

# Evidentiary and Analyte Integrity Policy Checklist

Product of the APHL Human and Animal Food Subcommittee

Regulatory and laboratory partners work together to maintain the integrity of evidence associated with samples. Laboratory and sample collectors must communicate expectations and essential required elements prior to sample collection. This checklist details considerations for maintaining integrity of legal evidence. Laboratories can use this checklist as a guide when discussing the essential elements needed to ensure evidentiary integrity with sampling partners.

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## ESSENTIAL EVIDENTIARY INTEGRITY ELEMENTS

Evidentiary integrity is maintaining the identity and authenticity of evidence. For samples collected as evidence, evidentiary integrity has three components:

1. Documentation of link between a test result and a specific decision unit.
2. Maintenance of analyte integrity by controlling risk to any sample or test solution of being adulterated, contaminated or compromised.
3. Establishment and maintenance of representivity by sufficiently controlling sampling errors so the analyte concentration (or characteristic) in the test portion is the same as the decision unit.

## Documentation Linking Test Results to Decision Unit

Maintaining evidentiary integrity requires documentation showing an unbroken trail from test results to the decision unit so the report of analysis can be traced back to the decision unit.

- Procedures shall include instruction for the collection and labeling of samples and the recording of all associated data.
- Laboratory sample documentation shall include:
  - Laboratory name and address
  - Name of individual who received the sample
  - Analysis requested
  - Date and method of delivery
  - Authorization for testing.
- Sample label information and submission form must match. Notes may be added on sample conditions observed in the field at the time of collection.
- Laboratory results shall, at a minimum, be accompanied by the following data elements related to the sample:
  - Amount inspected
  - Lot number or other traceback information of what is being sampled (see Decision Unit)
  - Test requested
  - Name(s) of person(s) performing sampling
  - Date sampled
  - Time sampled
  - Unique sample identification.
- Laboratory results and completed chain of custody records must be maintained. Sample integrity details include:
  - Transportation
  - Storage
  - Name of person(s) with custody
  - Record time/date of all custody transfers
  - Temperature
  - Sample quality.

## Maintaining Analyte Integrity

Maintaining analyte integrity involves taking steps to retain the physical and chemical or biological characteristics of the sample, so the analyte remains in its original state and form from collection of the primary sample through disposal. Where applicable, consider the impact of these measures on each sample matrix and analyte before collection:

- Use of custody seals
- Use of preservatives
- Control of temperature
- Use of proper containers
- Protection from light
- Maintenance of holding times
- Use of proper sampling techniques
- Use of correct packaging
- Preparation of materials for shipment
- Shipping Procedure
- Selection of a third-party courier
- Weather or other conditions that could lead to shipping delay.

## Establishing and Maintaining Representivity

Maintaining the representivity of the decision unit from primary sampling through selection of the test portion involves controlling sampling error in all processes up to the point of testing, including:

- Control of random error through collection of sufficient mass (and documentation to affirm)
- Control of random error through collection of sufficient number of increments (and documentation to affirm)
- Control of systematic error through education and training.

## IMPORTANT TERMS & CONCEPTS

The following terms and concepts are essential for understanding and preserving evidentiary and analyte integrity. Many of these concepts are further explained in [GOODSamples](#) and [GOOD Test Portions](#).

**Analyte Integrity:** The characteristic or concentration of the analyte of interest is maintained from collection of the primary sample through the test portion (maintain sample correctness).

**Custody:** A sample is “in custody” when: 1) the sample is in the sampler’s possession, 2) the sample was in the sampler’s possession and then secured by the sampler in a manner to detect or prevent tampering, or 3) the sample is placed in a designated secure area. The custody chain usually ends when lab discards/destroys the sample. Custody chain could extend if the sample is transferred to another party, which removes it from agency control.

**Chain of Custody:** The chronological documentation or paper trail that records an unbroken sequence of custody, control, transfer, analysis and disposition of a sample.

**Chain of Custody Documentation:** A record which tracks each step in the sample handling process and each responsible entity that handles the sample from the time it was collected up until the sample is tested, consumed/disposed or otherwise released.

**Decision Unit:** The material/source from which the sample is collected and to which an inference is made from the sample data. The entire target material (eg., field of tomatoes) subject to a regulatory decision from which a sample is collected, and to which inference is made from subsequent test results.

**Evidentiary Integrity:** The identification and authentication of evidence. In the laboratory this encompasses 1) information that traces the test result(s) back to the decision unit, 2) assurance that any sample or test solution has not been adulterated or compromised at any point after collection through disposal, and 3) systematic errors, random errors and blunders are sufficiently controlled to meet the sample quality criteria.

**Holding Times:** The allowed time from sample collection until analysis.

**Primary Sample:** The material selected from a decision unit.

**Representivity:** The application of sample collection and handling practices to assure that the test portion has the same properties as the decision unit.

**Secure Area:** An area to which entry is limited to a designated and known population with authorized access.

**Test Portion:** The mass or volume of material selected from an analytical sample for a single test.

# SAMPLE SOPS/WORK PLANS

## Maintaining Laboratory Integrity Policy

Sample policy for maintaining laboratory integrity created by the Minnesota Department of Agriculture, Laboratory Services Division.

<b>Objective:</b>	To define the minimum practices required by Laboratory A for sample collection, handling, and chain of custody in order to maintain sample integrity and ensure accurate and defensible test results.
<b>Scope:</b>	Applies to all divisions with programs engaged in sample collection and laboratory analysis used to support surveillance activities and enforce statutes, rules and regulations that protect public health, promote food safety and safeguard the environment.
<b>Policy Statement:</b>	<p>It shall be the policy of the Department of Agriculture that all samples collected for laboratory analyses will be obtained following established procedures that contain, at a minimum, the specific evidentiary and analyte integrity elements listed below to ensure the suitability of samples to support the Department's regulatory divisions and program data objectives.</p> <p>Each division submitting or analyzing samples will establish, maintain, and train staff on procedure(s) that conform to this policy and chain of custody principles. Conformance with this policy shall be reviewed using the process outlined in LAB-SOP-0016 "Requests, Tenders, and Contracts for Laboratory Analysis" and documented in Program Summaries.</p>
<b>Definitions:</b>	<p><b>Analyte Integrity:</b> The characteristic or concentration of the analyte of interest is maintained from collection of the primary sample through the test portion (maintain sample correctness).</p> <p><b>Custody:</b> A sample is "in custody" when: 1) the sample is in the sampler's possession, 2) the sample was in the sampler's possession and then secured by the sampler in a manner to detect or prevent tampering, or 3) the sample is placed in a designated secure area.</p> <p><b>Chain of Custody:</b> In legal contexts, refers to the chronological documentation or paper trail that records the sequence of custody, control, transfer, analysis, and disposition of sample.</p> <p><b>Chain of Custody Documentation:</b> A record which tracks each step in the sample handling process and each responsible entity that handles the sample from the time it was collected up until the sample is tested, consumed/disposed or otherwise released.</p> <p><b>Decision Unit:</b> The material/source from which the sample is collected and to which an inference is made from the sample data.</p> <p><b>Demonstrably Sealed:</b> A sample is demonstrably sealed when it is bagged or otherwise containerized, and the container is officially sealed with material that would show evidence of tampering.</p> <p><b>Evidentiary Integrity:</b> Demonstration that the analytical result(s) can be traced back to the decision unit without being compromised. In legal terms, it is the identification and authentication of the evidence through the entire chain of custody.</p> <p><b>Secure Area:</b> An area in which entry is limited to a designated and known population with authorized access.</p>

<p><b>General Standards and Expectations:</b></p>	<p><b>EVIDENTIARY INTEGRITY ELEMENTS</b></p> <p>Maintenance of evidentiary integrity gives assurance that any evidence (sample) collected for laboratory analysis has not been compromised from the time of collection until the generation of an analytical result. For purposes of this policy, evidentiary integrity focuses on the level of identification and authentication needed to link a test result to a specific decision unit.</p> <p>To achieve this, the divisional procedures on sample collection must include thorough documentation that can trace the sample back to the decision unit. Procedures shall include step by step instruction for the collection and labeling of samples and the recording of all associated data. Samples received at the laboratory must be accompanied by the following minimum data elements related to the sample(s) (usually on a sample submission form): identification of decision unit, name(s) of person(s) performing sampling, date sampled, time sampled, and unique sample identification.</p> <p>The sample label information and submission form must match in order to preserve evidentiary integrity. The Program, at their discretion, may add notes on sample conditions observed in the field at the time of collection.</p> <p>Samples must be accompanied by a chain of custody form and be demonstrably sealed.</p> <p><b>ANALYTE INTEGRITY ELEMENTS</b></p> <p>Maintaining analyte integrity involves taking steps to retain the physical and chemical, or biological characteristics of the sample so that it is and remains representative of the decision unit. These may include but are not limited to: use of preservatives, control of temperature, use of proper containers, protection from light, maintenance of holding times, use of proper sampling techniques, use of correct packaging, packaging configuration and the shipping procedure.</p>
<p><b>Statutory References:</b></p>	<p>State Statutes Chapter 18D.201 Inspection, Sampling, Analysis  State Statutes Chapter 31.13 Analysis; Evidence  State Statutes Chapter MS 25.41 Inspection, Sampling, And Analysis  State Statutes Chapter 32D.02 Inspection and Enforcement; Authority and Duties.  State Statutes Chapter 31A.25 Access by Inspectors</p>
<p><b>Technical References:</b></p>	<p>ISO/IEC 17025:2017 General Requirements for The Competence of Testing and Calibration Laboratories Section 7.3 Sampling  Association of American Feed Control Officials (AAFCO), "Good Samples", 2015  <a href="#">Manufactured Food Regulatory Program Standards (MFRPS)</a>  Animal Feed Regulatory Program Standards (AFRPS)  Voluntary National Retail Food Regulatory Program Standards (RFRPS)  Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Inspection Manual  U.S. Environmental Protection Agency guidance on environmental sampling  U.S. Department of Transportation Hazardous Materials regulations, 49 CFR Part 172</p>
<p><b>Policy of:</b></p>	<p>Laboratory A</p>

## Feed Program Analytical Work Plan

Sample feed program analytical work plan created by the Colorado Department of Agriculture Division of Laboratory Services—Biochemistry Laboratory.

### 1.0 Background

The State Department of Agriculture (Division of Inspection & Compliance Services (ICS)) is responsible for regulating the sale and distribution of animal feeds and pet foods in the State under CRS 35-60-101 (State B Feed Law). Feed regulation involves collection and analysis of official samples from a variety of sale and distribution points across the State. ICS inspection personnel collect the feed and pet food samples and they are analyzed by State B Biochemistry Laboratory (BCL) under authority of CRS 35-60-110 (Enforcement – Inspection - Sampling - Analysis).

The Feed Program (FP) is administered at ICS by the Feed Program Administrator (FPA). This Analytical Work Plan (AWP) is developed in conjunction with the FP annual sampling plan for each fiscal year (Appendix III). The AWP is the operating document BCL uses to ensure that the laboratory has clearly defined and documented customer expectations with respect to program requirements for animal feed and pet food sample analysis.

The BCL is an operating unit of the State Division of Laboratory Services (DLS) and is an ISO/IEC 17025 accredited laboratory. The Scope of Accreditation includes Chemical and Biological Testing (certificates 2851.01 and 2851.02).

#### 1.1 Scope

This Analytical Work Plan applies to animal food/feed, feed ingredients and pet food official samples submitted to the BCL for analysis.

#### 1.2 Purpose

This Analytical Work Plan describes the requirements for sample collection, preservation, chain-of-custody, preparation, analysis, reporting, data management, sample disposition, and waste management.

#### 1.3 Description of Services

This section contains a general description of the analytical services to be provided by the BCL and the fiscal responsibilities of the program participants.

##### 1.3.1 *Services to be Provided*

The analytical services to be provided by the BCL under this Work Plan include:

- (1) Procurement of analytical standards, test kits, reagents, chemicals, glassware and all necessary laboratory supplies
- (2) Maintenance and repair of analytical equipment and instrumentation
- (3) Sample preparation
- (4) Instrumental and/or cultural analysis of selected analytes and pathogens
- (5) Data management and reporting of results
- (6) Quality assurance and quality control
- (7) Sample disposition and waste management

## 2.0 Glossary and Abbreviations

AA	Atomic absorption
AFRPS	Animal Feed Regulatory Program Standards
AOAC	International Association of Official Analytical Chemists
AV	Analytical Variance
BCL	Biochemistry Laboratory
XX	State Department of Agriculture
XCO	Chain-of-custody record
DLS	Division of Laboratory Services
FDA	Food and Drug Administration
FPA	Feed Program Administrator
FP	Feed Program
HPLC	High Performance Liquid Chromatograph
ICP	Inductively Coupled Plasma spectrometer
ICS	Inspection and Consumer Services
ISO	International Organization for Standardization
LC/MS/MS	Liquid chromatograph tandem quadrupole mass spectrometer
LECO	LECO combustion analyzer
LOD	Limit of Detection
LOQ	Limit of Quantitation
RL	Reporting Limit
SOP	Standard Operating Procedure
SRM	Standard Reference Material
UHPLC	Ultra-High-Performance Liquid Chromatograph
USP	US Pharmacopeia

### 3.0 Work Requirements

Work Requirements are arranged into four sections: Sampling; Analytical; Data Management & Reporting; and Sample Disposition & Waste Management. These sections will be modified, revised, or updated as needed.

#### 3.1 Sampling Requirements

Sampling requirements consist of the types of samples to be collected, preservation and packaging, and characteristics. Feed sampling is to be performed according to ICS SOPs. The sampling plan for FY 2022 is contained in Appendix III of this work plan. ICS and the DLS BCL will meet annually, at a minimum, to discuss the sampling plan/schedule, sampling supplies and analytical requirements prior to the beginning of each testing season. Because of the expedited holding time for samples being analyzed for microbial contamination, all microbial samples must be scheduled using the Google Calendar Microbial Sampling Calendar. Inspectors must add all microbial sampling on this calendar so that the inspector and laboratory can coordinate to ensure these samples are analyzed as soon as possible.

##### 3.1.1 *Sample Sizes and Types of Containers*

Official samples for feed, feed ingredients and pet food (includes pet treats) analyses will typically be collected and submitted to the laboratory in appropriately sized Mylar bags. Products in sale containers up to 10 pounds may be submitted as well. Sale containers over 10 pounds or bulk product samples must be collected using AOAC methods (probe, trier, scoop, etc.).

Official samples for microbial analysis must be collected aseptically and submitted to the laboratory in suitable sized sterile sample bags, or in original, as found, packaging.

##### 3.1.2 *Collection, Preservation, Packaging, and Delivery of Samples*

Official feed and pet food bulk samples will be collected by transferring the sample directly from the sampling device into sample bags. Sale containers under 10 pounds may be submitted as found. Official samples collected for microbial analyses will be collected aseptically and transferred to sterile bags, or in original, as found, packaging.

Unless otherwise specified by the ICS Technical Services Section Chief, official samples collected for this program will be unpreserved and samples should be packaged for transport or shipment to the BCL in clean, undamaged shipping boxes or other suitable containers. Samples must be packaged to maintain sample integrity and to avoid cross-contamination and compromise of the sample. Feed samples and non-perishable pet food samples can be transported and/or shipped at ambient temperature.

Perishable frozen and/or refrigerated animal food samples will be placed in a cooler/refrigerated shipping box with adequate ice packs prior to transfer/shipment to the BCL. Samples may be shipped or hand-delivered to the BCL.

Samples for microbial analyses shall arrive at the BCL within 2 hours of sample collection or be shipped overnight priority to the BCL. Samples are collected and maintained under chain-of-custody and are sealed with tamper-resistant seals from the field to secure storage at BCL. All samples submitted for testing to the BCL shall have an intact tamper seal and a completed chain-of-custody (COC) form.

### 3.1.3 *Sample Characteristics and Documentation*

Sample containers will be labeled and listed on chain-of-custody (COC) records according to ICS SOPs. The product labels (actual label or digital photo) should accompany the samples along with a completed “Feed Sample Collection Report & COC” form. One form is required for each individual sample submitted to the BCL for testing.

### 3.1.4 *Sample Receipt*

Samples are received, handled, stored, protected and disposed according to BCL SOP SL-LBOP-013 Sample Receipt, Handling, Storage, Protection and Disposal. Samples that arrive with torn packaging, no tamper seal, are leaking, damaged, or at improper temperature at receipt (i.e. frozen sample is thawed) and/or no COC will be rejected and will not be tested by the BCL. The Feed Program Manager will be notified, and the sample will be disposed of.

Non-perishable samples will be stored in the secured, designated feed sample storage area until analysis. Frozen samples will be stored frozen at -15°C or below. Refrigerated samples will be stored at 2-8°C in a designated secured sample storage refrigerator. Samples will be logged into the BCL Laboratory Information Management System (LIMS) and COC forms will be scanned and saved electronically in the Google Shared Drive G:\Shared drives\Feed COCs. Samples arriving with incomplete information, incorrect information or other issues will be logged into the BCL LIMS and will be placed on “HOLD”. The Unit Leader or designee will contact the Feed Program Manager in writing to obtain correct or missing information or obtain further clarification.

## 3.2 Analytical Requirements

### 3.2.1 *General Laboratory Requirements*

The BCL has adequate facilities and workspace to meet the testing deliverables outlined in this analytical work plan. The State Department of Agriculture Biochemistry Laboratory is an integrated operational unit of the Division of Laboratory Services (DLS). The Biochemistry Laboratory includes microbiology and chemistry testing sections that support a variety of State regulatory and Federal cooperative agreement (CAP) programs.

The DLS is a secured facility and the main lobby area is the only public access area and all other areas are restricted to only those employees with approved key-card access. The BCL is composed of four main sections: Sample Receiving,

Pesticides, Feed and Fertilizer, and Microbiology. In addition, entry to the BCL Sample Receiving Room (138) is restricted and secured.

The BCL is accredited to ISO 17025:2017 and all requirements for sample handling and testing comply with these requirements.

### 3.2.2 Analysis Requirements

Official feed samples are typically analyzed for a suite of target analytes including nutritional components (protein, minerals, amino acids, and vitamins), antibiotics, drugs, microbial contamination, and naturally occurring toxins. These routine target analytes are listed in Appendices I-II.

Samples will be analyzed by the relevant BCL method SOP listed in Appendix II.

The analytical testing strategy is as follows:

- 1) For minimum claims with an  $AV \leq 20\%$  - we will retest the sample if the result falls outside of 80% to 200% of the guarantee.
- 2) For minimum claims with an  $AV > 20\%$  (For Example:  $AV = 25\%$ ) we will retest the sample if the result falls outside 75% to 200% of the guarantee.
- 3) For range claims we will retest the sample if the result is outside 80% of the lower claim value to 120% of the higher claim value. (For example: a Calcium claim of 1.0-1.5 would be retested if the value is less than 0.8 or greater than 1.8)
- 4) For maximum claims we will retest the sample if the result is outside -50% of the guarantee to 120% of the guarantee

Feeds and pet foods are formulated in a variety of configurations using various blends of ingredients. Certain formulations may be below the laboratory's levels of detection capabilities based on the method or instrumental platform. Table 1- Routine Feed Analyte List and Program Detection Limits below depicts the analytes the laboratory can test for and the levels of detection.

Feed and pet food samples are analyzed using the laboratory SOPs listed in Appendix II.

**Table 1 – Routine Feed Analyte List and Program Detection Limits\***

<b>Analyte</b>	<b>ICS Program Detection Limits or Method Cut-off Limits</b>	<b>Comments</b>
Protein (crude)	5%	
Amprolium	0.27g/ton, 0.00003%, 0.000135g/lb	
Decoquinatate	0.001%	
Lasalocid	0.003%	
Vitamin A	10,000 IU/lb, 10KU/lb, 625 IU/oz, 21 IU/ml, 22,000 IU/Kg, 22 KU/kg	Light and heat sensitive
Fumonisin, total	2.187 ppm	
Aflatoxins, total	B = 3.125 ppb and G = 6.25 ppb	
DON	1 ppm	
Calcium (Ca), Copper (Cu), Iron (Fe), Magnesium (Mg), Manganese (Mn), Phosphorus (P), Potassium (K), Zinc (Zn)	100 ppm, 100 mg/Kg, or 0.01% Phosphorus (P) 0.17%	
Lysine	0.15%	
Methionine	0.25%	
Taurine	0.05%	
Salmonella sp.	NA	Reported as Detected or Not Detected
Listeria monocytogenes	N/A	Reported as Detected or Not Detected
E. coli O157:H7	N/A	Reported as Detected or Not Detected
Ruminant Prohibited Material	N/A	Reported as Detected or Not Detected

\*Uncontrolled excerpt taken from BCL form SLL013A Analyte List and Program Detection Limits

### 3.2.3 Holding Times

Official samples for feeds and pet food nutrients and drug analysis will be sub-sampled, prepared, digested, and/or extracted as soon as practicable after receipt at the laboratory. Samples for microbial analysis must be analyzed on the day of arrival or as soon as practicable. The holding time is determined as the time a sample is logged into the BCL LIMS (LabWorks) system. This explicitly means that the sample has been received and all documentation verified, discrepancies or missing items resolved, and the sample logged into the Laboratory Information Management System (LIMS).

Once this process has been completed, the sample is considered “Received” by the BCL. In cases where there is an issue with a sample or the sample paperwork, the BCL will put the sample on “hold” until the issues are resolved. In these cases, the holding time does not start until the sample is logged in and officially “Received” by the laboratory.

#### 3.2.4 *Detection Limits*

Limits of Detection (LODs) and Limits of Quantitation (LOQs) are determined experimentally using the requirements in laboratory SOP SL-QAQC-022 Method Validation and Verification. Established Limits of Detection and Limits of Quantitation are referenced in individual method SOPs.

#### 3.2.5 *Method Verification and Validation*

Method verification and validation will be conducted according to BCL SOP SL-QAQC-022.

#### 3.2.6 *Expedited Analyses*

Unless otherwise requested by the FPA, samples will be prepared and analyzed in the order they are received. Switching the order of analysis and/or expediting a particular analysis for a sample or samples may be accomplished by request to the Laboratory Manager and/or Microbiological Sciences, Feed and Fertilizer Unit Leader.

#### 3.2.7 *Exceptional Laboratory Conditions*

The BCL does not anticipate any delays in completion of samples as the current sample plan compensates for the current staffing and resources at the BCL. If there are any circumstances in which the BCL cannot complete analysis such as equipment failure, building/facility issues or staffing issues, the Laboratory Manager will notify the FPA in writing.

#### 3.2.8 *Non-routine Analyses*

Non routine analyses included those analyses requested by the Feed Program Manager for which the BCL has the capability (technology, methodology, resources) to analyze but that are not routinely requested. These may include feed samples for an animal death or health investigation, or a special request made by the Feed Program Manager. The BCL has the capability to analyze samples for pesticides and pesticide residues, specific biothreat agents and specific microbiological contaminants not listed in Table 1. To request a non-routine analysis of a feed sample, the Feed Program Manager shall contact the BCL Laboratory Manager. It will then be determined if another division will need to be involved and/or if the BCL has the technology, method, resources, and trained personnel to run the non-routine sample(s).

### 3.3 Data Management & Reporting Requirements

#### 3.3.1 *Deliverables*

Deliverables under this Analytical Work Plan include the following:

- Chain-of-custody records
- Final Sample Analysis Results

#### 3.3.2 *Analytical Reports*

Data is collected, reviewed, and reported according to BCL SOP SL-DATA-002 Data Collection, Review, Approval, Storage, Protection, and Confidentiality. Final reports are validated and reported by the BCL Laboratory Manager or his/her designee. Final analytical reports are uploaded into a shared Google Drive G:\Shared drives\Feed Final Reports into folders and segregated by fiscal year.

Analytical reports will consist of electronic results in .pdf format. The final results will consist of the result for each analyte, analysis date, method used, and all identifying information for each sample collected.

#### 3.3.3 *Turnaround Times*

Routine sample results for official feed and pet food analyses will be electronically reported as stated above to the FPA within 30 days of receipt of the samples (the Received By date). In the event that reporting of results will be delayed due to unforeseen circumstances such as instrument failure, resource limitations, or other difficulties, an alternate delivery schedule will be determined in consultation with the FPA and ICS Technical Services Section Chief.

#### 3.3.4 *Raw Data*

Raw analytical data includes both hard copy and electronic files. Raw data consists of, but may not be limited to: instrument printouts, spectral data, data files, leak tests, spectral matches, confirmatory data, calibration sequences, validation studies, LOD/LOQ determinations, diagnostic testing, method verification and validation studies, quality control data and tabulations, back-up files, re-runs, directories, libraries, and any other data produced as a result of sample preparation and analysis. Raw data will be stored at BCL according to the DLS Data Retention Policy. Raw data is not considered a deliverable under this Work Plan.

#### 3.3.5 *Communications*

Routine communications for purposes of sample planning, scheduling and coordination of sample deliveries, pick-up of sampling supplies, materials ordering, and analytical requirements are done through a monthly scheduled meeting between the ICS Program Managers and the DLS BCL. All communications including email, memoranda, directives,

approvals/disapprovals, budget issues, etc. should be made through the DLS Division Director and the BCL Laboratory Manager.

### 3.4 Sample Disposition & Waste Management

#### 3.4.1 *Sample Disposition*

Residual samples and concentrates will be maintained at BCL according to SOP SL-LBOP-013: Samples will be disposed of 90 days after successful completion of analysis. Designated samples will be maintained until the final data has been accepted and disposition is approved by the FPM or in 6 months, whichever occurs first. Non-routine samples will be disposed of 90 days after successful completion of analysis.

#### 3.4.2 *Waste Management*

Residual/spent samples, standards, reagents, and associated chemical wastes will be managed as hazardous waste according to requirements in the BCL Chemical Hygiene Plan (SL-MANL-01). Disposition will be through BCL's waste management vendor. The program will be charged their apportioned share of waste/chemical management costs approximately every 6 months.

## 4.0 **Quality Assurance**

The BCL performs analytical work under a written quality assurance manual (SL-MANL-08) and attendant SOPs. Certain scopes of chemical testing and operations are accredited activities covered by ISO/IEC 17025. The accrediting organization is the American Association of Laboratory Accreditation (A2LA).

The quality system is implemented by laboratory management and quality processes are overseen by the Quality Assurance Unit.

### 4.1 Quality Assurance Program

The BCL quality assurance program is defined in the BCL Quality Manual (SL-MANL-08).

### 4.2 Quality Control

#### 4.2.1 *Quality Control Samples*

Quality control samples will be included in the analytical batches to monitor the quality and integrity of the work. Quality control samples include but may not be limited to: Laboratory Control Samples, Standards, Spikes, Surrogates, and Blanks. Quality control samples used will be specified in the methods and SOPs.

#### 4.2.2 *Quality Control Limits*

Quality control limits for spikes, surrogates, and blanks shall be established by the method and monitored using quality control charts. Quality control charts are used to monitor the quality of analytical work and identify anomalous

quality trends. Quality control charts are evaluated using BCL SOP SL-QAQC-015.

#### 4.2.3 *Standards and Reagents*

Standards, SRMs, reagents, and chemicals used shall be traceable and be the appropriate grade (HPLC, Trace Metal, etc.) for the application. Feed SRMs must be supplied from ISO 17034 accredited organizations, and/or NIST or USP (where available).

#### 4.3 Data Review

All data, results, and reports are subject to data review processes prior to release per BCL SOP SL-DATA-002 Data Collection, Review, Approval, Storage, Protection, and Confidentiality. Data review processes include quality assurance reviews, management reviews, and/or peer reviews. Some or all of these reviews may be conducted depending on the work product.

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## Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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