Status of the Integrated Consortium of Laboratory Networks

July 2021

Report to Congress

Countering Weapons of Mass Destruction

Message from the Acting Assistant Secretary for Countering Weapons of Mass Destruction

I am pleased to submit the following report, *Status of the Integrated Consortium of Laboratory Networks,* prepared by the Department of Homeland Security Countering Weapons of Mass Destruction Office, in consultation with the Departments of Agriculture, Defense, Health and Human Services, and the Environmental Protection Agency .

This report was prepared pursuant to Section 203, Integrated Consortium of Laboratory Networks, of the Food and Drug Administration Food Safety Modernization Act (Pub. L. No. 111-353) (codified at 21 U.S.C. § 2222) which mandates a biennial report to the relevant congressional committees on the progress of the integrated consortium of laboratory networks

Pursuant to congressional requirements, this report is being provided to the following Members of Congress:

The Honorable Gary C. Peters
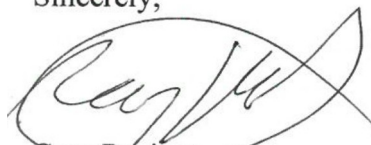Chairman, U.S. Senate Committee on Homeland Security and Governmental Affairs

The Honorable Rob Portman
Ranking Member, U.S. Senate Committee on Homeland Security and Governmental Affairs

The Honorable Bennie G. Thompson
Chairman, U.S. House of Representatives Committee on Homeland Security

The Honorable John Katko
Ranking Member, U.S. House of Representatives Committee on Homeland Security

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Gary Rasicot
Acting Assistantt Secretary

TABLE OF CONTENTS:

Contents

Executive Summary

This report, required by the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), Public Law 111-353, codified at 21 U.S.C. § 2222, provides the current status of the Integrated Consortium of Laboratory Networks (ICLN). The ICLN is a nationwide, integrated system of federal laboratory networks. The ICLN was established to assist federal agencies to respond to acts of terrorism and other events requiring an integrated laboratory response. The mission of the ICLN is to coordinate federally sponsored analytical laboratory services for chemical, biological, radiological, and nuclear (CBRN) incidents. The ICLN plans, identifies resources, provides laboratory surge capacity support, and defines key process steps for information exchange and data sharing during an incident.

This report summarizes the accomplishments of the ICLN since the last iteration, which covered January 2005 through October 2017. This report covers November 2017 through August 2020. The ICLN originated in the Department of Homeland Security (DHS) Science and Technology Directorate and was then transitioned in 2017 to the DHS Office of Health Affairs. In 2018, the Office of Health Affairs merged with the DHS Domestic Nuclear Detection Office (DNDO) to create the Countering Weapons of Mass Destruction (CWMD) Office. CWMD will deliver future reports on the status of ICLN.

The ICLN brings together seven federally sponsored laboratory networks (member networks) under a common framework to assist in integrated and coordinated responses to acts of terrorism and other major CBRN incidents (see Figure 1). The member networks agree to provide the requisite analytical capability and capacity to process samples collected during public health incidents for which their proponent agencies are responsible, subject to their respective statutory authorities and as directed by their proper chain of command. Because some CBRN incident response scenarios may present a larger number of samples requiring analysis than a given network can process in a reasonable time, the ICLN framework ensures gaps in laboratory analytical capability and capacity within a single member network can be filled by other member networks across the ICLN. Through the ICLN, laboratories in member networks ensure the provision of timely, credible, and interpretable data in support of surveillance, early detection, effective consequence management, and other needs. The ICLN coordinates the efforts of member laboratory networks under their common framework; it does not supersede any other relationships, policies, or operating procedures of those networks.

The ICLN is an operational system prepared to respond to large-scale contamination or disease incidents largely because of key accomplishments in the three areas outlined in FSMA. First, ICLN networks established laboratory methods as well as validation and quality assurance guidance enabling laboratories to effectively assist in the analysis of samples of multiple types, including human clinical, environmental, food, plant, and animal clinical samples. The ability of member network laboratories to support multiple networks has been demonstrated through an array of competency tests. Second, the ICLN Portal and its Data Exchange Utility (DEU) provide a means for members to work cooperatively to optimize national laboratory preparedness and organize surge capacity during emergencies as well as to aggregate and share data in a single database from all member networks participating in a joint response. Finally, ICLN coordinating bodies and member networks continue to engage in ongoing dialogue, exercises, drills,

interagency collaborations, and other activities that build relationships to support effective integrated responses during emergencies. Section VI of this report provides a list of ICLN activities and successes that were completed between November 2017 and August 2020.

Pursuant to the requirements outlined in Section 203, Integrated Consortium of Laboratory Networks, of the FSMA, this report fulfills the responsibility of the Secretary of the Department of Homeland Security in outlining the ICLN's progress to date and covers the reporting period of November 2017 through August 2020.

Because of a lack of dedicated funding in the FY 2019 budget, the ICLN program was paused between February 2019 and March 2020. The strategic coordination for a combined response was not available through the ICLN at that time, which represented a gap in response capability for the U.S. government. CWMD resourced and re-established formal operation of the ICLN in April 2020. CWMD is taking the requisite steps to ensure this does not occur in the future and has included requisite funding in the FY 2022 President's Budget.

Legislative Language

In accordance with the Food Safety and Modernization Act (FSMA), Section 203, codified at 21 U.S.C. § 2222, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency, shall maintain an agreement through which relevant laboratory network members, as determined by the Secretary of Homeland Security, shall:

1. Agree on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks and facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

2. Identify means by which laboratory network members could work cooperatively:

   a. To optimize national laboratory preparedness; and
   b. To provide surge capacity during emergencies; and

3. Engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.

(b) Reporting requirement

The Secretary of Homeland Security shall, on a biennial basis, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the progress of the integrated consortium of laboratory networks, as established under subsection (a), in carrying out this section.

This report is publicly available on the ICLN website at https://www.icln.org/.

Background of the Integrated Consortium of Laboratory Networks

The ICLN was established by a Memorandum of Agreement (MOA) signed in June 2005, updated and re-signed in 2012, and signed again in 2016 by stakeholder government agencies. These signatory agencies include the U.S. Department of Agriculture (USDA), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Department of the Interior (DOI), Department of Justice (DOJ), Department of State (DOS), and the Environmental Protection Agency (EPA). The ICLN was established to provide a nationwide, integrated system of federal laboratory networks to assist in responding to acts of terrorism and other events requiring an integrated laboratory response.

The signatory agencies recognize the capabilities of independent laboratory networks, such as the Centers for Disease Control and Prevention's (CDC) Laboratory Response Network (LRN) or the EPA's Environmental Response Laboratory Network (ERLN), can be leveraged in situations requiring the resources and capacities of more than one laboratory network. Establishing the ICLN contributes to stronger early detection and consequence management capabilities, consistent with the requirements of Homeland Security Presidential Directive (HSPD) 9 (Defense of U.S. Agriculture and Food), National Security Presidential Memorandum-14 (Support for National Biodefense), HSPD-21 (Public Health and Medical Preparedness), and HSPD-22 (Domestic Chemical Defense), Presidential Policy Directive-8 (National Preparedness), and the National Biodefense Strategy of 2018.

As outlined in the ICLN's MOA, the Integrated Consortium of Laboratory Networks fulfills the Nation's need for a system of federal laboratory networks capable of integrated and coordinated response to incidents involving:

- Multiple types of microbes (e.g., emerging infectious disease), agents (e.g., chemical, biological, and radiological), or mixed or unknown agents, where sampling, testing, interpretation of results, and response must be closely coordinated;
- Multiple sampling matrices, where laboratory testing is needed in multiple sample types (e.g., human clinical, environmental, food, plant, and animal) and where there is overlap in the need for methods, training facilities, equipment, reagents, and staff to carry out the testing;
- More than one sector or segment of the Nation (e.g., humans, animals, plants, food, and the environment) or more than one type of laboratory (e.g., screening/sentinel, confirmatory, forensic, and definitive reference); and
- Multiple phases of incident management (e.g., monitoring, emergency response, remediation/recovery, and forensic investigations).

Figure 1 depicts the ICLN organizational structure. Principal organizational elements include a Joint Leadership Council (JLC), a Network Coordinating Group (NCG), technical subgroups, and a Technical Project Management Team (TPMT). The Countering Weapons of Mass Destruction (CWMD) Office chairs the NCG and the JLC and provides administrative support

through the TPMT that is currently staffed via a DHS Time and Materials contract. CWMD is also the executive agent for day-to-day management of the ICLN's functional utilities and resources (e.g., the ICLN Portal, laboratory databases).

The JLC includes one senior policy member from each federal department or agency that participates in the ICLN. The council provides high-level policy guidance and support to the NCG, particularly when issues at the NCG-level require assistance. The JLC guides the ICLN in system-wide strategic planning through the NCG and approves the inclusion of additional networks into the ICLN, as well as modifications to the MOA. The JLC currently meets annually with the NCG.

The NCG is the focal point of federal network coordination. NCG membership consists of officially designated member laboratory network representatives who have the appropriate responsibility and authority to facilitate progress on ICLN goals and objectives. The NCG is the primary body responsible for coordination across the networks, which consists of establishing guidelines, analytic methods, and common data exchange and knowledge management procedures. The NCG also establishes and guides the ICLN technical subgroups in support of their roles to create standardized and integrated approaches for the ICLN and provide technical guidance on critical issues. The NCG meets monthly to discuss interagency issues, consider recommendations from the technical subgroups, and plan internetwork exercises to promote overall system readiness.

The TPMT provides technical administrative support to the organizational structure of the ICLN, including the JLC, NCG, and technical subgroups. The DHS ICLN NCG Chair provides oversight of the TPMT. The TPMT meets the ICLN's technical administrative needs, including managing internetwork communications, convening meetings, facilitating actions approved during meetings, assisting with writing of technical reports, and serving as the point of contact for external outreach and communications.

ICLN Organizational Structure

As outlined in Figure 1, seven networks comprise the analytical resources accessible within the ICLN: Department of Defense Laboratory Network (DLN); Laboratory Response Network (LRN [LRN-B and LRN-C]); National Animal Health Laboratory Network (NAHLN); National Plant Diagnostic Network (NPDN); Food Emergency Response Network (FERN); Environmental Response Laboratory Network (ERLN); and Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Four collaborating agencies (DOE, DOI, DOS, and FBI) are also members of the ICLN.
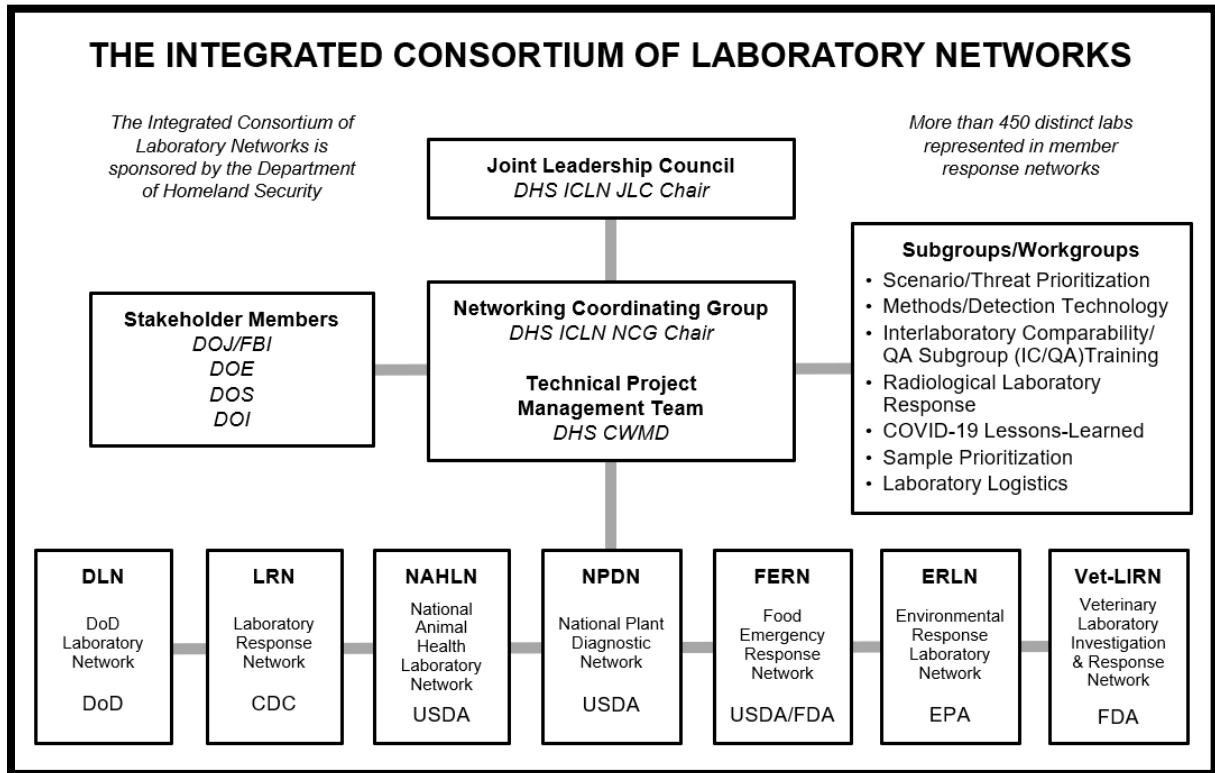
THE INTEGRATED CONSORTIUM OF LABORATORY NETWORKS

The Integrated Consortium of Laboratory Networks is sponsored by the Department of Homeland Security

More than 450 distinct labs represented in member response networks

Joint Leadership Council
DHS ICLN JLC Chair

Stakeholder Members
DOJ/FBI
DOE
DOS
DOI

Networking Coordinating Group
DHS ICLN NCG Chair

Technical Project Management Team
DHS CWMD

Subgroups/Workgroups
- Scenario/Threat Prioritization
- Methods/Detection Technology
- Interlaboratory Comparability/ QA Subgroup (IC/QA)Training
- Radiological Laboratory Response
- COVID-19 Lessons-Learned
- Sample Prioritization
- Laboratory Logistics

DLN	**LRN**	**NAHLN**	**NPDN**	**FERN**	**ERLN**	**Vet-LIRN**
DoD Laboratory Network	Laboratory Response Network	National Animal Health Laboratory Network	National Plant Diagnostic Network	Food Emergency Response Network	Environmental Response Laboratory Network	Veterinary Laboratory Investigation & Response Network
DoD	CDC	USDA	USDA	USDA/FDA	EPA	FDA

Figure 1. Organizational Structure of ICLN

The analytical scope of each of these networks is described below.

Department of Defense Laboratory Network: The DLN is a coordinated and operational system of DoD laboratories, programs, and activities possessing analytic and/or incident response capabilities. *The DLN provides timely, high-quality, actionable results for early detection, confirmation, and effective consequence management of acts of terrorism or warfare involving CBRN agents, infectious disease agents, and other all-hazards agents of military or national significance in support of the DoD's global and homeland defense missions.* In accordance with applicable laws governing the DoD and the Federal Government, the DLN provides support to civil authorities and participates in ICLN integrated incident responses.

Laboratory Response Network: The LRN is managed by HHS CDC. This includes the CDC LRN-Biological (LRN-B), the CDC LRN-Chemical (LRN-C), and the CDC Radiological Laboratory. It is a joint effort among CDC, DOJ, FBI, the Association of Public Health Laboratories, and DoD. *The current mission of the LRN is "to develop, maintain and strengthen an integrated domestic and international network of laboratories to respond quickly to biological, chemical, and radiological threats and other high priority public health emergency needs through training, rapid testing, timely notification and secure messaging of laboratory results."*

National Animal Health Laboratory Network: The NAHLN is a cooperative effort between two USDA agencies, the Animal and Plant Health Inspection Service (APHIS) and the National Institute of Food and Agriculture (NIFA). The implementation and success of the NAHLN relies

heavily on partnership among the state and university animal diagnostic laboratories that meet NAHLN capability and capacity requirements, the American Association of Veterinary Laboratory Diagnosticians, and the State Animal Health Officials. *The network's purpose is to enhance the Nation's early detection of, response to, and recovery from animal health emergencies, including bioterrorist incidents, newly emerging diseases, and foreign animal disease agents that threaten the Nation's food supply and public health.*

National Plant Diagnostic Network: The NPDN is managed by USDA NIFA. *The mission of NPDN is to enhance national agricultural security through rapid and early detection, diagnosis, and timely communication of outbreaks of potentially damaging pests of food, feed, fiber, fuel crops, and forest trees.* NPDN is designed to protect plant health and productivity of U.S. agricultural and natural ecosystems by providing early detection and identification of plant pests and diseases and to enhance agricultural biosecurity by detecting instances of biological attacks. The network is supported by the collective efforts of Federal, State, and Land Grant University-associated plant disease clinics. NPDN provides essential testing capacity for APHIS when needed to help with sample surge diagnostics of regulated pests during outbreaks.

Food Emergency Response Network: The FERN is a partnership managed by USDA's Food Safety and Inspection Service (FSIS) and HHS's Food and Drug Administration. Laboratories participating in FERN at the federal, state, and local level are responsible for detecting and identifying biological, chemical, and radiological agents in food. *The primary objectives of FERN are to help prevent attacks on the food supply through utilization of targeted food surveillance; prepare for emergencies by strengthening laboratory capabilities and capacities to respond to threats, attacks, and emergencies in the food supply; and assist in recovery from such an incident.* Program commodities could include, but are not limited to, imports, school lunch programs, and special events such as political conventions, major sporting events, or other events where large or high-profile groups of people are gathered.

Environmental Response Laboratory Network: The EPA established the ERLN to assist in addressing chemical, biological, and radiological threats during nationally significant incidents. The ERLN is managed by EPA's Office of Emergency Management and serves as a national network of laboratories that can be accessed as needed to support large-scale environmental responses by providing consistent analytical capabilities, capacities, and quality data in a systematic, coordinated response. *The ERLN provides analytical support to EPA regional responders and program offices such as the Office of Water and Office of Radiation and Indoor Air for characterizing the extent and degree of contamination in environmental media during response and remediation activities, as well as providing analytical support for post-decontamination and clearance activities.*

Veterinary Laboratory Investigation and Response Network: The Vet-LIRN is managed by FDA's Center for Veterinary Medicine. The primary objective of Vet-LIRN is to promote human and animal health by partnering with more than 40 state and university veterinary diagnostic laboratories. *Vet-LIRN laboratories help FDA investigate potential adverse events affecting the Nation's food or animal feed supply by testing animal diagnostic samples, veterinary products, or animal feeds.* Vet-LIRN laboratories develop chemistry and microbiology testing methods for nontypical biomatrices and analytes and maintain preparedness

by optimizing and harmonizing testing methods, conducting limited surveillance exercises, and participating in network proficiency exercises.

ICLN Subgroups/Workgroups

Permanent and ad hoc subgroups support NCG decision-making by providing consultation on matters such as training, logistics, and methods. ICLN subgroups include Scenario/Threat Prioritization, Methods Detection Technology, Proficiency Testing/Quality Assurance (PT/QA), Training, Radiological Laboratory Response, Sample Prioritization, and Laboratory Logistics. These subgroups typically comprise subject matter experts from federal, state, and local laboratory environments. A federal staff member within the response laboratory network system chairs each subgroup. The subgroups review key issues and network requirements as assigned by the NCG, such as agent prioritization, methods development and standards, information technology, and training requirements; they devise recommendations for operational options under consideration by the NCG and inform perspectives on evolving internetwork policies. Additionally, these technical subgroups produce reports for the ICLN, which the NCG reviews and processes as operational guidance for the ICLN. An expanded description of the subgroups and workgroups is included in Appendix A.

Common Laboratory Methods and Information Sharing

The ICLN has undertaken a series of efforts to establish common laboratory methods and facilitate sharing of methods to better prepare for and execute joint responses to large-scale incidents. The ICLN developed a <u>methods registry</u> that lists agents for which methods are available and cross-references them with several key attributes, including the matrix for which a method is suitable; level of validation of the method; instrumental parameters of the method; and a point of contact within the originating agency for further detailed information on the method. At present, the methods registry contains methods information for agents from within the chemical, biological, and radiological threat areas and across human clinical, animal clinical, food, and environmental matrices. The registry is accessible to approved ICLN member network staff via the ICLN Portal at www.icln.org.

The ICLN Methods subgroup is responsible for periodically updating the information in the methods registry. The development of methods relies on funding and staff available within the member network proponent agencies (see Figure 1). The principal responsibility for prioritization of agents for method development, however, resides in the ICLN Scenarios/Threat Prioritization subgroup. Risk assessments performed by DHS are viewed as an important source of information to guide agent prioritization.

To ensure a common understanding of the methods and their appropriate applications, the ICLN recognized the need to establish some key guidelines and supported the development of several documents conveying these guidelines:

- **Methods Validation Standard Operating Procedure (SOP)**. This document, publicly accessible via the ICLN Portal, broadly informs the process of defining and communicating the level at which method performance is understood in practice. Levels of validation extend from characterization of the method by a single originator in one laboratory (level 1) to full statistical characterization by multiple laboratory practitioners across a large number of laboratories (level 4). The Methods Validation SOP classifies the validation of methods to be used by member network laboratories in response to a CBRN incident.

- **Chain of Custody Form**. This resource, also publicly available at the ICLN Portal, documents the custody, control, transfer, and disposition of samples. Such documentation, which follows each sample being analyzed, is critical to ensuring that an individual lab result is associated with the correct sample. There is no universal standard form, and the ICLN imposes no requirement on any member network to use this particular form. However, all networks must use some form to ensure correct linkage of results with samples, and the ICLN Chain of Custody Form provides a model for new networks to use should the need arise.

- **Sample Collection and Handling Guidelines**. This document, also available at www.icln.org, provides the principles and procedures for sample handling to ensure that samples are appropriately and consistently handled across the member networks. These

guidelines help to ensure that samples are not contaminated or allowed to deteriorate prior to analysis in the laboratory.

Optimizing Preparedness and Surge Capacity

The ICLN was formed to enable federal laboratory networks to work cooperatively to optimize preparedness and provide analytical surge capacity in the event of large-scale incidents requiring the resources and capabilities of more than one network. In order to manage networks' joint participation in resolving a major incident, as well as to facilitate their collaboration in developing guidance documents and information repositories, the ICLN developed a web utility known as the ICLN Portal. A critical component of that portal is a means to aggregate laboratory data from the federal laboratory networks into a common data format and make that aggregate repository searchable by the network(s) having primary responsibility for resolving an incident, per their proponent agency's mission. This data aggregation tool is the Data Exchange Utility (DEU).

The ICLN developed an SOP to promote consistency and uniformity in communications among the ICLN member networks and key stakeholders during the execution of a joint response. The SOP is refined by being evaluated through the development and conduct of periodic exercises that mimic a large-scale contamination incident or through real-life incidents such as response to the COVID-19 pandemic. Another key resource developed and maintained by the ICLN is a database of the laboratories that are members of each of the ICLN networks. Each of these components of the ICLN preparedness posture is described in turn.

ICLN Web Portal

The ICLN Portal is a secure, password-protected web portal used by member networks daily or during an exercise or incident response. The portal, located at http://www.icln.org, hosts the ICLN's guidance documents and serves as a common resource location for members of the NCG, the technical subgroups, and others requiring access to a collaboration workspace for activities within the scope of ICLN. The home page of the website also includes a publicly accessible area where several guidance documents and recorded webinars are available for access.

During joint response incidents, the password-protected side of the portal serves as the single platform to facilitate communication and coordination among the participating member networks. The portal serves as a secure, online incident command center for the arrangement and conduct of meetings, including webinars, sending and receiving alerts, emails, and situation reports, and saving miscellaneous documents of importance to a given response. All communications through the portal are saved and archived and can serve as a historical record of a response.

Data Exchange Utility

The creation and refinement of the DEU was a critical step toward ensuring the capability to provide surge analytical capacity to a network overwhelmed by large numbers of samples. Hosted on the ICLN Portal, the DEU is an information technology infrastructure that supports the exchange of laboratory results data. Residing on the password-protected side of the ICLN Portal, the DEU transforms data presented by networks in their own "native" format into a common ICLN data format. This common ICLN format resulted from extensive engagement among member network representatives through the Methods subgroup to develop a format that accommodates needed mandatory and optional attributes associated with chemical, biological, and radiological samples from all types of matrices (including human clinical, environmental, food, plant, and animal clinical samples). The DEU permits users to search aggregated data using various search parameters and facilitates download of the data to a member network's system for further processing in the course of resolving an incident. Data relating to a given incident is maintained and archived on the ICLN Portal server for as long as the primary network in a response requires. The DEU was first implemented as an operational utility in 2012 and was updated in October 2017. Currently, a revised beta version of the DEU is being developed. It should be operational in the early part of fiscal year (FY) 2021.

Sharing of data among networks during an incident is governed by a formal document known as an Incident-Specific Data Sharing Agreement, which describes in detail the following attributes that contribute to the protection and security of data: which network is primary for the response and which networks are providing assistance, what data parameters are required by the primary network, the intended purpose of the data, how aggregated data will be shared and used, how accuracy of data is validated, which networks have permission to access and distribute the data, and how long data should be retained once the incident has been resolved. Direction and agreement on sample attributes to be reported along with the data are critical toward ensuring that the data associated with all samples are meaningful and interpretable in the context of the specific response challenge.

Standard Operating Procedure for Incident Response

The ICLN established and regularly refines an SOP to promote smooth execution of the relatively complicated series of actions that characterize an effective response by multiple agencies. The most current version of the ICLN SOP was finalized in May 2020. This SOP is followed by the ICLN NCG upon a notification by any member network that joint action is currently required, or may be required in the near future, to resolve a significant CBRN contamination or disease incident. The SOP guides NCG representatives through the use of the tools available through the ICLN Portal. While the primary users of the portal are NCG and other Federal Government laboratory network representatives, external experts can access the portal, if necessary, with limited permissions and for limited duration, to provide unique technical perspectives on an evolving incident.

The SOP outlines procedures that may be required during incident response. These procedures include using the ICLN Portal for communication and coordination during a joint response;

developing and sending alerts and situation reports; identifying and negotiating resources available to support the response; agreeing on methods to be used and the reporting and releasing of data among networks; and demobilizing resources and preparing an After-Action Report at the conclusion of incident response.

The SOP also includes emergency contact information for each ICLN member network representative as well as the specific templates for documents to be used during incident response, as outlined in the procedures. These documents ensure consistency in response, sample analysis, data transfer, and after-action reporting.

Exercises

A critical component of ICLN success in incident response management is communication before and during events. The ICLN has undertaken much work in this area to build the relationships necessary to support effective laboratory response. Ongoing exercises and efforts to measure sample throughput help identify room for growth and focal areas for improvement. The ICLN uses three exercise types that are more in depth than the standard Homeland Security Exercise and Evaluation Program exercise types. These include virtual tabletop exercises (TTX), periodic portal drills, and interagency collaborations. To improve use of the ICLN coordination tools by all NCG representatives, a program of periodic drills focuses on completing specific tasks on the ICLN Portal (see Table 1).

Virtual TTX are conducted over several days approximately twice per year. Since 2008, the ICLN has conducted 19 virtual TTX exercises that have spanned scenarios involving chemical, biological, and radiological agents in contamination of the environment and food matrices as well as in animals and plants (see Table 2). The conduct of TTX involves a subset of the seven ICLN member networks. In this extensive set of scenarios, all networks participate in the role of both a lead response network and a supporting response network assisting a lead network. These exercises enhance understanding of ICLN SOP procedures and network capabilities and limitations. The TTX provide the NCG with a better sense of needed changes to key ICLN infrastructure such as the ICLN Portal and guidance documents such as SOPs. These types of exercises have improved knowledge of network/agency responsibilities and capabilities, enhanced overall execution of the laboratory incident response process, and increased the use and quality of communications through the ICLN Portal.

Exercises in all forms constitute an essential element in maintaining ICLN readiness and promoting refinement of tools and procedures. Each exercise leads to further understanding of areas that might limit network interoperability. The lessons learned during these exercises lead to improved communication among NCG members, enhanced use of the ICLN Portal tools, and better maneuverability within the portal environment.

Table 1. Periodic Portal Drills (October 2017–August 2020)

- DEU Data Upload Training for the Mixed Agent TTX
- Complete and upload the Incident Closeout Form (pdf. version)
- Send Preparedness Alert via mobile device
- Update user profile on the ICLN Portal via mobile device
- Send email from the ICLN Portal via mobile device
- Test the discussion feature on the ICLN Portal
- Test the activity feed feature on the ICLN Portal
- Create an online meeting using Zoom.gov

Table 2. ICLN Exercises and Interagency Collaborations

Year	Analyte	Matrix	Scenario/Incident Description
2008	B. anthracis	Human clinical, environmental	Spores dispersed indoors
2008	Melamine	Human clinical, food	Melamine in macaroni product
2009	Avian Influenza (H5N1)	Human clinical, animal clinical, food	H5N1 outbreak in poultry
2010	B. anthracis	Human clinical, environmental	Anthrax released during parade
2010	C. botulinum	Human clinical, food	Ground beef contaminated with C. botulinum
2010	Sodium fluoroacetate	Human clinical, food	Sodium fluoroacetate in yogurt
2011	Foot and Mouth Disease (FMD)	Animal clinical, environmental	FMD outbreak in cattle, sheep, and pigs
2011	Rathayibacter toxicus	Animal clinical, environmental, plants	Infected seed galls in Rye grass
2012	Strontium-90 and Plutonium-238	Human clinical, animal clinical, food, environmental, plants	*Radiological* Dispersal Device (*RDD*) detonated in 3 different cities
2012	Classified Chemical Agent	Human clinical, animal clinical, food (civilian, military, and animal)	Chemical in milk powder (Military MREs, baby formula, and animal milk replacement)
2013	Foot and Mouth Disease	Human clinical, food, environmental	FMD in milk
2013	Mixed fission products	Human clinical, food, environmental	Radiological Improvised nuclear device (IND)
2014	B. anthracis	Human clinical, environmental	Interagency exercise, included spores dispersed outdoors.
2014	Cyclosarin	Human clinical, environmental	Dispersed in an airport; secondary contamination of subway
2015	Strontium, gross-alpha beta, and actinide series	Human clinical, animal clinical, food, environmental, plants	Nuclear Power Plant release after an earthquake
2015	Sodium fluoroacetate	Human clinical, animal clinical, food, environmental	Chemical in milk powder (baby formula and animal milk replacement)
2016	Strontium	Environmental	Interagency exercise, included laboratory analysis of samples (Northern Lights).
2017	Cyanide/Ethyl Parathion/ Strontium-90	Human clinical, animal clinical, food, environmental	Mixed agent release from train car crash.
2018	Opioid	Human clinical, animal clinical, food, environmental, and plants	Chemical sprayed onto lettuce in the field.
2020	COVID-19 Interagency Collaboration	Human clinical, animal clinical	Assisting with COVID-19 related laboratory preparedness

Member Network Laboratories Database

Provision of analytical services to resolve samples and provide data occurs at the individual laboratory level. Some 450 individual laboratories across the seven ICLN member networks constitute the analytical power available to ICLN in a joint response action. These laboratories have their daily work routines that substantiate their existence. When an ICLN member network is called upon to provide service in responding to a CBRN incident, the network will consider a number of factors in identifying and negotiating a network member laboratory's participation. Such factors include current standing on proficiency assessments, proximity to the location of the incident, potential sample throughput capability, and ongoing obligations of the laboratory. Additionally, many laboratories are members of multiple ICLN member networks.

The NCG determined that a database of all the laboratories in the ICLN member networks and their general capabilities would be important in identifying the analytical resources brought to bear in each response scenario. The NCG created and periodically updates this database to ensure it is as current as possible.

Building Relationships That Will Support a More Effective and Integrated Response During Emergencies

From its inception, the ICLN has recognized the very significant value of successful integrated response across multiple agencies. To this end, the NCG has met approximately monthly since 2005. Even during the unfunded period between February 2019 and March 2020, the ICLN NCG members still met 11 times on a volunteer basis. Funding was made available and ICLN re-established formal operations in April 2020 as a result of COVID-19. Generally, on an annual basis, the ICLN NCG meets with the Joint Leadership Council to present progress and discuss strategic direction policy and initiatives. The last official meeting of the ICLN JLC occurred in September 2018. At each of these meetings, the leadership of ICLN participant agencies as represented on the Joint Leadership Council have noted the remarkable success of the ICLN in maintaining its viability and increasing maturation across more than a decade of existence. As of this report, all the original membership of the NCG, technical subgroup leaders, and Joint Leadership Council senior policy members have changed, and the ICLN continues as a viable interagency organization, suggesting that it has become an essential element of the fabric of the member agencies.

The MOA that substantiates the existence of the ICLN was first created and signed in 2005 and updated in 2012 and 2016. The process of updating the MOA contributes not only to the formal establishment of the relationship that is the ICLN, but also necessitates a reflection upon the value of the ICLN relationship and the commitment each agency and member network brings to the relationship.

The 2016 update of the ICLN MOA incorporated the agreement among agencies to share data in emergency situations, the essential element of agreement that makes the ICLN viable as a functional integrating response entity. The data-sharing agreement establishes the framework for transfer, proper management, ownership, and the uses of data that the member networks will convey during an emergency response. It was developed over numerous discussions and refined through the relationship-enabling environment of the series of TTX and other joint activities.

Other activities have contributed to the strength of the ICLN relationship. It was recognized early on that networks must feel confident in the ability of laboratory members of other networks to competently perform analyses with methods and matrices they may not use on a regular basis (e.g., an analytical method provided by a lead network in an incident response to a network providing support during that response). The ICLN has conducted several laboratory-based exercises called Confidence Building Competency Tests (CBCTs) to promote such confidence in laboratory network performance during cross-network actions. The ICLN CBCTs are developed to assess specific aspects of interoperability of laboratory networks regarding the provision of agent detection and surge support to each other during a large-scale event. Specific aspects of interoperability explored as part of a CBCT include the ability to perform a nonroutine method at an acceptable level of quality and the ability to combine information from several networks using prescribed data communication procedures. The CBCT is explicitly not intended to be an exploration or demonstration of proficiency in a method, nor is it intended to indicate a quantitative expansion of capacity through sharing of samples across ICLN networks. These

more rigorous examinations would require more expansive tests involving much larger numbers of samples and participating laboratories.

In all such studies, it was observed that proficient laboratory analysts demonstrated competence at performing methods they don't perform in their everyday jobs. Accordingly, the networks have become very comfortable with the notion of depending on other networks for analytical support when they are overwhelmed with samples from a large incident.

The ICLN and its member networks recognized the importance of seeking visibility with the approximately 450 laboratories that provide the analytical capacity that is potentially available through the ICLN member networks. The member networks convene periodic conferences among their membership and frequently invite the managers of other networks, including the DHS NCG Chair, to make presentations or participate in panels before their constituencies in attendance. These activities help laboratory managers and practitioners to understand the organizational framework to which all contribute to a joint response coordinated through ICLN. Additionally, to ensure further understanding of the ICLN, an "Ask ICLN" link has been placed on the ICLN's public-facing web page (www.icln.org) that allows the public to ask a question of the ICLN leadership and/or ICLN network membership.

Finally, a key element of any organization is to undertake a periodic examination and adjustment of its strategy for the future. Strategic planning has been an essential element of the maturation of the ICLN, having conducted major strategic planning meetings in 2007, 2012, and 2015. In each of these face-to-face encounters among all NCG representatives and subgroup leaders, relationships have solidified as future objectives were considered and prioritized. During its 2015-16 planning cycle, the ICLN identified several objectives meriting additional focus over the near future:

- Integrate existence and processes of the ICLN with appropriate Incident Annexes of the National Response Framework.
- Identify regulatory requirements that may impede rapid response and assess possibilities for waivers or exclusions in the face of urgent need.
- Develop appropriate benchmarks against which to measure ICLN and member networks' capabilities.
- Integrate ICLN into other interagency and national-level exercises, as appropriate.
- Interface with international lab response entities to organize other countries' laboratory assets into similar integrated bodies with the eventual goal of optimizing laboratory response to any large CBRN incident worldwide.

The next major strategic planning meeting will be scheduled and executed in 2021.

ICLN Successes (November 2017–August 2020)

The ICLN has five strategic goals as part of its Integrated Response Architecture. These are:

- Goal 1: Strengthening ICLN incident response capabilities.
- Goal 2: Strengthening ICLN technical capacity.
- Goal 3: Improving and expanding ICLN exercises and participation in these exercises.
- Goal 4: Develop and build outreach for the ICLN.
- Goal 5: Addressing current topics of interest (e.g., COVID-19, improve coordination of equipment purchases, etc.)

ICLN NCG Accomplishments Since the 2018 FSMA Report (FY 2018):

- In January 2018, the ICLN published the report *Status of the ICLN Report to Congress*. This document supports the reporting requirement for the Food Safety and Modernization Act.
  - This report supports our FSMA biennial regulatory requirement and addresses the strategic goal to build ICLN outreach.

- Initiated periodic drills of the ICLN Portal.
  - Supports the ICLN exercise participation goal.

- Updated and revised the Key Process Steps Checklist to incorporate suggestions made during monthly drills and lessons learned during exercises.
  - Aided in the goal of strengthening incident response capabilities.

- Updated and revised the ICLN Integrated Response Architecture (IRA) operational diagram.
  - This diagram serves as a guide on the process of how assets and resources might be shared in response to an incident requiring involvement of multiple networks.

- Updated and revised the Responsible Federal Department/Agency matrix.
  - Revision of this matrix improves incident response by informing networks about which agency is responsible for each matrix or commodity (e.g., human clinical, animal clinical, food, environmental, plants/crops still in the field, animals still in the field) and which agent category of concern (i.e., chemical, biological, radiological/nuclear).

- Hosted a multi-agency forum on fentanyl and fentanyl analogs to examine the extreme hazard posed by contact, ingestion, and/or inhalation risks to our lab personnel and first responders.
  - The forum, held in January 2018, was developed to gather feedback on the larger issues related to fentanyl analysis and laboratory preparedness, including identifying gaps in laboratory response and ways in which the ICLN can assist.

This activity helped to strengthen ICLN incident response associated with opioids and strengthened technical capacity and capabilities.

- Organized multi-network discussions in May 2018 to determine networks' use of future technology to analyze for *C. botulinum* toxins and whether those efforts can be shared among ICLN members. This task was initiated because the healthcare company Roche recently stopped producing their test kits (Botulinum Toxin (A, B, E, or F) ELISA Kit).
  - This activity strengthened response and technical capacity of the ICLN by providing alternate technology to use when analyzing for *C. botulinum*.

- Continued to update and improve the ICLN Portal and DEU. Some high-level improvements included:
  - Created an electronic incident closeout form for which a decision is made on data retention for each incident.
  - Updated the electronic Situation Report Form on the ICLN Portal.
  - Updated the Data Exchange Utility User Guide and Combined Registry User Guide.
  - Updated the Minimum Data Elements file, the DEU User Guide, and the Incident Specific Data Sharing Agreement template to make data elements consistent; updated the Incident-Specific Data Sharing Agreement template to include conditional mandatory data fields.
  - Updated the Activity Feed area on the ICLN Portal to be more user friendly.
  - Updated the Discussion feature on the ICLN Portal.
  - Revised and tightened access restrictions to the Combined Registry database and the ICLN Portal.
  - Improved and tested ICLN Portal access from multiple types of mobile devices.
  - The outcome of these improvements is strengthened ability to communicate and share information and resources during incident response requiring support from multiple networks.

- Initiated the planning team process and moderated the ICLN Opioid TTX, which was held in September 2018.
  - This activity supported the goals of participation in exercises related to current events, improved incident response capabilities and enhanced technical capacity.

- The ICLN performed outreach activities to provide information to external parties about the ICLN and its products. These activities included the following:
  - Presented a poster on the ICLN at the National Association of County Health Officials Preparedness Summit, Atlanta, Georgia, April 2018.
  - Provided briefings at the DOE National Analytical Management Program/DOE/National Nuclear Security Administration Analytical Managers Meeting (NAMP/DAMM), held at Y-12, Oak Ridge, Tennessee, in June 2018. The presentations were "ICLN 101" and "ICLN Mixed Agent Tabletop Exercise Outcomes."
  - Wrote the ICLN Biennial Report as required by the Food Safety and Modernization Act.

- o Created the first draft of the ICLN Newsletter, introducing readers to the ICLN program and providing details on the ICLN TTX program.
  - o These activities supported the strategic goal to develop and build outreach for the ICLN.

- Methods/Detection subgroup – Revised documents, including the Chain of Custody Form, the Sample Collection and Handling Guidelines, and the Guidelines for Comparison of Validation Levels between Networks. The Methods subgroup also assisted in developing the ICLN August monthly exercise where members had to seek out answers from searching data in the Combined Registry on the ICLN Portal.
  - o This activity improved laboratory sample collection documentation and addressed the need to participate in ICLN exercises related to current day topics of concern.

- Radiological Laboratory subgroup (RLS) – Participated in the Northern Lights interagency exercise, updated a document on laboratory limiting issues, began drafting a white paper on critical needs for radiochemists, and conducted a workshop at the Radiobioassay and Radiochemical Measurements Conference on the ICLN Mixed Agent TTX.
  - o Activities of the RLS addressed current topics of concern (laboratory limiting issues) and represented participation in interagency exercises.

- Sample Prioritization subgroup – Finalized the Sample Prioritization document, which describes the types of decisions that will be needed during different phases of an incident as a means to frame sample prioritization during an incident.
  - o Development of this document strengthened knowledge related to incident response capabilities and procedures, specifically if there are multiple networks that need to utilize the analytical capabilities of the same laboratory.

ICLN NCG Accomplishments (FY 2019):

- Because of a lack of dedicated funding in the FY 2019 budget, the ICLN was paused between February 2019 and March 2020. CWMD resourced and re-established formal operation of the ICLN in April 2020.

- Although deactivated, network representatives of the ICLN continued to meet for the monthly NCG meeting.
  - o The ICLN NCG informally met 11 times over the 13 months that the program was unfunded.
  - o ICLN network members continued to promote the necessity of the ICLN program to senior agency executives during this period. NCG members also attended various federal CBRN-related meetings and discussed the benefits of the ICLN program (e.g., National Biodefense Summit).

- During this period, the Radiological Laboratory subgroup (RLS) and the Methods subgroups also continued to meet.

- o The RLS continued to meet on the first and third Thursday of each month. The RLS subgroup addressed the following projects during the 13-month shutdown:
  - ➤ Listing essential radiological laboratory supplies and equipment
  - ➤ Finalizing the *Lab Limiting Issues* document
  - ➤ Developing the *Radioanalytical Systems Lessons Learned* document intended to capture historical and institutional knowledge and experience of the aging radioanalytical workforce

- o The Methods subgroup reduced the frequency of their meetings from twice a month to once a month; however, they worked on the following activities during the 13-month shutdown:
  - ➤ The Methods subgroup met 12 times to discuss the following: Homeland Security Information Network (HSIN) migration of ICLN documents; access to the HSIN storage area; method gap analysis and method assessment (determining which analytes on the Chemical Terrorism Risk Assessment (CTRA) list networks have methods to identify); discussions of Chemical, Biological, and Radiological Risk Assessments (CTRA, Biological Terrorism Risk Assessment, Radiation and Nuclear Terrorism Risk Assessment); and new technologies and platforms.
  - ➤ The subgroup discussed inviting subject matter experts to speak at presentations:
    — Dr. Shanmuga Sozhamannan gave a presentation on April 16, 2019: Overview of Defense Biological Product Assurance Office.
  - ➤ Discussed National Biodefense Summit hosted by HHS Assistant Secretary for Preparedness and Response.

- During the resource lapse, the internal ICLN login was inactive, but the public ICLN.org website was still available.
  - o On the public website, more than 70 DOE radiological training videos were available at the following link: https://www.icln.org/webinars.cfm. These videos include 64 NAMP, 10 Gen IV International Forum (GIF), and 2 Hanford. Many of these webinars were recorded during the active ICLN years, but they were kept available as a remote radiological training option. There were 1,478 viewings of these training videos from May 2019 to March 2020.

The above activities helped fortify the ICLN goals related to strengthening ICLN technical capacities/capabilities, incident response, and outreach.

Fiscal Year 2020 (beginning April 2020):

- CWMD reengaged the ICLN in April 2020.

- The ICLN Portal was also restarted. This allowed internal communication between ICLN networks to occur within an electronic system.

- o Two separate training sessions were held for NCG members to refamiliarize themselves with available tools on the ICLN Portal.
  - o The ICLN Portal interface was revamped to make it more user friendly and intuitive. This included a new Situation Report interface.
  - o A mock incident was created so that network participants could practice using the ICLN Portal tools (Preparedness Alerts, Situation Reports, creation of a collaboration meeting, etc.).
  - o The above activities support the goals of strengthening incident response capabilities and the ability to improve incident response through participation in tabletop and multi-agency exercises.

- The ICLN NCG SOP was updated, including revising the Emergency Contact List that includes rosters of network coordinators and representatives along with their contact information (email, work phone, cell phone).
  - o This update strengthened ICLN incident response capabilities.

- Official monthly NCG meetings were reinstituted on the third Wednesday of each month. (These meetings had continued during the year the ICLN was deactivated, but they were sparsely attended.)
  - o This activity helped strengthened ICLN incident response capabilities and build outreach for the ICLN.

- Subgroup meetings began to officially convene again for the Methods subgroup and the Radiological Laboratory subgroup.
  - o This activity helped strengthened ICLN incident response capabilities and build outreach for the ICLN.

- Due to the COVID-19 pandemic, the ICLN was utilized to address many topics, including the following items:
  - o Created an ICLN COVID-19 incident to allow internal communication on updates related to human and animal testing.
  - o Addressed veterinary issues related to the COVID-19 response.
  - o Shared information on updates related to human-animal and animal-human infectivity of COVID-19.
  - o Discussed the possibility of using networks that perform animal testing to assist with human testing for COVID-19.
  - o Investigated the ability for networks to share supplies such as masks and reagents with networks performing human testing for COVID-19.
  - o Requested feedback on whether networks have the ability to test personal protective equipment to assist with identifying counterfeit N95 masks.
  - o These activities helped support the strategic goal of addressing current topics of concern.

- Created periodic (bimonthly) drills to practice utilization of specific tools and functions of the ICLN Portal. This supported the goal to improve and participate in ICLN exercises.

- Finalized the ICLN Rad Lab Subgroup's documents entitled *The Tenuous Future of Radiological Laboratories: Addressing the Declining Operational Readiness for Mission Critical Activities* and *Addressing the Unique Resources of Radiological Laboratories for Emergency Response: A Briefing for Senior Executives and Administrators.*
    - o This activity informed the goals related to ICLN technical capacity and incident response.

COVID-19 Response

The ICLN was not active in March 2020 when the COVID-19 response was initiated in the United States. Therefore, the ICLN did not substantially contribute to the coordination of the analytical laboratory response, although informal communications channels did remain open among the ICLN participating agencies. The ICLN Portal, the primary tool for communications and coordination, was inactive, but the capability remained ready to be activated once supporting resources and government executive direction were reestablished.

In April 2020, CWMD, at the initiation of the DHS/CWMD Chief Medical Officer, provided the requisite resources, directing that the ICLN capability be reestablished. An IT and administrative support contract was put in place under the former ICLN Program Manager to ramp up the capability as it had existed prior to February 2019. The ICLN Portal was reactivated and updated to allow access and utilization by the ICLN member networks, and formal Network Coordination meetings were resumed. With the resumption of the capability, the team recognized the need for a coordinated COVID-19 response among the laboratory networks. LRN-B, ERLN, NAHLN, Vet-LIRN and DLN networks were, and are, currently active in the COVID-19 response.

Despite the activation of the ICLN, at the direction of the Executive Branch, the national analytical response for COVID-19 was delegated to state and county public health laboratories, some of which are members of one or more of the ICLN member networks. Ad hoc communication and coordination channels, resulting from ICLN partnerships, were established among these laboratories on an as-needed basis, according to local needs and direction, without federal leadership. The increased analytical surge of COVID-19 samples was shared between academic, medical/clinical, and commercial laboratories that possessed Clinical Laboratory Improvement Amendments certification, while state and local capabilities and capacities were identified. It has been noted that during this time there was no centrally unified structure to help guide laboratory coordination, data sharing, sample analysis, and/or decision-making.

Since the reactivation of the ICLN in April 2020, this group has supported information sharing among the member networks with monthly COVID-19 updates and discussions, in addition to the ongoing day-to-day incident communications routed through the ICLN Portal. Some of the issues that the ICLN has addressed relate to animal testing and transmissibility, leveraging animal clinical resources to support the human clinical response activities, and a number of logistics issues (more completely addressed in the FY 2020 accomplishments noted above).

Critical Lessons Learned from the COVID-19 Response (Ongoing Effort)

The COVID-19 response identified several gaps and lessons learned that fall under the scope and purview of the ICLN. For example:

- ICLN participation is currently limited only to federal analytical laboratory networks, which is just a small subset of the national analytical capability and capacity, which includes academic, medical/clinical, commercial, and nonaffiliated state, local, tribal, and territorial laboratories (e.g., medical/criminal forensic labs).

- Not all federal analytical capability and capacity is affiliated with ICLN member networks (e.g., the Customs and Border Protection laboratory and the CDC Influenza laboratory network).

- Although ICLN member networks conduct surveillance according to their individual responsibilities and authorities, no coordinated mechanism is in place to share, analyze, track, and archive surveillance data for the purpose of enabling identification of suspicious events that might indicate the nexus of a potential incident and trigger a response.

- There is currently no coordinating body that would sustain analytical data aggregation and complete analysis in order to support decision-making, nor is there a mechanism to assess the quality and breadth of available analytical data that also would be used to support the public health decision-making process.

- Analytical logistics coordination needs to be integrated into the ICLN Portal process and tool set. This has been a consistent request from participating networks along with the ability to combine analytical data sets. The resulting analytical information can then be utilized to make appropriate time-sensitive public health decisions (e.g., whether to utilize community mitigation, medical pharmaceutical countermeasures (if available), or other necessary public health response actions).

These are complex issues requiring complex solutions that impact the tactical, operational and strategic levels. The lessons learned report will analyze the strategic implications and propose solutions to the identified issues.

Path Forward for the ICLN

Informed by lessons learned from the COVID-19 response and feedback from the ICLN member networks, ICLN leadership intends to evolve the program in the following directions. This is subject to the approval and support of the Joint Leadership Council and availability of budgetary resources:

1. Perform a strategic review of ICLN authorities, responsibilities, capabilities, gaps, and limitations to inform future planning activities. Initiate necessary legislative actions to address the gaps in authorities that are identified.

2. Perform a complete lesson learned analysis of the COVID-19 response with respect to analytical support and laboratory collaboration activities.

3. Perform a laboratory risk assessment to ensure future laboratory preparation for high-risk incidents.

4. Engage in outreach activities with the intent to partner with analytical laboratory stakeholders within and outside the Federal Government to enable a whole-of-Nation coordination of laboratory resources and response.

5. Develop a national analytical laboratory data aggregation and analysis capability.

6. Develop and integrate an analytical data surveillance and data mapping capability into the ICLN Portal.

7. Integrate ICLN capability into the national exercise and incident response framework.

Conclusion

The ICLN provides an operational, cost-effective contribution to national security. It is poised to deal with high-consequence, low-probability events by leveraging the capabilities of existing laboratory networks. It promotes laboratory network readiness and interoperability.

The need and value of the ICLN program became apparent during the one-year hiatus (February 2019 – March 2020). NCG members continued to meet to communicate, collaborate, and share updates about their networks' activities. Many NCG members assisted in notifying senior-level agency representatives of the importance of this program should a joint laboratory response ever occur and the need to bring the program back to operational status. When the COVID-19 pandemic surfaced, the ICLN was reengaged.

The important work of the ICLN will continue to evolve. As present in the FY 2022 Budget, exercises to test existing and planned capabilities, as well as coordinating meetings to maintain the operational status of the ICLN, will continue to occur on a regular basis. Most importantly, the ICLN is poised to continue to serve in the event its coordinated and operational system of laboratory networks is needed to provide timely, high-quality, and meaningful results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response.

APPENDIX A

ROLES AND ACTIVITIES OF THE ICLN

SUBGROUPS AND WORKGROUPS

Scenario/Threat Prioritization

The Scenario/Threat Prioritization subgroup is responsible for considering risk assessments in the Chemical/Biological/Radiological (CBR) domain to provide guidance to the ICLN regarding the highest risk scenarios and agents that may stress the ICLN member networks. This subgroup comprises the principal coordinators of ICLN NCG member networks as well as DHS and FBI.

Methods/Detection Technology

The purpose of the Methods subgroup is to consider network needs and identify available and emerging analytical methods and provide a mechanism to coordinate development, validation, and deployment of assays between networks and agencies to increase efficiency, transparency, and consistency.

The purpose of the Detection Technology side of the Methods subgroup is for NCG members to relay information about methods and technologies they are currently using or technologies they plan to adopt. This includes discussing current platforms and why one platform was chosen over another; sharing information on the technology they may be adopting in the near future and asking for feedback from others that have adopted similar technology; discussing ways to expand capacity of specific technology due to adaptations made by laboratorians; and to share on implementation adaptations that may increase throughput of a specific piece of equipment.

Proficiency Testing/Quality Assurance

The purpose of the PT/QA subgroup is to ensure confidence in laboratory results across networks through a coordinated approach for the development and implementation of PT/QA programs.

Training

The Training subgroup acts as a conduit for sharing training guidance, opportunities, and resources, and catalogues training programs for the ICLN to increase the Consortium's knowledge base.

Radiological Laboratory Response

The Radiological Laboratory Response subgroup seeks to increase laboratory efficiency across agency network programs and identifies radioanalytical laboratory gaps among the ICLN network radiological laboratories. In addition, this subgroup promotes consistency of analytical performance to ensure quality data supporting homeland security decisions and assessing and filling gaps in radioanalytical laboratory testing.

COVID-19 Lessons-Learned

The COVID-19 Lessons-Learned workgroup was established in October 2020 in response to gaps and lessons identified as part of the SARS-CoV-2 pandemic (also known as COVID-19). Shared feedback during the response to the pandemic led to documentation of gaps and lessons-

learned which were reported by ICLN laboratory network members. Network members were given an opportunity to rank the priority of the gaps/lessons-learned. The purpose of the workgroup is to review the high priority gaps/lessons-learned, propose solutions, and work towards an effective resolution of the specified gap/lesson-learned.

Sample Prioritization

The Sample Prioritization workgroup was established in April 2013 by the NCG as an outcome of the 2012 Strategic Planning Meeting and tasked with developing a document to promote the most efficient use of ICLN resources through sample prioritization. Given that a major chemical, biological, or radiological incident will likely result in analytical demands that exceed the Nation's laboratory capacity, there will be a need to prioritize samples in order to address the most time-critical response and recovery decisions. The document was developed to provide response and recovery management teams with insight and an understanding of the many issues related to laboratory testing in order to promote the most efficient use of laboratory resources through sample prioritization. It highlights the types of decisions that teams will need to make to best prioritize the samples being submitted to the various laboratories during a CBRN incident response. The document can be found at https://www.icln.org/subgroups.cfm#sample-prioritization. The Sample Prioritization workgroup is temporarily on hold and will be reactivated, as needed, in order to update the Sample Prioritization for Incident Decision Making document.

Laboratory Logistics

The Laboratory Logistics workgroup assessed the various aspects of the biological, chemical, and radiological laboratory's processes that may partially or severely limit the laboratory's response to an event of national significance. This workgroup generated a document that identified the following items:

- Critical resources that would or could be in limited supply that would be needed during a major national emergency response;

- A general inventory of critical equipment, instrumentation, supplies, and other consumable items for each of the network threat agent areas that are required to conduct laboratory analysis;

- Guidance on local vendor warehousing of critical laboratory components and supplies;

- Guidance or recommendations for stockpiling critical laboratory reagents, supplies, components, consumables, and other items; and

- Guidance on sharing key laboratory resources (including people) among networks during an incident response.

The *Lab Limiting Issues* Document

This document is updated periodically as new information is provided. It can be found at https://www.icln.org/subgroups.cfm#laboratory-logistics.