • Understand when a validation is needed versus a verification.	• Can identify criteria needed for validation versus verification. • Understand how the method validation process works. • Can utilize the single lab validation criteria. .

7. **Level 5 Competency:** Utilize training documentation to verify competency.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
• Can identify necessary training documentation. • Aware of what is contained in a personnel file. • Aware of how a personnel file is used. • Active participant in documentation of training. •	• Can list required training. • Proactively seek out training opportunities based on the needs of the lab.

Equipment/Instruments	
Temperature devices	Autoclave operation
Preventative maintenance	Running equipment
Equipment knowledge	Troubleshooting
Calibration/verification	Pipettes

Definition: Various pieces of equipment and instrumentation commonly used in shellfish laboratories.

Level 4 Competency: Explain how equipment/instrument use supports good laboratory practices.

1. **Level 5 Competency:** Demonstrate a volume check for a micropipettor.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
The laboratory analyst… • Can demonstrate setting different volumes on micropipettor • Can demonstrate volume check o Dispensing • Can locate the serial number on the micropipettor	The laboratory analyst… • Can calculate if volume check passes/is within range • Can assess when maintenance may be needed • Can document the volume check on the micropipettor (post-performance) using serial numbers or independent IDs

2. **Level 5 Competency:** Demonstrate how to immerse a temperature monitoring device.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High

The laboratory analyst …
• Can demonstrate how to properly immerse a TMD
  o Within the at use temperature
  o Identify the location of the immersion point of a TMD probe
	The laboratory analyst…
	• Can construct an immersion tube
	• Explain the purpose of an immersion tube

o Identify proper immersion liquid	
3. **Level 5 Competency:** Discuss the importance of documenting the correction factor on a calibrated temperature monitoring device.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can identify a correction factor on a calibration certificate. • Can demonstrate how to use a correction factor when using a temperature monitoring device. • Can explain the importance of documenting correction factors on calibrated TMDs o Affects final result (high or low)	The laboratory analyst… • Can calculate a correction factor • Can describe how to document correction factor on TMD and in records
4. **Level 5 Competency:** Describe the importance of instrument preventative maintenance documentation	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can find documentation of preventative maintenance • Can list examples of preventative maintenance that should be documented o Cleaning o Calibration (if needed) o Accuracy checks (as needed) • Can define data defensibility	The laboratory analyst… • Can explain how to document preventative maintenance of equipment. • Can generate documentation of preventative maintenance • Can determine appropriate frequency of equipment preventative maintenance • Can identify when preventative maintenance is needed.
5. **Level 5 Competency:** Describe the steps in troubleshooting an instrument/equipment.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**

The laboratory analyst…
• Can find manuals for equipment
  o Troubleshooting section
• Can find equipment SOP(s)
  o Is analyst performing something incorrectly?
• Can identify when to ask for assistance from supervisor or equipment manufacturer
	The laboratory analyst…
	• Can identify critical steps in SOP(s)
	• Can properly perform troubleshooting for integral pieces of equipment

Chemistry	
Marine biotoxins	Matrices
Proper pipetting	Blanks
Shucking	RBA
Dinoflagellate species	ELISA
Liquid chromatography	HPLC
Mass spectroscopy	LCMSMS
MBA mouse bioassay	UPLC
Chemical standards	Hazard classifications
Calibration curves	Risk assessment
Radiological safety	

Definition: Chemical analysis of marine biotoxins/toxic substances under the NSSP.

Level 4 Competency: Discuss the use of chemical analyses of marine biotoxins/toxic substances under the NSSP.

1. Level 5 Competency: Describe the shucking procedure to prepare shellfish for biotoxin analysis.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High

The laboratory analyst…
• Can describe the process of shucking marine biotoxin samples
  o Don't spill the liquor
• Can identify differences in technique based on shellfish type
	The laboratory analyst…
	• Can identify differences between microbiological and marine biotoxin shucking procedures
	  o Concerns about sterility in microbiological procedures

2. Level 5 Competency: List marine biotoxins associated with shellfish.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
The laboratory analyst… • Can list at least two marine biotoxins associated with shellfish	The laboratory analyst… • Can identify marine biotoxins regulated by the NSSP o PSP o ASP o NSP o DSP o AZP • Can explain when to report results to state control authority o When a result approaches the action level
3. Level 5 Competency: Demonstrate use of the Guide to identify appropriate methodology for analyte and shellfish species.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can locate the Guide • Can identify the appropriate section in the Guide for laboratory methods	The laboratory analyst… • Can identify the shellfish species and toxins that are tested using specific methodology, e.g. the receptor binding assay (RBA)
4. Level 5 Competency: Demonstrate the use of a calibration curve to quantify a chemical analyte in shellfish.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst • Can determine that a calibration curve is appropriate o R-squared value o LOQ • Can use a calibration curve to quantify an analyte	The laboratory analyst… • Can explain the consequences of not using controls (e.g. positives, dilutions, blanks) • Can explain the use of blanks (determine background) • Can explain the linear calibration range
5. Level 5 Competency: Describe the difference between micropipetting and volumetric pipetting.	
Based on Level 5 competency – Not an all-inclusive list	

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
The laboratory analyst… • Can define micropipetting • Can define volumetric pipetting • Can describe at least two differences between micropipetting and volumetric pipetting o Different equipment o Technique differences	The laboratory analyst… • Can describe appropriate use of micropipetting and volumetric pipetting in various situations
6. Level 5 Competency: List potential hazards during marine biotoxins/toxic substances analysis	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can list potential hazards of marine biotoxins/toxic substances o Death o Illness • Can list potential hazards of analysis methodology o Chemical o Radiological o Stabbing during shucking	The laboratory analyst… • Can identify the potential hazards associated with each marine biotoxin.
7. Level 5 Competency: Discuss potential matrix effects in chemical analysis.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can list matrix effects • Can describe how matrix effects can affect results • Can articulate that the method addresses potential matrix effects	The laboratory analyst… • Can discuss different matrix effects for each shellfish species

8. Level 5 Competency: Discuss why chemical standards are important for running chemical analyses.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can list standards for each chemical analyte • Can find in the method where the standards are located • Can describe how to prepare the appropriate standard level/concentration • Can discuss the importance of chemical standards	The laboratory analyst… • Can identify sources of standards (where to buy) • Can select the appropriate standards o In-house preparation o Purchasing

Microbiology	
MPN	Productivity controls
Proper pipetting (micro vs serological)	Norovirus
Point-to-point pipetting	Hepatitis
Not less than 10%	Real time PCR
Proper pipette tip	Membrane filtration
Shucking	Double agar overlay
Media preparation	HPC
Vibrio	Total coliforms
Fecal coliform	Enterococcus
Male specific coliphage	Hazard classification
Bacteria knowledge	Risk assessment
Control organism	Process controls
Indicator organism	

Definition: microbiological analysis under the NSSP.

Level 4 Competency: Discuss the use of microbiological analyses under the NSSP.

1. **Level 5 Competency:** Describe the key differences between micropipetting and serological pipetting.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can identify a micropipettor • Can identify a serological pipette • Can demonstrate proper use of a micropipettor and serological pipette	The laboratory analyst… • Can explain the volume one is able to pipette with a micropipettor • Can explain the accuracy limits when staying within the volume range for a micropipettor • Can explain the appropriate uses for a serological pipette

2. **Level 5 Competency:** Describe the shucking procedure to prepare shellfish for microbiological analysis.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
3. **Level 5 Competency:** Differentiate between productivity controls and process controls.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can describe when each is used • Can name bacterial cultures used for each. • Can define productivity controls • Can define process controls	The laboratory analyst… • Can describe the purpose for productivity control and process controls • Can identify appropriate productivity controls for m-A1 media • Can identify how to use process controls through the analysis on fecal coliforms using m-A1
4. **Level 5 Competency:** List the steps in the process of media preparation.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can locate SOP or WI for preparing media. • Can describe process of making media • Can list quality control needed for media prep.	
5. **Level 5 Competency:** Discuss the concept of bacteriological enumeration by MPN (most probable number).	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can describe how to perform an MPN • Can demonstrate how to use an MPN chart to quantify bacterial density	The laboratory analyst… • Can explain the advantages/disadvantages of enumeration of target bacteria for enumeration

	o Advantages: ease of interpretation, effective for analyzing extremely turbid samples, can be used for enumerating low numbers in foods o Disadvantages: time consuming, not as accurate as other enumeration methods, requires more glassware and media, may include false positives.
6. **Level 5 Competency:** List approved methods for growing area classification under NSSP.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • List methods. • Describe where to find list of Approved methods	
7. **Level 5 Competency:** List potential hazards during microbiological analysis.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can List hazards • Can locate safety section in QA manual or SOP	The laboratory analyst… • Can identify Hazards within the laboratory

Sampling, Analysis, and Reporting	
Sample receipt	Depuration
Chain of custody	Wet storage
Data reporting	Environmental testing
Shellfish species	Research/regulatory
Sample collection	Illness investigation
Matrices	Action limits
Holding times	Decision unit
Data integrity	Analysis requirements
Documentation process	SOPs

Definition: requirements for the lifespan of a sample to ensure data integrity.

Level 4 Competency: Discuss data integrity requirements for the lifespan of a sample.

1. **Level 5 Competency:** Explain the impact of NSSP defined hold times for water and shellfish samples.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
The laboratory analyst… • Can describe hold times for NSSP samples • Can identify actions per the NSSP checklist if times have been exceeded	The laboratory analyst… • Can identify contingency plan for marine biotoxins if one exists • Can explain the reporting contingency for classification samples that have exceeded hold times

2. **Level 5 Competency:** Explain how NSSP action limits influence reporting protocols.

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

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
The laboratory analyst… • Can identify action levels for marine biotoxins	The laboratory analyst… • Can discuss procedure for reporting to Authority

4. **Level 5 Competency:** List the steps of a sample intake procedure.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can identify SOP for sample receipt • Can identify 3 rejection criteria for sample	The laboratory analyst… • Can explain the cause for documentation of sample intake with initial, date, time and temperature upon arrival to the lab • Can describe the reason why if temperature of the samples is out of spec the sample must be rejected and re-collected.
5. **Level 5 Competency:** Discuss situations where an exception statement is needed.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can explain what an exception statement is • Can identify an exception statement	The laboratory analyst… • Can explain the requirement for an exception statement
7. **Level 5 Competency:** Explain how the type of sample influences analysis requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
The laboratory analyst… • Can identify sample types o Bacterial o Viral o Chemical	The laboratory analyst… • Can list rejection criteria for each sample type

Dairy Regulatory Programs

Definition: The basic theory and practice related to microbiological and chemical quality testing of Grade "A" dairy products.

Level 2 Competency: Attain certification/approval as a dairy laboratory analyst.

Level 3 Competencies:

- Articulate the requirements for the dairy laboratory program - Communication
- Explain their role in testing dairy samples in the laboratory program - Leadership
- Follow the requirements of the dairy laboratory program - Programmatic
- Perform test analysis according to the dairy laboratory testing program - Technical

Testing

BRAINSTORM

Approved test procedures (2400 forms)

- Total bacteria
- Coliform
- Somatic cells
- Drug residues
- Containers
- Phosphatase
- Dairy waters

Test parameters
Finished products vs raw
Corrective actions
Follow-up testing
Sequence of events
Drug residue confirmation

- Identify a confirmation laboratory

Chain of custody

- Sample handling
- Sample volume
- Sample receipt
- Temperature control

Responsibilities and awareness

- Grade "A" vs non-Grade "A"
- Allowed testing

Definition: NCIMS testing of Grade "A" milk and milk products.

Level 4 Competency: Perform NCIMS testing.

4. **Level 5 Competency:** Perform sample receipt procedures.

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

1. The laboratory analyst can explain the requirements for sample receipt. • Temperature control • Sample integrity 2. The laboratory analyst can perform sample receipt procedure.	1. The laboratory analyst can explain why the requirements for sample receipt are needed. 2. The laboratory analyst can determine whether they can officially receive/test the sample.
6. **Level 5 Competency:** Perform procedures according to the 2400 forms.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
4. The laboratory analyst can explain the requirements for sample testing. 5. The laboratory analyst can perform sample testing based on the requirements.	1. The laboratory analyst can explain why samples are tested as described in the dairy laboratory program. 2. The laboratory analyst can determine which analysis needs to be performed.
10. **Level 5 Competency:** Describe follow-up testing after an initial positive.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can explain the requirements for follow-up testing of an initial positive sample.	2. The laboratory analyst knows the implications and outcomes of follow-up testing.
11. **Level 5 Competency:** Perform follow-up procedures according to the 2400 forms.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can perform follow-up testing of an initial positive sample as required.	1. The laboratory analyst can perform follow-up testing independently.
12. **Level 5 Competency:** Describe the purpose of test methods.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can describe the test method.	1. The laboratory analyst can explain the significance of following the test methodology.
13. **Level 5 Competency:** Recognize regulatory implications of testing.	

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst knows the testing is regulatory in nature. 2. The laboratory analysts understands that their work has consequences.	1. The laboratory analyst understands that there are regulatory implications of test outcomes. • Fines • Recalls • Investigations
7. **Level 5 Competency:** Recognize that corrective action(s) are taken when problems are identified.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can recognize that a problem exists. 2. The laboratory analyst can recognize that a corrective action is required.	1. The laboratory analyst knows what corrective action is necessary.
8. **Level 5 Competency:** Identify allowed testing.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst knows what testing is allowed in the laboratory. 2. The laboratory analyst knows what testing they are allowed to perform.	1. The laboratory analyst knows why testing is allowed in the laboratory. 2. The laboratory analyst knows why testing is allowed by the analyst. 3. The laboratory analyst knows what testing is allowed by each analyst.

Resource Documents

PMO (Appendix N)
PMO (Section 6)
EML
- Describe LEO

Regulations
Memoranda
- Allowable antibiotic residues
- 2400 forms

21CFR
IMS list
SMEDP
Standards of identity
Federal state relationships
- Laboratory role

Definition: Documents related to Grade "A" milk laboratory testing.

Level 4 Competency: Utilize document(s) required for application.

4. **Level 5 Competency:** Recognize that there are regulatory standards/limits.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
5. The laboratory analyst knows that there are regulatory standards/limits.	1. The laboratory analyst can independently find the specific limits for a given test.

5. **Level 5 Competency:** Identify 2400 form(s) for specific testing activity.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can identify the correct 2400 form for any given procedure.	1. The laboratory analyst can independently find the specific information in the 2400 form that is needed.

6. **Level 5 Competency:** Recognize which documents describe program interactions at the lab level.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can identify the correct program documents for any given topic.	1. The laboratory analyst can independently locate the information within the program document.

Quality Control

- Validation protocols
- Recording/reporting
- Rounding rules
- Acceptable limits/tolerance levels
- Calculation of test results
- Basic math skills
- Media prep
- Autoclave usage
- Media prep
- Waste
- Preventive actions
- Problem solving
- Communication skills
- Personal errors
- Comparison counts
- Instrumentation QC
  - Microscope maintenance
  - Pipettor calibrations
  - Etc.
- Quality control testing

Definition: Means to validate test results.

Level 4 Competency: Employ procedures to validate test results.

1. **Level 5 Competency:** Describe standardized QA requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can describe QA requirements.	1. The laboratory analyst understands the ramifications of QA requirements.
2. **Level 5 Competency:** Describe standardized QC requirements.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst knows the QC requirement. 2. The laboratory analyst can recognize when QC is out of specification.	1. The laboratory analyst knows the specifics of the QC requirement. • Frequency 2. The laboratory analyst understands ramifications of QC.
3. **Level 5 Competency:** Perform standardized QC procedures.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can perform standardized QC procedures.	1. The laboratory analyst knows corrective action if QC is out of specification (invalid).
4. **Level 5 Competency:** Recognize validity of QC outcomes.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst knows if the QC result is acceptable.	1. The laboratory analyst knows corrective action if QC is out of specification (invalid).
5. **Level 5 Competency:** Perform required corrective action when QC is invalid.	
Based on Level 5 competency – Not an all-inclusive list	

BEHAVIORAL ANCHORS Average	BEHAVIORAL ANCHORS High
1. The laboratory analyst recognizes that QC is invalid (out of range/spec) 2. The laboratory analyst can perform the required corrective action.	1. The laboratory analyst knows why corrective action is required.
6. **Level 5 Competency:** Ensure media/reagents meet requirements as specified in 2400 forms.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can prepare media/reagents. 2. The laboratory analyst knows if media/reagents are acceptable based on requirements.	1. The laboratory analyst knows why media/reagents needs to be prepared in a certain way. 2. The laboratory analyst knows what to do if media/reagents fails to meet requirements.
7. **Level 5 Competency:** Ensure equipment/instrumentation operate within specified parameters.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can operate equipment/instrumentation within specification. 2. The laboratory analyst knows when an equipment/instrumentation is out of specification.	1. The laboratory analyst knows why equipment/instrumentation operate in a certain way. 2. The laboratory analyst knows what to do if equipment/instrumentation fails to meet requirements.
8. **Level 5 Competency:** Use 2400 forms rules for recording test results.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst knows the proper way to record test data. 2. The laboratory analyst can differentiate test result as valid or invalid.	1. The laboratory analyst understands why test results are recorded as required. 2. The laboratory analyst knows why the test result is valid or invalid.
9. **Level 5 Competency:** Use 2400 forms rules for reporting test results.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**

1. The laboratory analyst knows the proper way to report test data. 2. The laboratory analyst knows the proper way to report invalid test results.	1. The laboratory analyst understands why results are reported as required. 2. The laboratory analyst knows why the test result is invalid. 3. The laboratory analyst knows the implications of an invalid test result. 4. The laboratory analyst knows the implications of a test result that is outside of regulatory limits.

Performance Checks

- PT Split samples
- On-site evaluation
- Analyst certification/approval
- Laboratory accreditation/approval
- Analyst status levels
- Prepare for audit

Definition: Means to evaluate test performance.

Level 4 Competency: Recognize means to evaluate performance.

1. **Level 5 Competency:** Discuss the purpose of analyzing split samples.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can discuss the importance of analyzing split samples. a. Impact laboratory's status to perform testing	1. The laboratory analyst can discuss the purpose of analyzing split samples. 2. The laboratory analyst can suggest improvements to technique if split sample results are unacceptable.

2. **Level 5 Competency:** Perform annual split samples for certified/approved methods.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can perform annual analysis of split samples.	

3. **Level 5 Competency:** Discuss the purpose of an on-site evaluation.

Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can discuss the purpose of an on-site evaluation.	1. The laboratory analyst understands the importance of an on-site evaluation.
4. **Level 5 Competency:** Demonstrate satisfactory performance of certified/approved test methods during on-site evaluation.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can correctly perform procedures during an on-site evaluation.	
5. **Level 5 Competency:** Implement corrective actions provided by the LEO.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can implement necessary corrective action as directed.	1. The laboratory analyst understands necessity of corrective actions.
6. **Level 5 Competency:** Explain steps in analyst certification/approval status.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst can discuss the steps in analyst certification/approval. 2. The laboratory analyst understands ramifications of certification/approval.	1. The laboratory analyst understands how status is assigned/changed. 2. The laboratory analyst knows the steps to achieve/maintain full certification/approval. 3. The laboratory analyst understands implications of the loss of certification/approval.
7. **Level 5 Competency:** Identify steps in laboratory accreditation/approval status.	
Based on Level 5 competency – Not an all-inclusive list	
BEHAVIORAL ANCHORS Average	**BEHAVIORAL ANCHORS High**
1. The laboratory analyst has awareness of the laboratory's accreditation/approval process. a. On-site evaluation b. Annual split samples	1. The laboratory analyst understands how accreditation/approval is granted. 2. The laboratory analyst understands implications of the loss of accreditation/approval.
