Purpose: The Integrated Consortium of Laboratory Networks (ICLN) seeks to provide general guidelines as to effective principles and procedures for sample collection and handling that optimizes sample throughput in a given laboratory network. Sample collection and handling activities where the guidelines can be applied include, but are not limited to, exercises, laboratory throughput of samples during a chemical, biological, or radiological (CBR) incident response and recovery, and analyses related to monitoring and surveillance of the nation's food, feed, plant, and environmental infrastructure and the health of its human and animal (e.g., pets/companions, agricultural stock raised for food, or wildlife) populations.

1. Each network will generally establish its own standard of operating procedures for preserving, packaging, shipping and receiving samples. Each laboratory network should, within its established procedures, provide guidance to those individuals who design sample collection protocols as to the laboratory daily throughput capacity in order to inform decisions on sample collection numbers and logistics. Each network may have situational sample collection and handling protocols that may provide additional information to the guidelines outlined in this document.

2. **Scope:** These guidelines may be considered when establishing procedures that the networks will use to define criteria for appropriate sample collection and sample handling which include, sample packaging, sample shipping, sample qualification/acceptance criteria, sample inspection and receipt, sample processing, sample labeling, and sample storage/disposal across networks. Alternative approaches to achieving the intent of these guidelines may be used. These guidelines do not address health and safety issues which should be addressed in network specific policies. It is not intended to restrain or restrict a network's ability to define what procedures are needed to ensure samples presented to it will lead to accurate and timely reporting of laboratory data. It is understood that sample collection and sample handling will be in accordance with all state and federal regulations and agency policies.

3. **Other Resources:**

- ICLN Chain of Custody Form
- Vet-LIRN Chain of Custody
- LRN-B Chain of Custody
- FSIS Form 10,625-1 (3/91) Evidentiary Sample Control Form
- Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121) http://www.selectagents.gov/
- Proper Biosafety Level reference: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

4. Specific Procedures

4.1 Sample Collection

The level of coordination required for actions regarding sample collection will differ depending on why samples are being taken. To assure that a proper sample is collected, the involved network laboratories should communicate with the group or individuals that are collecting the samples.

4.1.1 It is important that the submitters of samples communicate with the receiving laboratory. Information such as the number of samples, sample collection methods, types of sample matrices, urgency of the sample analysis, desired turn-around-time, suspected agents, any field test results and when and how the sample will arrive at the laboratory should be included when notifying a receiving laboratory of impending sample delivery.

4.1.2 Whether an exercise, surveillance program, or actual event, each Laboratory Network organization, or incident command center should coordinate and communicate with the sample collection entities to ensure that:

Plans and procedures should include the following details, as appropriate:

- procedures for collecting samples
- determination of minimum sample size needed based on activity and resolution required for appropriate response
- consideration of laboratory and/or network sample analysis capacity and throughput (including storage space, processing and data management capability, diagnostic equipment, and surge capacity)
- plan for distribution of surge samples across network
- location for sampling and sample types to be collected
- sample collection equipment to be used
- packaging, shipping and receiving instructions

4.1.3 Communications with the field where samples will be collected should be based on/in accordance with the network's/agency's policies and/or through the lead investigation agency's policies.

4.2 Sample Packaging and Shipment Guidelines

Whether an exercise, surveillance program, or actual event, each Laboratory Network organization, or incident command center, should coordinate and communicate with the sample collection entities to ensure that specific

requirements for proper packaging and shipment are documented and clearly understood; instructions regarding requirements, as appropriate, may include:

4.2.1 Packaging Guidelines

- Identification/designation of appropriate sample containers.
- Labeling and packaging of shipping containers in accordance with network/agency policies and state and federal regulations.
- - Labeling of sample containers with specific receipt storage conditions.
- - Preservation of samples to maintain the physical condition of the samples until a sample is opened for processing or analysis (e.g., package integrity, temperature, chemical preservation).
- - Documentation of all pertinent site information for each sample (e.g., sample location and contact information for person(s) taking the sample).
- - Placement of evidence tampering tape/seals on all sample containers (if applicable)
- - Documentation of chain-of-custody (if applicable)

4.2.2 Shipment Guidelines

- Samples need to be shipped in a timely fashion.
- Verify that authorization appropriate to samples being shipped is in place to receive diagnostic/regulatory samples potentially containing APHIS/CDC select agents.
- When transporting/shipping Infectious Substances, please refer to Appendix C within the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition (http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)
- Samples shipped to a Radiological Laboratory should be properly surveyed and shipped in accordance with relevant Department of Transportation regulations. Before shipment, verify that the receiving laboratory has the appropriate radioactive materials license.
- Verify that the receiving laboratory has the proper CBR facilities and trained staff to receive and analyze hazardous materials.
- Primary and secondary points of contacts should be established between sample teams and the laboratory (Laboratory, Field and Program offices). Clear instructions need to be written to as to whom to contact under normal and emergency circumstances.
- All procedures for sample drop-off need to be established, to include drop-off location, directions to the laboratory, custody transfer and to who results will be communicated.

4.3 Sample Qualification/Acceptance Criteria

4.3.1 All samples will be handled within network capabilities and in accordance with network protocols.

4.3.2 Factors that determine whether/if a laboratory or network can accept a sample include, but are not limited to:

- Laboratory accreditation/approval based on network requirements to perform the requested test (if required)
- Current laboratory capacity, capability (e.g. proper equipment and certified analysts)
- Laboratory's ability to safely handle the samples

4.3.3 If a laboratory cannot accept a sample for any reason, the laboratory must contact the appropriate network coordinators for guidance.

4.4 Sample Inspection/Receipt

4.4.1 Drop-off, Unloading and Custody Control

- Laboratories must assure that personnel are present to receive and properly store or process samples during non-routine hours of operation or as required by the response operation.
- Properly trained and authorized laboratory personnel should perform a receipt screen to verify compliance of the shipment with the Department of Transportation, International Air Transport Association (IATA) and any other federal/state compliant regulations. Shipping requirements should be met prior to accepting the shipment and opening the shipping container, where appropriate.
- Immediately inspect chain-of-custody forms for completeness. The laboratory shall document the acceptance of the samples on the chain-of-custody form and return a copy to the originator if requested. In cases of non-compliance with chain-of-custody forms and documentation procedures, the network contact person responsible for the sample must be contacted immediately for resolution.
- Most sample containers will arrive by other carriers or are hand-delivered. The sample should be accompanied by information to identify its source, sampling procedure used, identification of sampler, and diagrams or other equivalent means to identify the sampling location as necessary.
- If sample containers cannot be inspected immediately, they should be moved to a secure climate controlled location until they can be inspected.

4.4.2 Sample Container Inspection

- After receiving the sample the laboratory shall move it to the proper BSL/or hazard receipt area to open and record, at a minimum, the

following sample receipt information and complete actions, as appropriate:

- Courier name
- Sample receipt date and time
- Sample receipt condition and if containers were sealed
- Assure chain-of-custody is initiated signed and dated (if applicable)
- Temperature of sample (if applicable)
- Take a picture of the sample container (if applicable)
- Assign the unique laboratory identifier for the sample per Network and/or laboratory procedures
- Correlate laboratory sample documentation with sample collection documentation.

4.4.3 Sample Acceptability Inspection

The sample identity, acceptability, and analysis requirements are confirmed by:

- Inspecting the samples to determine that they are appropriately preserved.
- Inspecting the physical condition of the sample to determine if the sample is suitable for the requested analyses.
- Determining the requested analyses and prioritizing the sample.
- Ensuring that requested analyses are consistent with any prior-determined analysis information.
- Ensuring that the laboratory has, or will have, a qualified method.
- Screening in accordance with network protocols, policies and procedures.

4.4.4 Evidentiary Sample Inspection

- Assure that the sample container is correct and that there is an evidentiary seal. Taking a photo of the sample container is highly recommended.
- Follow laboratory protocols for opening the sample container within the appropriate containment area (e.g., appropriate Biosafety Level) and with the appropriate personal protective equipment (safety goggles, gloves, gown, respirator, and any other required protective equipment.
- Taking photos of the sample(s) and appropriately archiving them is highly recommended.
- Forms needed:
    - ICLN Chain of Custody Form or network document that contains the equivalent information

- Form for recording sample information
- Forms for recording appropriate laboratory test information

- Save all shipping documentation

Note: For issues in which samples do not meet the requirements of the sampling plan or the laboratory requirements, the laboratory receiving the sample (e.g., undocumented samples) will follow their internal corrective action policies.

4.4.5 Final Inspection

- Prior to proceeding with sample processing, assure that the record of samples being logged into the laboratory sample management system is complete.
- Verify that all of the sample units have been removed from the containers.

4.5 Sample Processing

Samples should be processed in accordance with laboratory and network protocols and applicable SOPs.

- Sample processing should be in a manner appropriate for the test method that is going to be employed.
- The objective of sample processing is to obtain a homogeneous material for testing that truly represents the sample submitted to the laboratory.
- It is understood that at times samples and test requests will change from the original request; if that happens, there are procedures that should be followed, i.e., bulking/compositing samples, splitting samples:
  - Persons submitting the samples should communicate the changes to the appropriate laboratory and assure that the desired changes are appropriate and within the capability of the laboratory.
  - The persons submitting the sample must follow-up all communications to ensure that all samples are correctly identified and the request change noted.

4.6 Storage

4.6.1 Temporary storage

Perishable sample reserves or retained samples should be stored in an assigned laboratory freezer or refrigerator until the analysis is completed. For samples that require special attention (nuclear samples, select agents, toxin limits, etc.) all federal/state regulations should be followed. Storage

conditions are determined based on the sensitivity of an analyte or microorganism to refrigeration or freezing. Shelf stable products such as dehydrated or canned foods may be stored at room temperature. Product labels shall be maintained with the sample reserve. Samples containing high levels of contaminants should be segregated from those containing much lower levels to prevent sample cross-contamination. If necessary, ensure storage location is secure.

4.6.2 Long-term secure storage

Laboratories should have procedures and equipment in place for proper long-term storage of samples to assure security as well as sample integrity. For samples that require special attention (radiochemical samples, select agents, toxin limits, etc.) all federal/state regulations should be followed. Such procedures should comply with agency and law enforcement requirements as needed. Evidentiary samples held for long term (months or years) should be returned to the sample handling specialist or other designated laboratory personnel for secured storage. Each lab should have designated refrigerators, freezers or secured area for appropriately storing evidentiary or other samples requiring special attention.

4.7 Disposal of Sample Reserves or Retained Samples

4.7.1 Radiologic, Microbiologic and Chemical Reserves

Samples must be disposed of in accordance with all local, state and federal regulations with proper documentation.

4.7.2 Evidentiary samples

Guidance will be sought from law enforcement officials regarding disposition of sample reserves, records, and documentation.