Radiological Laboratory Response- Limiting Issues

Radiological Laboratory Working Group

Integrated Consortium of Laboratory Networks

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Overview

Executive Summary

Immediately following a Radiological Dispersal Device (RDD) (i.e. "Dirty Bomb") or from the detonation of an Improvised Nuclear Device (IND), the nation's radiological laboratories will be called upon to assist with the exposure assessment of the environment, people, food, and other matrices. This will require a massive effort on the part of the nation's radiological laboratories, both governmental and commercial, to respond rapidly to the anticipated enormous sample load while producing high-quality radioanalytical results.

To assist local, state, and federal organizations in the preparedness planning for an effective and efficient national response to a potential catastrophic terrorist attack involving a radiological device, the White House's Homeland Security Council has developed the National Planning Scenario #11, with interagency involvement. This scenario envisions the detonation of a RDD in three major downtown urban areas. That scenario was tested in a national exercise, TOPOFF 4, in 2007. The results of that test showed that the nation was not adequately prepared for a rapid analytical response to an event of national significance. The analytical laboratory requirements for responding to a potential large-scale radiological emergency are immense considering the need for human, environmental, food, plant and animal testing of tens to hundreds of thousands of samples. Based on the nation's current radiological analytical capability/capacity for most of the priority radionuclides, it would take months or years to process, analyze, and report the laboratory results. In addition, the state public health laboratories (PHL) would be responsible for all sample matrices: environmental, food, and clinical. According to both the Conference of Radiation Control Program Directors, Inc. (CRCPD) and the Association of Public Health Laboratories (APHL) surveys, the state PHLs are more prepared for environmental and food than for clinical samples.

Concerns about the public's exposure to radiological agents in the event of a nuclear or radiological incident underscore the importance of ensuring that the nation has a robust laboratory infrastructure that can respond rapidly to such an emergency. Should a large-scale event occur, some radiological laboratories may be inadequately prepared to conduct large-scale radiological testing of clinical, environmental, food and other sample matrices. The information obtained from such laboratory testing is essential for providing timely, high-quality, and interpretable analytical results for the local, state, and national decision-makers in the various response phases of a radiological or nuclear attack.

The following table lists various aspects of a laboratory's processes that may limit or severely limit the laboratory's response to an event of national significance. In such an event, the demands on laboratory testing will place a serious strain on all aspects of the laboratory's processes. In the attached table, the major steps of the process are listed along with specific process components. The table is organized by the major operational components of a laboratory process. Any one of these components may have a drastic effect of limiting the overall analytical throughput from receipt of samples to reporting of results. In addition, the authors have proposed possible solutions to these rate-limiting components. There has been no attempt to prioritize individual issues within the major laboratory components.

Pre-Analytical

Limiting Issues	Potential Solution
Agency- and priority-related issues— • Limited supply of competent radioanalytical 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 exists currently to weigh the appropriateness of priorities for each of these agencies.	For most events, define in advance which samples have priority (e.g. clinical, environmental, food).
Absence of laboratory analytical requirements and associated action levels for sample measurements (Data Quality Objectives (DQOs) and Measurement Quality Objectives (MQOs), etc.) for each phase of the response (monitoring/surveillance, incident response [early and intermediate] and remediation/restoration) and the associated action levels will result in a lack of appropriate data to support decision-making.	• Estimate appropriate DQOs and MQOs before an event. • Investigate using the Department of Energy (DOE) Automated Laboratory Detection Limit Assistant (ALDLA).

Sample Receiving and Screening

Limiting Issues	Potential Solution
• Inadequate sample accession, ID (bar code labeling), and tracking-retrieval processes (e.g., local, agency, lab) for retesting. • Lack of a plan to address changing DQOs and MQOs with changing phases of the event (ongoing issue).	• Use remote electronic sample accession and data transmission to the laboratory. • Use minimum bar code standards (e.g., Code 128 at 3 mil) for readers and printers. • Estimate appropriate DQOs and MQOs before an event.
Insufficient infrastructure and protocols for shipping samples among network laboratories.	• Establish procedures and contracts with overnight carriers in advance. • Train laboratory personnel in Department of Transportation (DOT) shipping regulations.
Insufficient space to screen, process, label, and package samples.	Create remote, auxiliary, or satellite locations to process receipt of samples.
Lack of provisions for the security of samples.	Provide for a secure location for forensic samples.
Insufficient equipment (e.g., computers, bar-code scanners, photocopiers, printers, document scanners, bar-code label stock).	• Develop a robust sample screening protocol and ensure that there are sufficient computers, barcode scanners and label stock, printers, and photocopiers to cope with influx. • Purchase or borrow additional equipment.
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. • Use modular procedures and training. • Plan in advance for multiple shifts to cover 24/7 for weeks. • Proper training for use of screening instruments, procedures, and the proper use of personal protective equipment (PPE).
Inconsistent 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.
Lack of a uniform process for screening contaminated samples.	Develop a process and train staff in advance to screen and identify samples outside the laboratory's acceptance criteria.
Limits on laboratory's radioactive material license from the Nuclear Regulatory Commission (NRC) or 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. • Maintain current phone numbers and contact information.

Analytical Processing

Limiting Issues	Potential Solution
Lack of an analytical method for a specific analyte/matrix combination (e.g., cesium in urine). Pre-approved procedures for analytical method modification to comply with regulatory or compliance need to meet screening, quantification, and confirmatory DQO requirements.	Develop, validate, document, and adopt rapid methods for use during an emergency response. Integrated Consortium of Laboratory Networks (ICLN) and American Society for Testing and Materials (ASTM) have a group working on this issue.
An unsatisfactory length of time to produce the first analytical results (including all QC reviews and organizational sign-offs).	Laboratories should have a staffing plan to address 24/7 operations.
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.
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. • Laboratories should develop a plan and exercise for long-term operations.
An undesirable complexity and duration of the radiochemical separation process.	Minimize method complexity when possible and ensure the proficiency of technicians through training.
Inadequate number of instruments; limited automation.	Increase instrument automation, emergency purchase of additional instruments, cross or full use of complementary instruments, and secure emergency purchase/loan of instruments from manufacturers or other organizations.
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).
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. Lack of planning for additional shifts.	• Use modular pre-analytical and analytical processes. • Cross-train personnel to improve flexibility and coverage. • Use of refresher training and exercises to stay current. • Laboratories should have a staffing plan to address 24/7 operations.

Data Processing & Reporting

Limiting Issues	Potential Solution
An unacceptably slow conversion of an instrument result to an appropriate sample result.	Automate data-processing steps as much as possible.
An unacceptably slow QC data review and approval. This process includes determining acceptable parameter performance and Laboratory Control Sample, blank, matrix spike, and duplicate acceptance criteria.	Automate the QC review as much as possible using a Laboratory Information Management System (LIMS) or another type of information system.
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 of personnel in the QC review process.
Inadequate pre-defined data-reporting formats, including Electronic Data Deliverable (EDD) formats specifications.	• Standardize and communicate requirements to the laboratory community. • Establish who will receive analytical results from the labs and how data will be shared among networks. • Install infrastructure (e.g., databases, EDD input and export routines) in advance that will be used to receive and export EDD messages during an event.

Sample & Waste Disposition

Limiting Issues	Potential Solution
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.
Inadequate waste generation and removal. Many laboratories will want assurances of a disposal pathway for secondary waste (e.g., liquid waste, paper, glass, plastic, gloves, etc.) produced during the analytical process.	• Combine waste into larger containers. • 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.
Liability issues related to contamination of a laboratory.	Possible solutions require further discussion with the organizational management.

Sustaining Operations

Limiting Issue(s)	Potential Solution
Vendor-related issues— • Unavailability of vendor technicians to repair equipment/instrument in the event of failure. • Inability of instrument or equipment vendors to respond 24/7.	Establish formal or informal agreements with the equipment and instrument vendors.
Unavailability of radioactive tracers for recovery or quantification and radioactive standards for calibration and QC.	• Determine in advance a laboratory's total throughput based on an inventory of in-house supplies and the need to obtain additional supplies for a predetermined period. • Determine whether inventory will meet organizational or agency requirements. • Develop dilution and measurement verification methods to produce user units of traceable tracers, making sure to stabilize the units, and then warehousing them at several central locations for interagency use.
Unavailability of specialized reagents, such as liquid scintillation counting (LSC) cocktail or solid-phase extraction columns; specialized extraction and purification columns.	• Determine in advance the laboratory's total throughput based on an inventory of in-house supplies and the need to obtain additional supplies for a predetermined period. • Determine whether inventory will meet organizational or agency requirements.
Unavailability of vials, bottles, and containers for samples; hotplates, vacuum boxes, PPE, gases, waste containers, and other items.	Laboratories should develop a plan for inventory of essential analytical supplies or a system of "just-in-time" inventory.
Insufficient continuity of infrastructure (power, water, phone, Internet).	Work with the organization's facilities management and information technology to ensure the continuity of services.
• Unavailability of radionuclide matrix standards for method validation and QC. • Insufficient number of available hoods or biological safety cabinets (BSC) for sample preparation.	• Determine in advance matrices, radionuclide mix, massic activity of Standard Reference Materials needed for method validation and QC. • Determine in advance interagency total amount needed for a supply of at least 1-4 years. • Develop sufficient laboratory engineering controls.