Laboratory Logistics Limiting Issues

Laboratory Logistics Working Group

Integrated Consortium of Laboratory Networks

Executive Summary

Immediately following a chemical, biological, or radiological terrorist attack or a major release of chemical, biological, or radiological agents by other means, the nation's laboratories will be called upon to assist with the assessment of exposure to people, the environment, food, and other matrices. This will require a massive effort on the part of the nation's laboratories, both governmental and commercial, to respond to the anticipated overwhelming sample load while producing high-quality results to support decision making as well as response and recovery activities. The main body of this document lists various aspects of a laboratory's processes that may limit or severely limit a laboratory's transition from routine operations to surge capacity operations in response to an incident of national significance. The aspects of a laboratory's processes covered in the main document are general enough to apply to chemical, biological, and radiological laboratories. Issues specific to chemical, biological, or radiological laboratories are covered in separate appendices to the main body of the document. *The limiting issues and potential solutions that are general enough to be applicable to biological, chemical, and radiological laboratories are not repeated in the appendices in order to minimize redundancy in the document. Therefore, it is critical that readers of the document read the main body as well as the relevant appendices and not view the appendices as stand-alone documents.* In addition to identifying aspects of a laboratory's processes that limit a laboratory's transition from routine operations to surge capacity operations, the main body of the document and the appendices list possible solutions to the limiting issues identified. A basic assumption of this document is that the laboratory is a fully functional chemical, biological, or radiological facility that has everything in place (e.g., quality system, validated methods, trained analysts, data reporting capability, procedures for handling forensic evidence, etc.) for routine work but has not adequately planned for the transition to surge capacity work. This guidance document also identifies areas where stakeholders at the network and at the agency and interagency level may be called upon to play a role in the solution. It should be noted that there has been no attempt to prioritize the laboratory's processes that may limit the transition to surge capacity work. We have noted in the "Potential Solutions" sections of the document the primary organization(s) that the working group considers to be responsible for implementing the "Potential Solutions," e.g., [A] Agency/Interagency, [N] Network, [L] Laboratory, or some combination of these organizations. This document is intended as guidance to laboratories that wish to evaluate the impact of issues that may limit their operations during an emergency, and implement solutions, where feasible, in advance of an incident. The "Potential Solutions" should not be viewed as prescriptive, nor will they necessarily represent the best option for every operation. Instead, each laboratory is encouraged to evaluate and identify specific limiting issues that apply to its operation and to develop solutions that both provide benefit and are within the bounds of resources available to the laboratory. Where possible, participation in desktop through larger-scale exercises may be helpful in fine-tuning and ensuring the measures, as implemented, will provide optimal benefit to the laboratory.

The Integrated Consortium of Laboratory Networks (ICLN) Network Coordinating Group's (NCG) Laboratory Logistics Working Group developed this document. Please send comments to the co-chairs of the workgroup, Robert Jones, CDC, at rljones@cdc.gov, or John Griggs, EPA, at griggs.john@epa.gov.

Pre-Analytical

Limiting Issues	Potential Solutions
Agency and Sample Priority Related Issues	
• Limited supply of qualified (network) laboratories will lead to competing prioritization of analytical efforts among agencies. • Regulatory responsibilities vary with each agency (whether dealing with clinical, environmental, food, animal, or plant samples). • No overarching plan currently exists to coordinate and communicate the priorities for each of the responsible federal agencies.	• For most incidents, attempt to define, in advance of the incident, which samples have priority (e.g., clinical, environmental, food). [A,N,L] • Contact responsible agency for guidance on scientific and policy issues. [A,N]
Sample Collection and Field Related Issues	
• Lack of full evaluation of laboratory capacity and capability.	• Conduct capacity exercise to determine a realistic estimate of the laboratory's capacity. [N,L] • Match analytical needs with laboratory capabilities. [A,N,L] • Consider shipment of samples to alternate, qualified laboratories. [N,L] • Communicate priorities to the lab (from the field, lab, internal agency, or network). [A,N,L] • Composite or pool samples in field. [N,L]
• Number of samples exceeds single laboratory's capabilities or capacity.	• Establish contacts and procedures for coordinating capabilities and capacities with other network surge laboratories. [N,L] • Shut down part of the laboratory and shift equipment and cross-trained personnel to support incident critical plans and operations. [N,L]
• Improper containers or sample packaging. • Inadequate sample size. • Inadequate sample preservation. • Improperly collected samples. • Contamination of sample containers in field. • Improper analytical method selection by field project personnel.	• Identify lab and field personnel as points of contact. [N,L] • Field personnel contact lab for guidance. [A,N] • Prepare information for field personnel prior to incident, addressing requirements/protocols for sample and shipping containers, sample size and preservation, and screening. [N,L]

Pre-Analytical (cont.)	Limiting Issues	Potential Solutions
	• Insufficient infrastructure and protocols for shipping samples from the field collection sites to network laboratories.	• Establish procedures and contracts with overnight carriers in advance. [N,L] • Establish a process for providing field operations with just-in-time supplies (e.g., sample kits and shipping containers). [L] • Train field personnel in Department of Transportation (DOT), International Air Transport Association (IATA), Domestic Mail Manual (DMM), and other applicable shipping regulations. [A,N]
	• Field screening results not provided to the lab. • Inadequate documentation provided to the laboratory about sample collection (e.g., sample preservation, sample location, sample type, etc.).	• Notify field personnel to provide missing documentation. [L] • Develop/promote guidance to field personnel about needed documentation. [N,L]
	• Chain of Custody (COC) absent or incomplete.	• Notify field personnel that a properly completed COC must be included for all samples submitted to the laboratory. [L]
	• Inadequate procedure for maintaining COC in the laboratory.	• Develop procedure for maintaining COC in the laboratory. [L] • Develop laboratory guidance for maintaining COC in the laboratory. [A,N]
	• Lack of adequate documentation, e.g., credible threat assessment performed by law agencies.	• Seek clarification from the responsible agency, when necessary. [N,L]
	• Short analyte lifetime (holding time) may compromise the integrity of samples.	• Field personnel contact lab for guidance on sample collection, preservation, and shipping. [N] • Field personnel pre-notify laboratory of incoming samples. [N] • Provide login information prior to receipt. [N] • Put in place an alternative plan for analysis of samples. [L]
	Absence of Analytical Requirements	
	• Absence of laboratory analytical requirements and associated action levels for sample measurements for each phase of the response *(monitoring / surveillance, incident response [early and intermediate], and remediation / restoration)* results in a lack of appropriate data to support decisionmaking.	• Define analytical action levels before an incident. [A,N] • Estimate appropriate analytical requirements before an incident. [A,N] • Develop and validate analytical methods for priority threat agents that are capable of achieving estimated analytical requirements and action levels. [N,L]

Pre-Analytical (cont.)	Limiting Issues	Potential Solutions
	Continuity of Operations (COOP) Related Issues	
	• Laboratory shut down and inoperable prior to an incident. • Inability of suppliers/vendors to provide critical supplies, calibrators, quality control materials, reagents, etc., to accommodate surge capacity testing requirements.	• Develop, share, and implement an alternative plan (e.g., COOP) for analysis of samples to ensure that alternate laboratories are available. [N,L] • Develop a list of alternate vendors for critical items. Validations required to qualify the specialized reagents, short and long lead time reference standards, supplies, and other items that may be obtained from an alternate source of supply should be accomplished in conjunction with qualifying the alternate vendor as an acceptable source of supply in accordance with the laboratory's quality system. [N,L]

Sample Receiving and Screening	Limiting Issues	Potential Solutions
	Sample Acceptance and Screening Related Issues	
	• Lack of notification of incoming samples.	• Ensure that sample collection documentation provided to first responders specifies that the lab is to be notified prior to shipping samples to the lab. [N,L] • Begin sample receipt/screening if documentation required for receipt is included with samples; contact field personnel regarding the lack of notification. [L] • Safely store samples and contact field personnel. [L]
	• Inadequate sample documentation (e.g., COC, field screening, guidance on prioritization).	• Contact field personnel to obtain missing documentation. [L] • Develop sample acceptance policy/protocols. [N,L]
	• Inadequate and/or inconsistent sample screening at the laboratory's sample receipt area(s).	• Develop a more robust sample screening protocol. [N,L] • Train lab personnel receiving samples on appropriate screening of unknown samples. [N,L] • Ensure that sample screening is consistent with laboratory's equipment and training. [L] • Ensure an adequate supply of personal protective equipment (PPE) is available for sample screening. [L]

Sample Receiving and Screening (cont.)

Limiting Issues	Potential Solutions
• Lack of a process for accepting or rejecting samples.	• Develop sample acceptance and rejection policy/protocols. [N,L] • Establish criteria for minimum screening needed to safely handle samples. [L] • Establish procedures to evaluate the adequacy of field screening results. [L]
Space, Equipment, and Personnel Related Issues	
• Insufficient space to receive, screen, process, label, package, and store samples. • Insufficient infrastructure for decontamination, removal, storage, and/or disposal of used packing and shipping materials.	• Create remote, auxiliary, or satellite locations to process receipt of samples. [L] • Have a plan to reprogram existing space and personnel to meet the surge. [L] • Develop infrastructure for decontamination, removing, storing, and/or disposing of used packing and shipping materials. [L]
Other Issues	
• Insufficient equipment (e.g., computers, bar-code scanners, photocopiers, printers, document scanners, bar-code label stock, refrigerators, and freezers).	• Ensure that there are sufficient computers, bar-code scanners and label stock, printers, refrigerators, freezers, and photocopiers to cope with influx of samples. [L] • Secure emergency purchase, leasing, or loan of additional equipment. [N,L]
• Inadequate number of personnel trained to manage sample receipt and login during an emergency response and insufficient personnel to staff all shifts 24/7 for several weeks.	• Cross-train personnel. [L] • Use modular procedures and training. [L] • Plan in advance for multiple shifts to cover 24/7 for weeks. [L] • Cross-train personnel for use of screening instruments, procedures, and the proper use of PPE. [L] • Shut down another part of the laboratory and shift equipment and cross-trained personnel to support incident critical operations. [L] • Make arrangements to ship samples to another laboratory. [L]
• Limits on laboratory's ability to handle and test regulated materials (e.g., select agents, radioactive material).	• Identify regulating authorities and ensure that permits and licenses are in place, or can be rapidly put into place. [N,L] • Maintain relevant current phone numbers and contact information. [N,L]

Sample Receiving and Screening (cont.)	Limiting Issues	Potential Solutions
	• Insufficient infrastructure and protocols for shipping samples among network laboratories.	• Establish procedures and contracts with overnight carriers in advance. [N,L] • Establish a process for obtaining just-in-time supplies (e.g., sample kits and shipping containers). [N,L] • Train laboratory personnel in Department of Transportation (DOT), International Air Transport Association (IATA), Domestic Mail Manual (DMM), and other applicable shipping regulations. [N,L]
	• Lack of provision for the physical security of samples.	• Provide for a secure location for several to many forensic samples. [L] • Make provisions for rapid transfer of samples to law enforcement. [N,L]
	• Inadequate procedure for maintaining COC (including forensic COC, where applicable).	• Put in place procedures for maintaining COC in the laboratory. [L]
	• Inadequate sample accession, ID (bar-code labeling), and tracking-retrieval processes (e.g., local, agency, lab). • Lack of a plan to address changing analytical requirements and action levels with changing phases of the incident (ongoing issue).	• Use remote electronic sample accession and data transmission to the laboratory. [N] • Use minimum bar-code standards (e.g., Code 128 at 3 mil) for readers and printers. [N,L] • Integrate field and sample collection data with laboratory information management system (LIMS). [N,L] • Predefine data fields for network specific sample collection, receipt, and test orders. [N] • Develop flexible procedures before an incident that will allow laboratories to accommodate changing analytical requirements and action levels. [N,L]

Analytical Processing	Limiting Issues	Potential Solutions
	• Lack of an analytical method for a specific analyte/matrix combination.	• Develop, validate, document, seek appropriate approvals, and adopt rapid methods for use prior to or during an emergency response. [N,L] • Harmonize the instrumental portion of analytical methods to facilitate cross-network surge. [A,N] • Establish pre-approved procedures for analytical method modification that comply with regulatory or compliance obligations (or requirements) for screening, quantification, and confirmatory analyses. [A,N,L] • Available methods should be validated in multiple matrix types (clinical, water, food, environmental, etc.), as appropriate. [N,L] • If methods must be validated during an emergency incident, the laboratory should consider the possibility of utilizing method development expertise from other laboratory sites to reduce impact on its facility's surge response. [L]
	• An unsuitable length of time for pre-analytical sample preparation and processing.	• Coordinate sample receipt with inbound shipments to minimize sample "dead time." Automation and cross-training of personnel may prove useful. [L] • Pre-triage/internally prioritize samples at the laboratory. [N,L] • Laboratories should develop a plan and exercise for long-term surge operations, including pre-analytical processes. [L] • Rapid methods should have shorter and more efficient sample preparation and processing. [N,L]
	• An unsatisfactory length of time to produce the first analytical results due to normal workweek limitations (including all QC reviews and organizational sign-offs).	• Laboratories should have a staffing plan to address 24/7 analytical processing. [L]
	• An unacceptably low daily throughput in number of analytes per analysis per matrix per day. Multiple matrices may limit pre-analytical throughput.	• Monitor capacity of laboratory throughput daily to ensure optimum use of available resources. Total throughput depends on the matrix, analytical method, instrumentation, and available staffing. [L] • Identify rate-limiting steps and develop mitigation strategies. [N,L]

Analytical Processing (cont.)	Limiting Issues	Potential Solutions
	• An undesirable complexity and duration of the process used to purify or isolate analytes.	• Minimize method complexity when possible. [N,L]
	• Inadequate number of instruments.	• Increase capacity through expanded or cross-use of capable instrumentation from other areas of the laboratory. [N,L] • Secure emergency purchase, leasing, or loan of additional instruments. [N,L]
	• Inadequate level of automation.	• Increase automation of analytical methods. [N,L]
	• An unacceptable possibility of cross-contamination of samples and instruments from mixture of high- and low-level samples.	• Define and develop procedures and processes to minimize cross-contamination (laboratory and instrumentation). [N,L] • Develop procedure for pre-screening and segregating samples prior to analysis. [N,L]
	• Insufficient number of available and trained personnel to perform the pre-analytical and analytical processes, as well as insufficient number of expert instrument operators available to run the more complex analytical instruments.	• Use modular pre-analytical and analytical processes to reduce individual training needs. [L] • Cross-train personnel to improve flexibility and coverage. [L] • Use of refresher training and exercises to keep training current. [L]

Data Processing and Reporting	Limiting Issues	Potential Solutions
	• Lack of planning for additional shifts.	• Laboratories should have a staffing plan to address 24/7 operations for a sustained period of time. [L]
	• An unacceptably slow or labor intensive conversion of raw test results to appropriate reportable results.	• Automate data processing and reporting steps as much as possible. [N,L]
	• An unacceptably slow QC and data review and approval.	• Automate the QC and data review process as much as possible using a Laboratory Information Management System (LIMS) or another type of information system. [L]

Data Processing and Reporting (cont.)	Limiting Issues	Potential Solutions
	• Insufficient number of approved, trained, and qualified personnel available to review and approve analytical results based on the specific laboratory's requirements.	• Conduct cross-training and exercising of personnel process used for review and approval of analytical results. [L] • Arrange for emergency loan of technicians and analysts from other labs. [N,L]
	• Inadequate pre-defined data reporting formats, including Electronic Data Deliverable (EDD) formats specifications.	• Standardize and communicate requirements within the laboratory community. [A,N] • Establish who will receive analytical results from your lab. [A,N,L] • Establish how data will be transferred to your customer, submitting entity or requesting agency. [N,L] • Install and test infrastructure (e.g., databases, EDD input and export routines) in advance that will be used to receive and export EDD messages during an incident. [N,L]

Sample Storage and Waste Disposition	Limiting Issues	Potential Solutions
	• Insufficient sample storage facilities (e.g., security of samples, storage temperature, short- and long-term storage).	• Arrange for acquisition of temporary storage space in advance (e.g., lockable tractor trailers with appropriate security, and temporary secure outdoor refrigerators, freezers, or storage sheds). [L]
	• Excessive waste generation and inadequate removal.	• Combine waste into larger containers. [L] • Determine and document the entity or group in charge of sample waste at any given time and determine who will manage the sample waste during and after the analytical process. [L] • Increase frequency of pickups and/or increase holding space. [L]
	• Lack of a procedure or protocol that defines when a sample may be disposed.	• Clearly define when a sample may be disposed. [A,N]
	• Lack of knowledge of requirements and procedures for storing samples (preservation, compatibility, etc.).	• Develop procedures for appropriate storage of all types of samples that could be received. [L]
	• Lack of awareness of regulatory requirements for possessing, handling, transporting, or disposing of sample residuals and waste.	• Identify applicable requirements, develop and implement procedures to ensure compliance with requirements. [N,L]

Sustaining Operations

Limiting Issues	Potential Solutions
Vendor Related Issues	
• Unavailability of vendor technicians to repair equipment/instrument in the event of failure.	• Establish formal or informal agreements with the equipment and instrument vendors. [L]
• Inability of instrument or equipment vendors to respond 24/7.	• Pre-train/badge vendor technicians for rapid access to facility. [L] • Train in-house personnel on select repairs of critical equipment. [L]
Instruments or Equipment Related Issues	
• Inability to rapidly obtain replacements for select instrument parts.	• Identify and maintain a reserve of select instrument parts. [N,L] • Identify other laboratories that use similar equipment and determine replacement parts stored at their location. Establish an agreement(s) with laboratories willing to participate in parts sharing during a surge incident. [N,L]
Standards, Reagents, and Supplies Related Issues	
• Unavailability of reference standards for calibration and quality control.	• In advance, determine the laboratory's capacity and capability based on in-house inventory of reference standards. [L] • Project need for reference standards for a predetermined period. [N,L] • Evaluate whether existing inventory will meet organizational or network requirements. [N,L] • Where possible, develop protocols for manufacturing quality control and/or calibration materials in the laboratory. [N,L] • Consider establishing laboratory and/or network contracts with suppliers for the provision of required reference standards and QC materials where the vendor stores/maintains additional inventory that is guaranteed to be available on request. [N,L] • Maintain 24/7 contact information for all suppliers. [N,L]

Sustaining Operations (cont.)	Limiting Issues	Potential Solutions
	• Unavailability of specialized reagents.	• In advance, determine the laboratory's total capabilities and capacity based on an inventory of specialized reagents. [N,L] • Project need for additional specialized reagents for a predetermined period. [N,L] • Evaluate whether existing inventory will meet organizational or network requirements. [N,L] • Consider establishing laboratory and/or network contracts with suppliers for the provision of required specialized reagents where the vendor stores/maintains additional inventory that is guaranteed to be available on request. [N,L] • Maintain 24/7 contact information for all suppliers. [N,L]
	• Unavailability of long-lead-time specific reference standards and QC materials for method validation and quality control.	• In advance, determine matrices, analytes, and concentrations for reference materials needed for validation and QC of methods. [N,L] • Estimate total interagency supply needed for one to four years of operation. [N,L] • Establish arrangements or put contracts in place with standards and QC materials providers to ensure that sufficient stocks will remain available over time. [N,L] • Consider establishing laboratory and/or network contracts with suppliers for the provision of required reference standards and QC materials needed for validation and QC of methods where the vendor stores/maintains inventory for immediate and sustained use. [N,L] • Consider working with suppliers to develop shelf life extension programs for required reference standards and QC materials needed for QC of methods. [N,L] • Maintain 24/7 contact information for all suppliers. [N,L]

Sustaining Operations (cont.)	Limiting Issues	Potential Solutions
	• Unavailability of supplies such as vials, bottles, sample containers, hot plates, PPE, gases, waste containers, and other items.	• In advance, determine the laboratory's total capabilities and capacity based on an inventory of supplies and the need to obtain additional specialized reagents for a predetermined period. [L] • Determine whether inventory will meet organizational or agency requirements. [N,L] • Develop either a plan to inventory essential analytical supplies or a just-in-time inventory system. [N,L] • Develop a list of alternate vendors. [N,L] • Consider establishing laboratory and/or network contracts with suppliers for the provision of required supplies where the vendor stores/maintains additional inventory that is guaranteed to be available on request. [N,L] • Maintain 24/7 contact information for all suppliers. [N,L]
	Infrastructure Related Issues	
	• Insufficient continuity of infrastructure (power, water, phone, Internet).	• Work with the organization's facilities management and information technology personnel to ensure the continuity of services. [L] • Establish redundant back-up for power and communication systems. [L]
	• Insufficient number of available hoods or biological safety cabinets (BSC) for sample processing/preparation for routine samples.	• Develop sufficient laboratory engineering controls. [L] • Move or expand operations to other parts of the facility that provide additional infrastructure. [L]

Sustaining Operations (cont.)	Limiting Issues	Potential Solutions
	Personnel Related Issues	
	• Inadequate staff available to support required operations. • Inflexibility in work hours or contractual limitations.	• Cross-train staff from other parts of facility and from other facilities. [N,L] • Need to address human resources, unions, overtime, salaries. [L] • Review existing health and safety plans to ensure adequacy for surge operations. [L] • Review security issues and establish protocols to allow for cross-training and access for all needed personnel during an incident. [N,L] • Consider developing a corps of trained and qualified volunteers. [N,L] • Develop 24/7 work schedule/personnel matrix to support all required laboratory surge operations. [L]
	Contamination Control Related Issues	
	• Costs and time lost related to contamination of a laboratory.	• Establish procedures to minimize the likelihood or risk of contamination. [L] • Establish protocols for decontamination of laboratory and equipment. [L] • Ensure protocols that clearly define responsibilities in case of a contamination incident. [L] • Identify and establish agreements with cleanup or decontamination contractors. [L]

Biological Appendix

	Limiting Issues	Potential Solutions
Pre-Analytical	**Sample Collection and Field Related Issues**	
	• Inadequate sample preservation.	• Field personnel must contact laboratory prior to sample collection and shipment to discuss any specialized collection procedures or sample treatment (e.g., dilution) and/or packaging requirements (e.g., temperature control) prior to transport to the laboratory. [A,N]
	• Insufficient infrastructure and protocols for shipping samples to network laboratories.	• Laboratory should establish procedures and arrangements for non-contract carriers (e.g., Highway Patrol, National Guard, Civil Support Teams, local law enforcement and emergency response personnel). [L]
	• Insufficient sample collection kits or materials available (i.e., swabs, media, etc., in a clinical setting).	• Laboratory should establish points-of-contact within the Logistics/Supply Department/Section of the medical treatment facility (e.g., hospital, clinic, physician office) to encourage them to maintain adequate supplies of sample collection kits/materials to accommodate potential surge requirements. If manufactured by lab (e.g., viral media or micro media), ensure plans exist to expand production capacity. [L]
	Standards, Reagents and Supplies Related Issues	
	• Limited availability of select agent reference cultures and/or specialized analytical reagents/supplies, or negative matrix controls (animal tissue, food types, etc.).	• Identify sources of select agent cultures, specialized reagents/supplies, or negative matrix controls (may have to identify international sources). [N,L]
	Continuity of Operations (COOP) Related Issues	
	• Laboratory shut down and inoperable prior to incident.	• Put in place an alternative plan for analysis of samples. Alternative laboratory sites must have acceptable facilities, space, and analytical capabilities (BSL-3 laboratory space, select agent approvals, equipment, etc.). [N,L]

	Limiting Issues	Potential Solutions
Sample Receiving and Screening	**Sample Acceptance and Screening Related Issues**	
	• Lack of a process for accepting or rejecting samples based on screening results. • Lack of a process for accepting or rejecting samples based on sample condition upon receipt.	• Develop sample acceptance and rejection policy/protocols. [N,L] • Establish criteria for minimum screening needed to safely handle samples. Samples submitted for biological testing would potentially be screened for gross radiological contamination and/or explosives and/or volatile chemical contaminants before being analyzed in the laboratory. Reference for APHL All Hazards Screening Protocol: http://www.aphl.org/aphlprograms/phpr/ahr/Documents/AHRF_Screening_Protocol.pdf.[L] • Laboratories should have procedures developed to accept or reject samples based on sample condition. Laboratories should also have procedures developed to address destruction/disposal of compromised (damaged/leaking) select agent samples. [L]
	Other Issues	
	• Limits on laboratory's ability to handle and test regulated materials (e.g., select agents, radioactive material).	• Laboratories that will be confirming toxins or organisms that are identified as select agents in the current regulations (**7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73**) must be registered to possess, use, or transfer these agents and must adhere to all regulatory requirements. [N,L] • Laboratories should ensure that adequate numbers of select agent approved individuals are available to assist with receipt of confirmed select agent samples. [L] • Laboratories should ensure that any additional local or Federal permits required for receipt of pathogenic organisms or toxins are in place (APHIS, etc.). [N,L] • Clinical or diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin, or an overlap select agent or toxin, that is contained in a specimen presented for diagnosis or verification, are exempt from Select Agent Regulations as long as the agent/toxin is transferred or destroyed within seven days of identification, the agent/toxin is secured against theft or loss while maintained, and the agent/toxin identification is reported to CDC or APHIS as outlined in the regulation (**42 CFR 73.5 and 73.6**). [L]

	Limiting Issues	Potential Solutions
Analytical Processing	• Possibility of analytical issues because sample matrix needs to be diluted or concentrated before analysis.	• Develop procedures for sample dilution or concentration for matrices that may require it (i.e., water, etc.). [N,L]

	Limiting Issues	Potential Solutions
Data Processing and Reporting	• Inadequate IT support for troubleshooting data reporting issues.	• Laboratory should identify IT point of contacts that will be available to assist with data reporting, or LIMS issues/troubleshooting. IT personnel are usually not part of the laboratory personnel structure and laboratories may need to identify staff from other operating divisions to assist during an incident. [L]
	• Additional regulatory reporting requirements may be applicable and must be fulfilled.	• Laboratories that have confirmed the presence of a select agent or toxin contained in a sample are required by regulation (**7 CFR 331, 9 CFR 121, and 42 CFR 73**) to report their findings to APHIS or CDC. [L]

Sample Storage and Waste Disposition	Limiting Issues	Potential Solutions
	• Insufficient sample storage facilities (e.g., security of samples, storage temperature, short- and long-term storage).	• Arrange for acquisition of temporary storage space (e.g., lockable tractor trailers with appropriate security) in advance. Other space may include temporary secure outdoor refrigerators, freezers, or storage sheds. [L] • Samples containing select agents must be maintained and stored as outlined in current select agent regulations. Temporary outdoor storage would not be appropriate for select agent samples. [L]
	• Lack of awareness of regulatory requirements for possessing, handling, transporting, or disposing of sample residuals and waste.	• Identify applicable requirements (select agent, etc.), develop and implement procedures to ensure compliance with requirements. [N,L]
	• Tracking and storage of samples that are sub-sampled/split within the laboratory.	• Ensure that the storage location of all sample portions that are split within the laboratory (i.e., cow necropsy-tissue sub-samples) is documented and tracked to ensure sample is disposed of correctly (especially if the sample contains a select agent). [L]

Sustaining Operations	Limiting Issues	Potential Solutions
	• Inability or unwillingness of maintenance staff to service or repair equipment in the BSL-3 laboratory.	• Ensure maintenance contracts include provision for servicing equipment within the BSL-3 laboratory. [L]

Chemical Appendix

Pre-Analytical	Limiting Issues	Potential Solutions
	Sample Collection and Field Related Issues	
	• Insufficient infrastructure and protocols for shipping samples to network laboratories.	• Contingencies need to be developed for specialized shipping of hazardous or large volumes of samples (acids, gases, volatile liquids, flammable or explosive materials, etc.). [N,L]
	• Field screening results not provided to the lab. • Inadequate documentation provided to the laboratory about sample collection, including COC.	• Coordinate with field teams to ensure documentation and clear understanding of field screening techniques used. [L] • Coordinate with field teams to ensure detailed sampling information is supplied on COC or sample tracking forms in order to monitor sample holding times, e.g., date, time, and manner of sample collection, preservation, etc. [L]
	• Short analyte lifetime (holding time) may compromise the integrity of samples.	• Develop guidance on holding times and preservation methods for non-traditional chemical threat agents and degradation products. [N]
	Absence of Analytical Requirements	
	• Absence of laboratory analytical requirements and associated action levels for sample measurements for each phase of the response *(monitoring / surveillance, incident response [early and intermediate] and remediation / restoration)* results in a lack of appropriate data to support decisionmaking.	• Use of data will dictate action levels. Action levels will be needed in order to select appropriate analytical methods during various phases of a response. [A,N]

Sample Receiving and Screening

Limiting Issues	Potential Solutions
Space, Equipment, and Personnel Related Issues	
• Insufficient space to receive, screen, process, label, and package samples.	• Develop options for receiving, screening, processing, labeling, and packaging chemical samples that may require special consideration depending on the nature of the chemical hazard involved, e.g., flammability, corrosivity, volatility. [L]
• Insufficient infrastructure for decontamination or proper disposition of flammable or corrosive waste materials.	• Develop options to dispose of flammable or corrosive waste materials. [L]
Other Issues	
• Limits on laboratory's ability to handle and test regulated materials.	• Develop options for meeting regulatory/safety requirements, such as the limits on the amount of flammable material in a laboratory or the storage of regulated chemicals, etc. [L]
• Insufficient infrastructure and protocols for shipping samples among network laboratories.	• Cross-train staff and stock shipping material to ship samples for chemical analysis that will require special containers, packaging, and labeling in order to comply with air and ground transport regulations by common carriers. [N,L] • Plan for efficient transport of chemical samples that cannot be shipped by air. [N,L]

Analytical Processing

Limiting Issues	Potential Solutions
• An unsatisfactory length of time to produce the first analytical results.	• Develop and validate high-throughput or rapid chemical methods. [N,L]
• An unacceptably low daily throughput in number of analytes per analysis per matrix per day. Multiple matrices may limit pre-analytical throughput.	• Develop and validate high-throughput or rapid chemical methods. [L] • Screening methods need to be developed to address high-throughput needs for major incident response. [N,L]
• An unsuitable length of time for pre-analytical sample preparation and processing for chemical methods.	• Plan for cross-laboratory use of aliquoting and sample cleanup equipment to speed sample throughput. [L]

Analytical Processing (cont.)	Limiting Issues	Potential Solutions
	• An unacceptable possibility of cross-contamination of samples and instruments from mixture of high- and low-level samples.	• Develop sample screening procedures using high through-put semi-quantitative analytical methods to avoid introduction of "hot" samples into more sensitive equipment designed for low-level quantification. [N,L]
	• Insufficient number of available and trained personnel to perform the pre-analytical and analytical processes as well as insufficient number of expert instrument operators available to run the more complex analytical instruments for chemical analysis.	• Cross-training both within and between laboratories will aid surge capacity. [N,L]

Data Processing and Reporting	Limiting Issues	Potential Solutions
	• An unacceptably slow QC data review and approval process. This includes determining acceptable parameter performance and Laboratory Control Sample, blank, matrix spike, and duplicate acceptance criteria.	• Chemical QC requirements require substantial review and interpretation. This places an extra burden on chemical labs to develop surge strategies that include identifying and training supplemental staff, and using automated data review. [N,L]
	• Inadequate pre-defined data-reporting formats, including EDD formats specifications.	• Laboratories participating across networks need cross-training on each specific EDD format. [N,L]

Sample Storage and Waste Processing	Limiting Issues	Potential Solutions
	• Insufficient and/or inadequate storage facilities (e.g., security of samples, storage temperature, short- and long-term storage.	• Evaluate needs for explosion-proof refrigeration necessary for some chemical sample types. [N,L] • Evaluate needs for ultra-low temperature freezers that may be required to ensure sample integrity for some sample matrices. [L]
	• Excessive waste generation and inadequate removal.	• Chemical labs will need to make sure they have considered waste disposal issues associated with a high volume incident, and the Resource Recovery and Conservation Act (RCRA) impacts. [L]

Sustaining Operations	Limiting Issues	Potential Solutions
	Instruments or Equipment Related Issues	
	• Inability to rapidly obtain replacements for select instrument parts that are subject to corrosive or damaging chemicals.	• The laboratory should maintain an adequate supply of instrument parts that are subject to corrosive or damaging chemicals. [N,L]
	Standards, Reagents, and Supplies Related Issues	
	• Unavailability of unique chemical reagents and reference standards for calibration and quality control.	• Laboratories may want to consider special arrangements with commercial suppliers and alternative sources of unique chemical reagents, reference standards, and other materials. [N,L]
	• Unavailability of an adequate supply of appropriate chemical PPE.	• Develop a plan for obtaining adequate chemical PPE for surge personnel. [L]

Sustaining Operations (cont.)	Limiting Issues	Potential Solutions
	Infrastructure Related Issues	
	• Insufficient continuity of specialized infrastructure.	• The laboratory should plan for surge needs for special chemical infrastructure such as high air turnover rates for volatile materials, anticorrosion work surfaces, explosion-proof work areas, etc. [L]
	Safety and Contamination Control Related Issues	
	• Costs and time lost related to contamination of a laboratory.	• The laboratory should have a plan for minimizing loss of capacity due to chemical spills or contamination. [L] • The laboratory should plan for spill control/cleanup and decontamination capacity to handle expected sample volume. [L] • Plan for segregation of analysis space, low-level and high-level samples to prevent cross-contamination. [L]

Radiochemical Appendix

Pre-Analytical	Limiting Issues	Potential Solutions
	Sample Collection and Field Related Issues	
	• Lack of consideration of lab capacity and capability.	• Make arrangements to divert samples to other qualified laboratories prepared to accept, handle, and analyze elevated (high-level) activity or low-level activity samples for the radionuclides and analytes of interest. [A,N,L]
	• Number of samples exceeds laboratory's capacity.	• Develop a graded approach for prioritizing incoming laboratory samples based on screening measurements performed in the field or type of sample (e.g., clinical, environmental, food) to allow the laboratory to focus limited resources on the most important samples. [L]
	• Common carriers or courier services will not accept all shipments of radioactive materials. • US Postal Service limits the shipment of materials as defined as radioactive under **49 CFR 173.**	• Ensure that procedures and personnel training are current in shipping and receiving radioactive samples. [N,L] • Department of Transportation (DOT) regulations (e.g., **49 CFR Parts 172, 173 and 71**;) or • International Air Transport Association (IATA) regulations for air shipments of radioactive materials (e.g., **IATA 10.3-10.10)**. • US Postal Service shipment of radioactive materials (e.g., **49 CFR 173)**. • Other state, local, or facility requirements.
	• Field screening results for radionuclides or radioactive level not provided to the lab.	• Notify field personnel regarding documentation required on current or future shipments. [L]
	• Field personnel do not have laboratory's radioactive materials license and cannot ship radioactive samples to the laboratory.	• Ensure that field personnel are proactively provided with a copy of the laboratory's radioactive materials license so that they can verify that the laboratory may receive radioactive materials shipments with known levels of radioactivity. [N,L] • Train field personnel to understand the difference between transferring radioactive material and shipping laboratory samples for analysis.[A,N]

Pre-Analytical (cont.)	Limiting Issues	Potential Solutions
	• Insufficient infrastructure and protocols in place for shipping samples from field collection sites and for receiving samples at network laboratories.	• Contact common carriers or courier services in advance to verify that they accept radioactive materials shipments and to identify any applicable requirements or protocols that must be put in place. [N,L] • Identify and secure compliant containers, shipping supplies, labels, and screening equipment for shipping radioactive samples. [N,L] • Encourage the training of field collection personnel on shipping regulations related to radiological materials and laboratory samples for analysis pre-incident, including the difference between radiological materials and laboratory samples. Include training concerning the limitations of US Postal Service and other common carriers regarding shipments with radioactive materials and what constitutes a radioactive package. [A,N]
	• Short radionuclide half-lives compromise the integrity of samples that cannot be analyzed promptly.	• Develop protocols to facilitate rapid analysis of samples that contain short-lived radionuclides. [N,L] • Evaluate the laboratory's capacity for performing different analyses. [N,L] • Make arrangements to divert samples to other labs in cases where the laboratory's capacity has been exceeded. [N,L] • Consider developing the capability to analyze in the field and/or in a mobile laboratory. [A,N]
	Absence of Analytical Requirements	
	• Absence of laboratory analytical requirements and associated action levels for sample measurements for each phase of the response (monitoring / surveillance, incident response [early and intermediate] and remediation / restoration) results in a lack of appropriate data to support decisionmaking.	• Provide labs with default analytical requirements and action levels before an incident. [A,N] • Develop default analytical parameters and validate analytical methods for priority radiological threat agents that are capable of achieving estimated analytical requirements and action levels. [N,L]

Sample Receiving and Screening	Limiting Issues	Potential Solutions
	Sample Acceptance and Screening Related Issues	
	• Inco • nsistent or inadequate sample screening at the laboratory's sample receipt area(s).	• Ensure that sample screening is consistent with laboratory training level and the lab's radioactive material license. [L] • Develop, validate, and implement effective sample screening protocols , including: • Techniques for rapid non-destructive identification of gamma-emitters. [N,L] • Techniques for rapid screening for gross alpha and beta activity in samples, including liquid scintillation techniques. [N,L] • Increase screening capacity by making arrangements with field personnel to deliver samples in containers for which the laboratory maintains calibrated gamma geometries. [N,L] • Maintain a stock of containers that correspond to calibrated gamma geometries that can be rapidly shipped to the field. [N,L]
	• Lack of a process for rapidly accepting or rejecting samples based on radiation levels and lab-specific limits.	• Develop sample acceptance and rejection policy/protocols for radioactive levels allowed by the lab and communicate these policy/protocols to the field personnel and agency. [L] • Establish criteria for minimum rapid screening needed to safely handle radioactive samples. [L]
	Space, Equipment, and Personnel Related Issues	
	• Inadequate gamma and alpha/beta screening equipment for sample receipt and login during an emergency response.	• Identify cost-effective solutions for screening samples (e.g., NaI(Tl) gamma counters, portable liquid scintillation counters (LSC)). [L] • Obtain sufficient gamma and alpha/beta counters to support projected screening needs. [L] • Develop and validate measurement protocols and procedures to ensure that screening equipment will perform as expected and ensure that is it held ready for immediate use. [N,L]

Sample Receiving and Screening (cont.)	Limiting Issues	Potential Solutions
	Other Issues	
	• Limits on laboratory's radioactive material license from the Nuclear Regulatory Commission (NRC), state regulatory agency, or both (regulatory agency required to modify the laboratory's license on short notice).	• Identify licensing authorities and ensure that they can rapidly modify licenses. [L] • Maintain current phone numbers and contact information for the NRC or state regulatory agencies. [L]
	• Insufficient space to receive, screen, process, label, package, and store radioactive samples (especially high-level radioactive samples). • Insufficient infrastructure for removing, storing, or disposing of used packing and shipping materials with radioactive contamination.	• Create remote, auxiliary, or satellite locations to process receipt of radioactive samples. [L] • Have a plan to reprogram existing space and personnel to meet the surge in high-activity samples. [L] • Develop infrastructure for removing, storing, and disposing of used packing and shipping materials with radioactive contamination. [L]

Analytical Processing	Limiting Issues	Potential Solutions
	• An unsuitable length of time for pre-analytical sample preparation and processing. • An unacceptably low daily throughput in number of results per analysis per matrix per day. Multiple matrices may limit analytical throughput. • An undesirable complexity and duration of the process used to purify or isolate analytes.	• Identify simpler, more productive rapid analytical methods. [N,L] • Develop simpler, more productive rapid radioanalytical methods. [N,L] • Validate and implement rapid radioanalytical methods and maintain them ready for use. [L]
	• An unacceptable possibility of cross-contamination of samples and instruments from mixture of high- and low-level samples.	• Screen all gamma-emitting samples using gamma counting and all pure alpha- or beta-emitting samples using gross alpha and beta counting. [L] • Decrease sample quantity and segregate samples of incompatible activity to minimize risk of cross-contamination of samples or contamination of the laboratory. [L]

Sample Storage and Waste Disposition

Limiting Issues	Potential Solutions
Sample Acceptance and Screening Related Issues	
• Accumulation of high-activity samples and sample residuals leads to unacceptable exposure to radioactivity for workers or the lab environment.	• Arrange for acquisition of remote storage space (e.g., lockable containers, tractor trailers with appropriate security) in advance. [L] • Ensure that the facility definition in the radioactive materials license and radiation protection plan measures addresses the remote facility. [L]
• Excessive waste generation and inadequate removal of waste leads to unacceptable exposure to radioactivity for workers.	• Increase frequency of removal of radioactive-containing waste from work areas. [L] • Establish holding areas for radioactive-containing waste that are remote from occupied areas in the facility. [L] • Make arrangements with waste disposal contractors for increased frequency of pickups of radioactive-containing waste. [L]

Sustaining Operations

Limiting Issues	Potential Solutions
Instruments or Equipment Related Issues	
• Increased risk of contamination of equipment or instruments due to handling of higher-activity samples.	• Screen all samples for radioactivity prior to processing. [N,L] • Screen all prepared test sources for high levels of radioactivity using handheld equipment prior to loading onto instruments. [L] • Increase frequency of background checks of instruments. [L] • Increase frequency of contamination surveys of preparation equipment. [L] • Carefully document what samples are processed on what equipment in case corrective action is needed. [L]

Sustaining Operations (cont.)

Limiting Issues	Potential Solutions
Standards, Reagents, and Supplies Related Issues	
• Unavailability of radioactive tracers for chemical yield measurements. • Unavailability of carrier solutions for chemical yield measurements. • Unavailability of radioactive standards for calibration and QC.	• Determine in advance a laboratory's total capabilities and capacities based on an inventory of in-house supplies and the need to obtain additional supplies for a predetermined period. [L] • Obtain additional standards, tracers, and carriers to support operations for a predetermined period. [L] • Determine whether inventory of standards, tracers, and carriers will meet organizational or network requirements. [N,L] • Develop dilution and measurement verification methods to produce traceable tracers, making sure to stabilize them, and then warehouse them at one or more locations for laboratory or network use. [N,L]
• Unavailability of specialized reagents, such as LSC cocktail or solid-phase extraction columns, specialized extraction, and purification columns.	• Determine in advance the laboratory's total capabilities and capacities based on an inventory of in-house supplies and the need to obtain additional supplies for a predetermined period. [L] • Determine whether inventory will meet organizational or agency requirements. [N,L]
• Unavailability of radionuclide matrix standards for method validation and QC.	• Determine in advance matrices, radionuclide mix, massic activity of Standard Reference Materials needed for method validation and QC. [A,N,L]
Personnel Related Issues	
• Inadequate number of staff trained for operations with radioactive materials.	• Identify any staff beyond routine radiochemistry staff who will be cross-functioned and include them in radiation worker training. [L]

Sustaining Operations (cont.)	Limiting Issues	Potential Solutions
	Contamination Control Related Issues	
	• Increased risk of contamination of processing areas, facilities, and personnel due to handling of higher activity samples.	• Screen all samples for radioactivity prior to processing. [N,L] • Screen all prepared test sources for high levels of radioactivity using handheld equipment prior to loading on instruments. [L] • Increase frequency of contamination surveys in receiving, sample storage, preparation, chemical separation, counting, waste handling, administrative, and other areas. [L]
	• Insufficient number of available hoods or biological safety cabinets for sample preparation.	• Develop sufficient laboratory engineering controls. [L]