

Prioritization of Laboratory Samples Following a Radiological Event: Considerations

Introduction

After a radiological event, many questions may need to be answered to help health officials mitigate a public health crisis, such as: Where did the fallout spread? Did it impact crops, livestock, or water supplies? Who was exposed, to what, and how much?

Laboratory testing may be necessary to answer these vital questions, but very few (if any) U.S. laboratories possess the capacity to analyze the large number of clinical, environmental, food, or agricultural samples that would arise during a radiation emergency on U.S. soil.¹ Given such limited capacity, decisionmakers and laboratory directors face difficult decisions about the order in which samples are analyzed.

For example, decisionmakers may need to decide which is more important: determining who was exposed or determining which blocks to evacuate. If human exposure or dose assessment is most important, clinical samples will be given priority. If understanding the extent of the contamination is more important, environmental samples will be given priority. Even within such broad categories, there may be a need to further triage samples due to laboratory limitations. For example, clinical samples may be further prioritized based on symptoms or proximity to ground zero.

For these and other reasons, decisionmakers and responders should consider including laboratories in the emergency planning, exercising, and response process at the state and local level. During an emergency, decisionmakers often realize too late that their expectations for laboratories regarding capability, capacity, and turnaround time (TAT) are unrealistic.

Laboratories themselves will be confronted with complex or unusual analytical issues. For example, radioactivity in samples will range from high levels near the event's center to background levels in unaffected areas. In addition, unprecedented demands for high sample throughput and quick TATs will persist for an extended period. Without prior preparation, a laboratory's routine systems, protocols, and personnel will be pushed beyond the breaking point. In preparation for an emergency response, laboratories can develop and implement incident response plans to address and streamline the transition from routine analytical operations to incident response operations.²

¹ In fact, capacity may be overestimated because data collectors tend to ask separate questions about different types of samples (such as clinical, food, and environmental), rather than total radiological testing capacity. This remains problematic since laboratory resources—such as scientific staff and instrumentation—often are shifted to support different testing needs.

² For guidance on incident response plans, see *Guide for Laboratories—Identification, Preparation, and Implementation of Core Operations for Radiological or Nuclear Incidents*, EPA 540-R-10-002, June 2010.

This document provides an overview of some considerations that decisionmakers might include in the prioritization process. It is not a guidance document, as each incident will present its own challenges. A task force created by the National Alliance for Radiation Readiness developed these considerations; see Appendix A for a list of task force members.

Background

The considerations presented here may not apply in every type of event. Possible scenarios involving a release of radioactive materials include:

- A nuclear power plant accident.
- A nuclear detonation.
- An accidental release from a medical or industrial device.
- Nuclear weapons testing.
- An intentional release of radioactive material as an act of terrorism (“dirty bomb”).

2009 H1N1 Influenza Pandemic

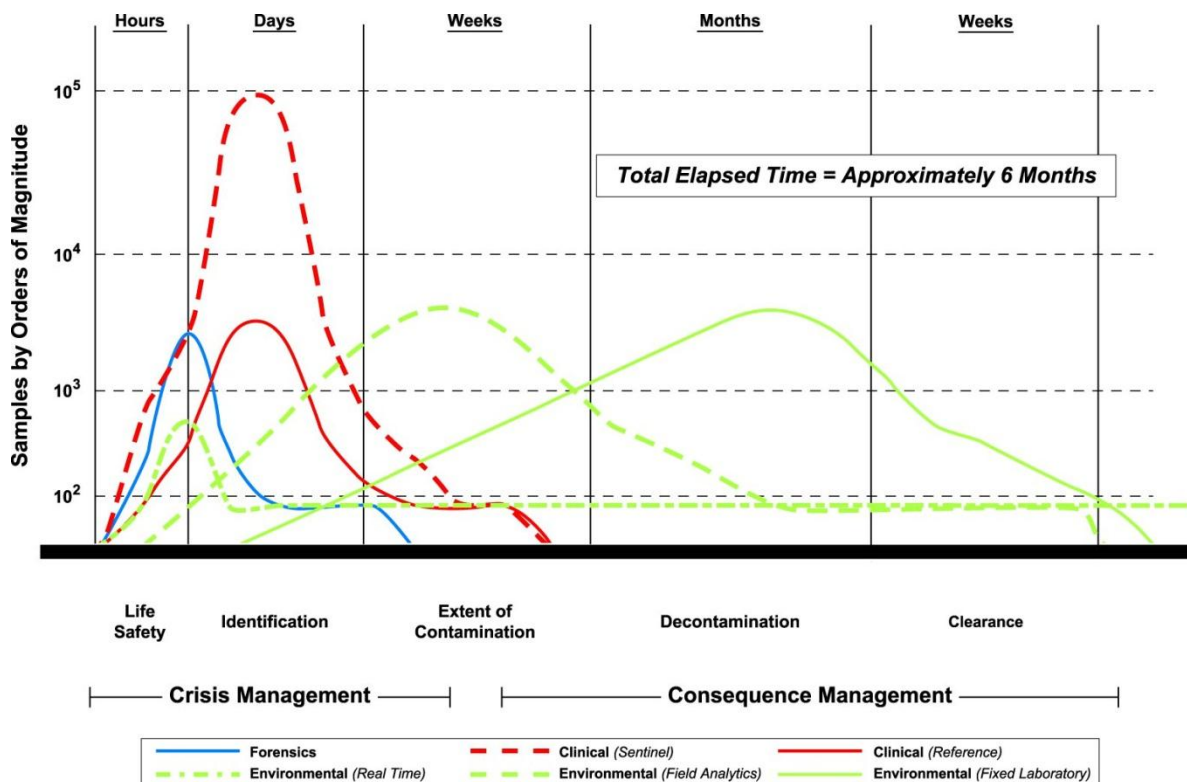
During the novel H1N1 influenza epidemic, U.S. laboratories saw unprecedented numbers of specimens. In Texas, sample load went from eight specimens a day to more than 1,100 a day in three days. Normal flu season usually involved 100 samples a week, but the Texas lab at one point was receiving 1,400 samples a day.

To better handle the influx, the lab switched from diagnostic testing (which identifies whether a specimen is positive for novel H1N1 virus) to surveillance testing (which detects novel influenza viruses and identifies antiviral resistance). This led to more targeted testing, resulting in the positive rate increasing from 10 percent to almost 80 percent.

Rather than test every sample immediately, labs changed their algorithms to include a risk assessment and tested specimens based on severity of symptoms and other demographic characteristics that could impact public health, including age, occupation, travel history, and suspected antiviral resistance.

Similarly, priorities may change based on the phase of the response (see Figure 1). For example, there are more clinical samples than environmental samples in the early phases of incident response. Although clinical samples rapidly decline after the first few days of a response, environmental samples will be required throughout the entire response.

Figure 1: Phases of Disaster Response³



According to the Association of Public Health Laboratories’ (APHL) all-hazards preparedness survey from 2009 and a 2011 radiation readiness survey⁴, 60 percent of respondents reported the ability to test environmental samples, such as air, soil or surface water for radiation; 48 percent reported the ability to test non-milk food samples; 47 percent reported the ability to test milk; and 56 percent reported sending data for drinking water to EPA. Furthermore, 27 percent of respondents reported the ability to measure radionuclides in clinical specimens and six percent reported that another state agency or department accepts and analyzes these samples via a radio-analytical method. Therefore, some states can sample, analyze, and report four basic types of samples for laboratory testing—environmental, food, drinking water, and clinical.

Results from the first three types of media will be sent on to state radiation bureaus to determine the contamination and radioactivity levels. Some protective action recommendations may need to be made prior to sampling, including evacuation, sheltering livestock and human population, placing livestock on stored feed, and instructing the public on how to mitigate their exposure/contamination. Some of these recommendations may be based on conditions of the emergency, such as the state of the power plant or explosion zone, and not on sampling data.

³ <http://www.fsea.net/library/ppts/fseameetingoct2007allanantley.ppt>

⁴ See Latshaw MW, Mangal C, Barkey A, McNamara D, Kim D, Pierson JB. Public Health Laboratories and Radiological Readiness. *Disaster Med Public Health Prep.* 2011;5:213-217. <http://www.dmphp.org/cgi/content/abstract/5/3/213>.

The fourth media type, clinical, will need to be sampled and analyzed to assess the dose that an individual receives from the exposure of activity and whether it is an internal or external exposure. However, currently no state radiation labs and very few commercial labs have methods to effectively analyze clinical samples during a radiation emergency that are approved by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The resources necessary to support the clinical analysis of radiological samples at the state level are lacking and consequently, there is virtually no experience (e.g. CLIA-validated analytical methods) with analyzing and processing clinical specimens for radionuclide contamination. Currently, states plan to submit clinical samples to CDC until other laboratories can build the capability and capacity to accept the clinical samples. Subject matter experts at the federal level will analyze the clinical samples and assess dose, which will then be submitted to the requestor (state public health department, medical facility, etc.).

Sample Load Projections

In the aftermath of a radiological incident, there will be thousands of samples from people (clinical), environmental, food, and agricultural sources. People may need to be evaluated for internal contamination to determine if they need medical management or therapy. Local authorities will need to know if buildings are safe to occupy or if the radiation poses a public health risk. Local areas such as streets, sidewalks, and parks will need to be evaluated to ensure public safety and that local traffic does not redistribute radioactive material. Similarly, cars, trucks, and other transportation vehicles near the incident site will need to be evaluated to ensure that radiation contamination does not spread. If there are agricultural sites near the incident or under the radioactive plume, crops and livestock will need to be evaluated, as well as pets near the incident. Consequently, there will be a large number of samples with a wide range of radioactivity levels. Before developing a prioritization scheme, it is important to understand the types and quantities of samples that may result from a radiological emergency.

Clinical Samples

It may be necessary to evaluate the possible internal exposure or contamination of a few people or hundreds of thousands near the radiological incident site. In cases involving a “dirty bomb,” the resulting radioactive explosion site may cover many city blocks that contain thousands of people. Although the level of radiation contamination may be below a public health level of concern, there will likely be many citizens who want to be tested.

Food & Agricultural Products

Sampling of food and agricultural products requires monitoring in the intermediate and recovery phases of emergency response. Plants and animals will accumulate radionuclides through various routes, leading to different timetables for contamination. Some radionuclides will persist in plants, animals, and food supplies for decades and some may disappear in weeks or months. The radionuclides that persist for decades will require continual monitoring to ensure the food supply's safety. Not only are plants and vegetables a concern, but it is also important to monitor dairy-producing cows that graze in contaminated pastures. There are a wide range of food and agricultural products that must be monitored, but the specific number will vary depending on:

- Amount of radioactive material released.
- Geographic range of the radioactive material.
- Regional weather events during dispersal.

Environmental Samples

Thousands of environmental samples will be collected and require laboratory analysis. The quantity will depend on a number of factors, including the extent of the contamination, the radionuclide or

Food and Agricultural Real-Life Sample Loads

Fukushima - March 2011

To handle the increase in sample testing, Japan created 1,000 new testing centers and processed more than 120,000 food and milk samples.⁵ In the first two months following the explosion, 200-400 samples per week were analyzed, but in the third month after the explosion, the number of samples doubled.⁶

Chernobyl - April 1986

The weather greatly affected the response to contamination from the Chernobyl accident, leading to different response needs in Hungary and Ireland. Due to two waves of contamination caused by weather, the Hungarian Ministry of Agriculture and Food expanded their radiation laboratories from 23 to 43 to handle the large increase in sample submission, from 3,000 per year to 44,000 per year.⁷

In contrast, only 1,440 food and agriculture samples were tested in Ireland during the six month period following Chernobyl.⁸ Significant rainstorms occurred as the radioactive cloud arrived, resulting in deposition "hot spots" that contaminated crops and livestock in a few localized regions.

⁵ Martin J. Frid (March 2012). The Asia-Pacific Journal: Japan Focus, 10 (12), No 1.

⁶ IAEA.org (June 2011) Fukushima Nuclear Accident Update Log. Accessed online on 04/09/2012 at: <http://www.iaea.org/newscenter/new/2011/fukushimafull.html>

⁷ Animal Health and Food Control Centre, Hungarian Ministry of Agriculture and Food (1988). *Rev.Sci. tech. Off. Int.Epiz.* 7, 93-95

⁸ Radiological Protection Institute of Ireland (1987). Detailed report published on the effects of Chernobyl on Ireland. Accessed online 04/09/2012 at <http://www.rpii.ie/Site/Publications/Chernobyl-its-effect-on-Ireland.aspx>

radionuclides involved, meteorological conditions, the nature of the dispersal of the radioactive material, etc. Some examples of environmental samples that will be collected are air filters, swipes, water, soil, and other solids including urban materials like cement, brick, and sheet rock.

In addition to determining the contamination level in contaminated areas, there will also be considerable sampling in other areas to demonstrate to the public and public officials that the radiological event did not impact those areas. Not only will there be environmental samples collected during the early, intermediate, and clean-up and recovery phases following a major radiological incident, but there will also very likely be environmental monitoring generating thousands of samples for months or longer following the clean-up and recovery activities.

Sample Management

Prior to developing a prioritization scheme, it is imperative that laboratories, emergency response, public health officials, and executive decisionmakers understand the capabilities of their state, commercial, and federal laboratories. Knowing ahead of time when and where to send clinical samples will prevent them from going to a laboratory that is unable to perform the analysis, which delays delivery to a capable laboratory. It is also important to know the sample acceptance criteria for different laboratories. Certain laboratories may not accept high activity samples. Prior knowledge of sample acceptance criteria may allow for the reduction of activity of samples in the field that would allow them to be acceptable to the laboratory, thus more efficiently moving the sample through the analysis process.

Sample management is essential following a radiological incident because you cannot communicate about samples or prioritize them if it is unclear how many samples have been taken, where they were taken, where they currently are, if they were taken correctly so they can be tested, or how they are identified. Laboratories must keep track of the samples they receive, especially during an emergency when the number of samples being sent to the lab has increased exponentially. Laboratory tracking systems need to coordinate with field tracking systems to facilitate effective communication. Providing responders in the field with sampling instructions, preapproved by the laboratory, will assist laboratories in tracking samples as they arrive. The sampling instructions may include information on:

- Creating a standardized unique identifier for each sample.
- Sample volumes needed for testing.
- Acceptable sample container types.
- Contamination control measures.

Once samples have been appropriately collected in the field, they must reach the laboratory. Different emergency response phases may require different sample transport mechanisms. For example, in the early stages of a response, samples may require police transport to the laboratory. Most likely the first priority will be to identify the radioisotope(s) and the area that is contaminated. Questions to consider when determining prioritization for initial environmental samples include:

- Will officials make decisions based on preliminary information from field data or will they need laboratory-confirmed results?
- Will a laboratory only need to analyze a few of the environmental samples from one area and then be able to switch to another set of samples or will all samples from one area need to be tested prior to moving to samples from a different location?

Clinical Sample Triage

It is important to identify people who have incorporated radioactive materials into their body or become internally-contaminated to determine who needs countermeasures, the effectiveness of countermeasures being used, the correct course of treatment, and those needing long-term followup.

The laboratory method used to identify internal contamination—a urine bioassay—is resource-intensive, and there is currently an extremely limited capacity for conducting a large number of bioassays. Therefore, after an incident resulting in more clinical specimens submitted for analysis than there is available laboratory capacity, it is important to consider triaging samples that are sent to the laboratory. Specific individuals, such as pregnant women and young children, are more vulnerable to radiation’s effects than others. Some individuals are at a higher risk of being contaminated internally due to their location during the event. Information collected at community reception centers or healthcare facilities can be used to prioritize who should provide a clinical sample and which clinical samples should be sent to the laboratory first for analysis.

When developing a prioritization scheme for sample collection and analysis, the following criteria should be considered:

- Demographic groups more sensitive to radiation exposure:
 - Age 18 years or younger.
 - Pregnant women.
- Characteristics that may increase risk of internal contamination:
 - During radiation screening:
 - Radioactive material detected in breathing zone (face/front of neck).
 - Radioactive material detected anywhere on the body even after decontamination.
 - Presence of open wounds/burns or radioactive debris embedded in the skin.
 - Individual was present within contaminated zone, especially if outside a shielding structure.
 - Individuals who were first responders at the incident site, especially if personal protective equipment was not utilized.
 - Presence of signs and symptoms due to acute radiation health effects (acute radiation syndrome or local radiation injury).

CDC has developed questionnaires for dose reconstruction that use results from the initial laboratory tests to estimate an individual’s internal radiation dose. Collecting additional variables, such as height, weight, age, time of exposure, and time of urine collection that can be incorporated into the dose

reconstruction model and improve its accuracy. These tools can be utilized to assist in developing a prioritization scheme.

Sample Screening

To ensure worker safety and prevent laboratory contamination, the large number of samples and range of radioactivity in the samples will require the laboratories to prescreen the samples upon arrival. Samples with high levels of radiation can be hazardous to an unknowing person or have the potential to contaminate the laboratory so that low-level recovery samples cannot be analyzed due to high background radiation levels in the laboratory. Thus, a robust screening of the samples must be implemented as soon as possible.

To assist with samples screening prior to their analysis, prioritization information may be indicated on the collection information forms that accompany the samples. It is important that laboratory staff and officials filling out the collection forms are familiar with them. Many forms provide spaces to document human exposure from decontamination/triage areas/hospitals or pre-screened survey meter readings and can provide prioritization information to the laboratory about which clinical or environmental samples need to be analyzed quickly. For example, samples yielding high-level readings during screening may be priorities in the lab to confirm the initial assessment.

Quality Assurance

Beyond worker safety, a laboratory's most critical concern during incident response is data reliability and defensibility. Laboratories have rigorous quality assurance plans (QAPs) in place to ensure that data quality objectives are met. Although quality assurance plans ensure that test results are both dependable and defensible, they may also delay results reporting.

For routine operations, it can take more than a month to obtain a test result for a typical radiochemical analysis of an environmental sample. However, laboratory directors recognize that initial test results will need to be turned around in days, if not hours, following a nuclear or radiological incident.

Consequently, laboratories have been developing and refining rapid response methodologies for years, particularly during the last decade.

Rapid response methodologies are intended to decrease TATs and increase a laboratory's capacity. However, rapid response methodologies do not excuse a laboratory from adhering to its QAP requirements. Although a laboratory's QAP cannot be ignored to expedite TATs, many laboratories are adopting QAPs with separate guidelines for routine and emergency response samples, allowing emergency response samples to be processed faster.

Sustaining Emergency Testing Operations

The large number of samples for analysis and the demand for quick TATs will require emergency testing operations on a 24/7 basis for an extended period of time (weeks or months, depending on the scenario). To sustain this effort, strategies should be devised that provide support for expanding staffing resources, replenishing necessary supplies, and protecting personnel and instrumentation from increased risks of exposure and contamination. When prioritizing clinical, environmental, and food/agricultural samples, it is important to assess the potential limitations of sustaining emergency testing operations.

Directors of field sample collection and public health/ environmental laboratories should be encouraged to cross-train a portion of their non-radiological staff in radiological sample collection, screening, preparation, and analysis. During an emergency, these staff members can be shifted from their routine duties to supporting the emergency testing operation. Volunteer emergency organizations could be tapped for assistance with sample delivery, receiving, and tracking, although privacy requirements that accompany clinical samples must be upheld. Annual refreshers or practice drills would be necessary to keep cross-trained and volunteer staff prepared. In addition, potential schedules for 24/7 staffing for the emergency response should be composed to assess what levels of sample collection and data output are reasonably attainable.

State officials should also consider employing continuity of operations planning and memorandums of understanding (MOUs) with local and regional entities to contribute to the emergency testing efforts. For example, basic sample collection and laboratory testing supplies from commercial vendors may become limited in a large-scale nuclear emergency. Therefore, consider supplementing with supplies (and potentially some staff) from neighboring state facilities, local analytical and industrial laboratories, and regional universities and research institutes. Hospitals would most likely require all their resources during an emergency, but commercial medical testing facilities (e.g., Quest, LabCorp, etc.), urgent care chains (e.g., NextCare, Doctors Express, U.S.HealthWorks, etc.), and medical or nursing schools may be able to provide supplies and part-time staff to assist with clinical sampling and testing. To augment animal testing capabilities, contact veterinary hospitals, practices, and schools for potential assistance. All outreach endeavors should be included in an organized plan that allows the suppliers to be contacted efficiently and the supplies transported as needed during the emergency response.

It is also important to consider any contractual obligations the laboratory has to outside agencies. For example, some state laboratories have federal contracts for analyzing samples. If the emergency is in a state with a lab that has such a contract, then the involved state laboratory may not be able to analyze the federal samples and they may have to be analyzed at another laboratory. There are a number of issues to consider if the state laboratory has an existing contract in place with other agencies including:

- In the existing contract, is there language regarding priority of federal samples?

- Does the laboratory have enough staffing and instrumentation to analyze samples from several agencies simultaneously? If not, how will different samples arriving from several agencies fit into the prioritization scheme?

Clinical Data Reporting

When developing a prioritization scheme, it is important to understand how sample results and data are reported and identify the rate limiting steps in laboratory analysis. After subject matter experts at the federal level analyze the clinical samples, the dose information will be submitted to the requestor (state public health department, medical facility, etc.). The state will then delegate a staff member to contact the person to confidentially relay the results. Prior to contacting the patient, the staff member must locate the individual's contact information, which is located on the registry forms collected from the community reception center, hospital, or other location. This process has several serious limitations that cause delays in the reporting of patient results to the patient and their treating physician.

In addition, the subject matter experts at the federal level who are able to analyze the clinical samples and assess dose are few. During Fukushima, there were too few radiation subject matter experts, even though the response did not involve analyzing and assigning a dose to clinical samples.

Data Sharing

Prior U.S. planning for a radiological incident⁹ indicates that the Department of Energy will activate its Federal Radiological Monitoring and Assessment Center (FRMAC) early in the response. Each federal department and agency that either collects or uses environmental, food, and drinking water monitoring data will send representatives to the FRMAC to ensure that they all contribute collected data and have access to the total range of data and resulting interpretations. Although FRMAC will share data with the states to the greatest extent and as rapidly as possible, there is no data repository for states to share data amongst themselves.

State, local, and tribal public health officials must have information like projected plume arrival time and locations, radionuclides identified in the release, environmental monitoring data collected within their jurisdiction, and monitoring information for incoming cargo. The difficulty of obtaining this data during a response will result in delayed or incomplete assessments needed to support public health decisionmaking. State, local, and federal public health agencies should work together to determine how data will be aggregated, analyzed, shared, and archived during a radiological incident. If the gap is not closed, state, local and federal agencies will lack the data necessary to make appropriate public health protective actions. In addition, the inability to share information with states will strain working relationships with essential public health partners and make decisionmaking at the state level more difficult.

⁹ FEMA (2008) Nuclear/Radiological Incident Annex to the National Response Framework. Accessed online on 6/27/12 at: http://www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf

The Integrated Consortium of Laboratory Networks (ICLN) was established by a memorandum of agreement (MOA) signed in June 2005 by senior officials of federal agencies with primary responsibility for current and emerging networks, as well as officials with strong supporting roles. Federal agencies to this agreement include U.S. Department of Agriculture, Department of Commerce, Department of Energy, HHS, Department of Homeland Security, Department of Interior, Department of Justice, Department of State, and EPA. The goal of the effort is to create the basis for a laboratory networks system capable of integrated and coordinated response to, and consequence management of, acts of terrorism and other major incidents requiring laboratory response capabilities.

The ICLN Portal is a secure, password-protected website that acts as a common resource location for members of ICLN, including network coordinators, network representatives, ICLN working groups or subgroup chairs, and others provided with access to collaborate. The ICLN Portal is available to enhance communication and coordination during an incident or event. It can host databases, email communications to a restricted list of participants, provide an area for document storage and management, and make webinar services available, as well as many other functions. All work space within the site can be set up to limit access to selected individuals.

Network coordinators, network representatives, and designated persons with a need-to-know status on the ICLN Portal can establish a limited access work space and access support documents and communications such as preparedness alerts or SITREPs associated with a specific incident. The ICLN Portal can also transfer laboratory emergency response data from one federal network to one or more collaborating federal laboratory networks in a secure manner, allowing agencies to respond more efficiently. Planning indicates that ICLN will be a recipient of FRMAC laboratory data.

ICLN will share data or data summaries as able to the states. To address the clinical sampling and data challenges presented above, the use of MOUs should be considered. The MOUs should have specific language included to clarify the expectations between the partners. For data handling purposes, this could mean specifying how clinical data will be used to assess dose, how the data transfer for all types of data (environmental, food, drinking water, clinical) will occur, and who will cover expenses.

Nontraditional partners might be consulted to provide mutually-beneficial services through an MOU. Partners such as universities, hospitals, local chapters of professional radiation protection/nuclear medicine societies, and nuclear power plants should be considered.

In addition to establishing MOUs, it is important to consider defining responsibilities and establishing criteria and checklists for response to an incident. Consider exploring the following:

- Ensure your state participates in CDC's Laboratory Response Network (LRN), USDA & FDA's Food Emergency Response Network (FERN) and EPA's Environmental Response Laboratory Network (ERLN) and Water Laboratory Alliance.
- Investigate/implement a standardized electronic data deliverable format.¹⁰ This ensures that data can be quickly shared and compared.

¹⁰ Contact eh@aphl.org for a copy of an electronic data deliverable that can be adopted by laboratories as well as state, local & federal agencies. It is method, matrix, and agency-agnostic, making it ideal for sharing data from various sources and with various end users. See http://www.aphl.org/aphlprograms/eh/Documents/EH_2010Dec_EDM_WhitePaper.pdf for more information.

- Automate data processing and reporting, QC, and data review as much as possible using Laboratory Information Management Systems (LIMS) or other information systems, such as EPA's WebEDR.¹¹
- Conduct capacity exercises to realistically estimate the laboratory's data processing and review capacity.
- Exercise data transfer to emergency response customers, (e.g., ERLN, LRN, FERN, etc.)

Conclusion

A radiological incident in the United States, whether resulting in mass casualties or more limited effects, would quickly overwhelm most state laboratories with clinical, food and agricultural, and environmental samples. Although laboratories often operate on a "first in, first out" methodology, it is important to realize that this methodology will not provide decisionmakers with the information needed for an effective response. Laboratories can provide decisionmakers with actionable data by prioritizing samples, allowing decisionmakers to have a big-picture view of the level of exposure and contamination.

Laboratories cannot develop a sample prioritization scheme in isolation. It is important for laboratory personnel, first responders, public health, and decisionmakers to collaborate to discuss the issues that will arise when planning how to prioritize samples in a radiological emergency. This collaboration will allow for a greater understanding of capability level and resource availability.

This document presents a number of considerations to prompt discussion among laboratories, first responders, public health, and decisionmakers as they begin developing a laboratory sample prioritization scheme for radiological emergencies.

¹¹ WebEDR is a web-based application, which performs an electronic review on any uploaded data deliverable. It provides laboratories with the capability to manage, store, and submit data files, check files for content and completeness prior to submission, and review the status of previous submissions. WebEDR provides data reviewers with a standardized procedure for obtaining, reviewing, and managing the data and its results. <http://webedr.fedcsc.com/app/>

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