

Status of the Integrated Consortium of Laboratory Networks

October 2017
Report to Congress



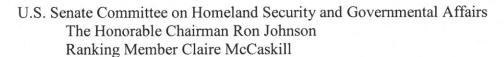
Message from the Under Secretary (Acting) for Science and Technology

October 2017

I am pleased to submit the following report, "Status of the Integrated Consortium of Laboratory Networks," which was prepared by the Department of Homeland Security Science and Technology Directorate, in coordination with the DHS Office of Health Affairs, and 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 (FDA) Food Safety Modernization Act (Public Law 111-353).

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



House Homeland Security Committee The Honorable Chairman Michael McCaul Ranking Member Bennie Thompson

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

Sincerely,

William N. Bryan

Under Secretary (Acting)

Science and Technology Directorate

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Executive Summary

This report, required by the FDA Food Safety Modernization Act, Public Law 111-353 (FSMA), provides the current status of the Integrated Consortium of Laboratory Networks (ICLN). The ICLN is a nationwide, integrated system of laboratories 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 does this through planning, identifying resources, providing laboratory surge capacity support, and defining key process steps for information exchange and data sharing during an incident. This report summarizes the accomplishments of the ICLN since its creation, highlighted by the ICLN's transition to a fully operational status over the past two years. As a central element of this transition, programmatic and budget responsibilities for ICLN have transferred from the Department of Homeland Security (DHS) Science and Technology Directorate to the DHS Office of Health Affairs.

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. Each network is individually constituted to provide the requisite analytical capability and capacity to process samples collected during responses for which their sponsor agencies are responsible. Because some CBRN incident response scenarios may present more samples requiring analysis than a given network may be able to process in a reasonable time, the ICLN framework ensures gaps in laboratory analytical capability and capacity within a single member network may be filled by accessing the analytical power of other member networks across the ICLN. Through the ICLN, laboratories in other member networks are utilized to ensure the provision of timely, credible, and interpretable data in support of surveillance, early detection, effective consequence management, and other needs. Importantly, the ICLN coordinates the efforts of member laboratory networks under their existing guidance; it does not supersede any other relationships, policies, or operating procedures of those networks.

The ICLN is an operational system and is prepared to respond to large-scale contamination or disease incidents; achievement of this status is largely due to key accomplishments in the three areas outlined in FSMA. First, ICLN coordinating bodies have established a set of laboratory methods as well as validation and quality assurance protocols that enable laboratories to assist effectively in the analysis of samples of multiple types, including human clinical, environmental, food, plant, and animal samples. The ability of member network laboratories to support other ICLN member networks has been demonstrated through an array of competency tests. Second, the ICLN's web portal and its Data Exchange Utility (DEU) provide means through which members can work cooperatively to optimize national laboratory preparedness, organize surge capacity during emergencies, and aggregate and share data from all member networks participating in a joint response into a single database. Finally, ICLN coordinating bodies and member networks

continue to engage in ongoing dialogue, exercises, and other activities that build relationships to support effective integrated responses during emergencies.

Pursuant to the requirements outlined in Section 203, Integrated Consortium of Laboratory Networks, of FSMA, this report fulfills the responsibility of the Secretary of DHS in outlining the ICLN's progress to date.

I. Legislative Language

In accordance with FSMA (Public Law 111-353, Section 203), the Secretary of DHS, in coordination with the Secretary of Health and Human Services (HHS), the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency (EPA), maintains an agreement through which relevant laboratory network members 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.

This report is submitted pursuant to Section 203(b) of FSMA, which requires the Secretary of DHS to submit biennial reports on "the progress of the integrated consortium of laboratory networks..." to the relevant committees of Congress and make them publicly available on the ICLN's website (https://www.icln.org/).

II. Background

The ICLN was established by a Memorandum of Agreement (MOA) signed in June 2005, which was updated and re-signed in 2012 and 2016 by stakeholder government agencies. In addition to DHS, 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 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 laboratory networks to assist in responding to acts of terrorism and other events requiring an integrated laboratory response.

The signatory agencies recognize that the capabilities of Federally-sponsored laboratory networks, such as those depicted at bottom Figure 1, page 3, can be leveraged in situations that might require 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 US Agriculture and Food; HSPD-10: Biodefense for the 21st Century; HSPD-21: Public Health and Medical Preparedness; HSPD-22: Domestic Chemical Defense; Presidential Policy Directive 8: National Preparedness (PPD-8); and the *2012 National Strategy for Biosurveillance*.

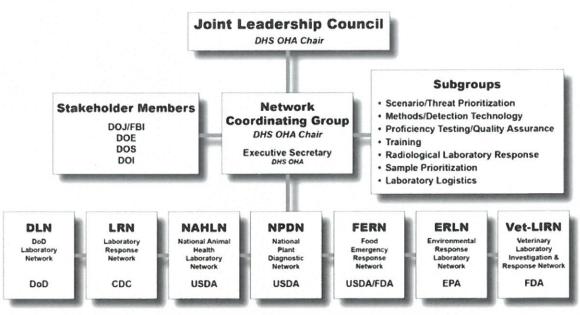
As outlined in the ICLN's MOA, the ICLN fills the United States' need for a system of laboratory networks capable of integrated and coordinated response to incidents involving:

- Multiple types of microbes (e.g., emerging infectious disease), agents (e.g., chemical, biological, 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, 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, the
 environment) or more than one type of laboratory (e.g., screening/sentinel, confirmatory,
 forensic, definitive reference); and
- Multiple phases of incident management (e.g., monitoring, emergency response, remediation/recovery, forensic investigations).

The ICLN organizational structure is depicted in Figure 1. Principal organizational elements include a Joint Leadership Council (JLC), a Network Coordinating Group (NCG), an Executive Secretary (ES), and technical subgroups. DHS chairs the NCG and the JLC, and provides administrative support through an ES that DHS staffs. DHS is also the lead agency for day-to-day management of the ICLN's functional utilities and resources (e.g., the ICLN web 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 Network Coordinating Group, particularly when issues at the NCG-level require outside assistance. The JLC guides the ICLN in system-wide strategic planning via the NCG and approves the inclusion of additional networks into the ICLN as well as modifications to the Memorandum of Agreement. The JLC currently meets approximately annually with the NCG.

The NCG is the focal point of network coordination. Its membership consists of officially designated member laboratory network representatives who have the appropriate responsibility and authority to facilitate progress on ICLN goals and objectives as well as manage their networks. 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. It 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 inter-network exercises to promote overall system readiness.



More than 450 distinct labs represented in member response networks

Figure 1. Organizational Structure of ICLN

The ES provides administrative support to the ICLN, including the JLC, NCG, and technical subgroups. The DHS Chair of the NCG provides oversight of the ES, while DHS staffs the ES. The ES meets the ICLN's administrative needs, including managing inter-network communications, convening meetings, facilitating actions approved during meetings, and serving as the point of contact for external outreach and communications.

Permanent and ad hoc subgroups support NCG decision-making by providing consultation on matters such as training, logistics, and methods. 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 inter-network policies. Additionally, these technical subgroups produce reports for the ICLN, which the NCG reviews and processes as operational guidance for the ICLN.

As outlined in Figure 1, seven networks comprise the analytical resources accessible within the ICLN. The analytical scope of each of these networks is described below:

DoD 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, and other all-hazards agents of military or national significance. 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 CDC, a component of HHS. It includes the CDC LRN-Biological (LRN-B), the CDC LRN-Chemical (LRN-C), and the CDC radiological laboratory. The LRN was established per guidance in Presidential Decision Directive-39. Primary partners with CDC on the LRN are the Association of Public Health Laboratories (APHL) and the FBI. 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 (AAVLD) 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 (FAD) agents that threaten the nation's food supply and public health.
- National Plant Diagnostic Network The NPDN is managed by USDA NIFA and functions in close collaboration with APHIS. The mission of NPDN is to enhance national agricultural security through rapid detection, diagnosis, and early communication of outbreaks of potentially damaging pests of food, feed, fiber, fuel crops and forest trees. This is accomplished by the collective efforts of many Land Grant Universities, Federal agencies, State departments of agriculture, and other stakeholders. The network is designed to quickly detect and identify high consequence pests and pathogens introduced deliberately or accidentally into commercial and natural ecosystems and to report them to appropriate responders and decision makers. Since its inception, NPDN has grown into an internationally respected consortium of plant diagnostic laboratories covering all 50 States.
- Food Emergency Response Network The FERN is managed by USDA's Food Safety and Inspection Service and the HHS 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 to 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 ERLN is managed by EPA. The
 ERLN provides analytical support to EPA regional responders and program offices—such
 as the Office of Emergency Management, Office of Water, and Office of Radiation and
 Indoor Air— for characterizing the extent and degree of contamination in environmental
 vectors 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 collaborating with veterinary diagnostic laboratories to ensure that veterinary products and animal feeds are safe from disease and contamination.

III. 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 registry 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 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 web portal at www.icln.org (see Section IV).

The ICLN Methods Subgroup is responsible for periodically updating the information in the methods registry. It is also responsible for collaborating to develop, refine, and validate new methods. The development of methods relies on funding and staff available within the member network sponsor 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, all available on the public side of the ICLN portal website:

ICLN Guidelines for Comparison of Validation Levels between Networks (https://www.icln.org/resources/subgroups/methods/methods-validation-sop/). This document, updated in 2017, 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.

Proficiency Testing Guidelines

(https://www.icln.org/resources/subgroups/pt-qa/proficiency-testing-guidance/). Proficiency testing (testing the capability of laboratory staff to perform a method to a minimal target level of quality) is an important element toward ensuring that when a laboratory is called upon to analyze a batch of samples in response to an incident, the results of the laboratory can be regarded as accurate and deliverable in a timely fashion. The conduct of proficiency testing of the laboratories within a given member network is entirely the responsibility of that network. To promote confidence among the ICLN member networks that the results coming from one network in a joint response can be relied upon by another network, the ICLN developed the *Proficiency Testing Guidelines* which shares best practices of the ICLN member networks and ensures that testing practices are as consistent and standardized as practicable. This document was published in 2011 and is being updated to reflect current practices.

Chain of Custody Form

(https://www.icln.org/resources/subgroups/methods/chain-of-custody-form/). This resource 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 universally 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 such need arise. This document was updated in 2016.

Sample Collection and Handling Guidelines

(https://www.icln.org/resources/subgroups/methods/sample-collection-and-handling-guidelines/). This document, updated in 2017, 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 nor allowed to deteriorate prior to analysis in the laboratory.

IV. Optimizing Preparedness and Surge Capacity

The ICLN was formed to enable 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 the 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 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 sponsor agency's mission. This data aggregation utility is described as the 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 through periodic exercises that mimic a large-scale contamination incident. Another key resource developed and maintained by the ICLN is a list 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.

A. ICLN Web Portal

The ICLN Web Portal is a secure, password-protected web portal that member networks may use daily or during an incident. The portal, located at www.icln.org, hosts the ICLN's guidance documents and serves as a common resource location for members of the Network Coordinating Group, the technical subgroups, and others requiring access to a collaborative 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.

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. Following each joint exercise among ICLN networks, the functionality of the portal is reviewed and changes made to improve functionality. Typically these adjustments are relatively minor.

B. 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 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. The DEU permits users to search aggregated data using various 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 last updated in October 2017.

Sharing of data among networks during an incident is governed by a formal document known as an Incident-Specific Data Sharing Agreement (ISDSA), which describes in detail the following attributes: 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. The format and content of the ISDSA was agreed to by all parties in 2016.

C. Standard Operating Procedure (SOP) for Incident Response

The ICLN established and regularly refines a standard operating procedure to promote smooth execution of the relatively complicated series of actions that characterize an effective response by multiple agencies. This standard operating procedure 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 may be invited to 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 to initiate and conduct a joint incident response. A joint incident response is generally triggered by a request from a member laboratory network for assistance in resolving an incident involving the analysis of a potentially overwhelming number of samples. The- procedures incorporated in the SOP include using the ICLN portal for communication and coordination; developing and sending alerts and situation reports; identifying and negotiating resources available to support the response; agreeing on reporting methods and data release protocols; and demobilizing 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 aforementioned procedures. These documents ensure consistency in response, sample analysis, data transfer, and after-action reporting.

D. Exercises

A critical component of ICLN success in incident response management is communication before and during events. The ICLN has worked hard to build the relationships necessary to support effective laboratory response. Ongoing exercises and efforts to measure samples throughput help identify areas for improvement. The ICLN utilizes three exercise types which are more in-depth than the standard Homeland Security Exercise and Evaluation Program exercise types. These include virtual tabletop exercises (TTXs), monthly portal drills, and interagency operational exercises.

Virtual tabletop exercises are conducted approximately twice per year over several days. Since 2008, the ICLN has conducted 17 such 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 1). The tabletop exercises normally involve a subset of the

Table 1. ICLN Tabletop and Interagency Operational Exercises

- Biological agent release in air (December, 2008)
- Chemical contaminant in food product (December, 2008)
- Avian flu exercise (2009)
- Biological agent release in air (July 2010)
- Biological agent release in air (October, 2010)
- Biological agent in food product (October, 2010)
- Chemical contaminant in food product (October, 2010)
- Foot and Mouth Disease in cattle (March, 2011)
- Rathayibacter Toxicus (September, 2011)
- Radiological dispersal device: (February, 2012)
- Chemical in food product (August, 2012)
- Biological in food product (May, 2013)
- Improvised Nuclear Device (July, 2013)
- ICLN Validation Exercise (biological agent release in air, April, 2014) **
- Chemical agent release (September, 2014)
- Nuclear Power Plant (June, 2015)
- Chemical in food product (December, 2015)
- Northern Lights radiological response operational exercise (October, 2016)
- ** Conducted in concert with emergency response officials of Baltimore City, State of Maryland, and federal agencies HHS and EPA

seven ICLN member networks. Over this extensive set of scenarios, all networks experience the position of being both a lead response network and a supporting response network. These exercises facilitate better understanding of SOP procedures and enhance understanding of network capabilities and limitations. The tabletop exercises provide the NCG with a better sense of needed changes to key ICLN infrastructure, such as the ICLN portal and guiding documents. These types of exercises have improved knowledge of network/agency responsibilities and capabilities, enhanced overall execution of the laboratory incident response process, and increased use and quality of communications through the ICLN portal.

To promote NCG representatives' improved capability with the ICLN coordination tools, a program of monthly exercises focusing on specific tasks was instituted in 2016. A specific task is practiced during each monthly exercise. Tasks have included the following: profile check (updating specific profile information within the Portal contacts area to include verifying phone and email information), completion of a Preparedness Alert and a Situation Report, generation of a completed Incident-Specific Data Sharing Agreement, and a search for specific information and answering questions related to the methods registry.

Exercises in all forms are essential to maintaining ICLN readiness and promoting refinement of tools and procedures. Each exercise leads to further understanding of areas which might limit network interoperability. The lessons learned during these exercises leads to improved communication among NCG members, enhancement of the ICLN portal tools, and improved maneuverability within the portal environment.

E. Member Network Laboratories Lists

Provision of analytical services to resolve samples and provide data on them 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 daily work routines that substantiate their existence. When an ICLN member network is called upon to provide service in resolving a CBRN incident, the network will consider a number of factors in identifying and negotiating participation by a member laboratory. Such factors will include current standing on proficiency assessments, proximity to the location of the incident, potential sample throughput capability, and on-going obligations of the laboratory. Additionally, many laboratories are members of multiple ICLN member networks.

The NCG determined that having a list of all the laboratories that are members of ICLN member networks and their general capabilities is an important element of information in identifying the analytical resources that can be brought to bear in a given response scenario. The NCG has created such a list and periodically updates the list to ensure it is as current as possible. The list was first created in 2010 and most recently updated in 2016, with the next update likely beginning in second quarter FY2018.

V. 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 effective, positive relationships toward realizing the goal of successful integrated response across multiple agencies. To this end, the NCG has met approximately monthly since 2005. Approximately annually, it meets with the JLC to present progress and discuss strategic considerations. At each of these meetings, the leadership of ICLN participant agencies as represented on the JLC 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 JLC 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 created the ICLN was first signed in 2005 and updated in 2012 and 2016. The process of updating the MOA contributes not only to the strengthening 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 provisions to share data among agencies 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 the transfer, proper management, ownership, and use of data that the member networks will convey during an emergency response. It was developed over numerous discussions and refined through the TTXs 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 other laboratory members 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). The ICLN has conducted several laboratory-based exercises to promote such confidence. The most recent such exercise was completed in May 2017 and involved liquid samples spiked with Malathion, a toxic chemical pesticide. In all such studies, it has been observed that proficient laboratory analysts are very competent at performing methods they do not 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 have recognized the importance of raising awareness of 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 in 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, which allows anyone to ask a question of the ICLN leadership and membership.

Finally, a key practice 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; major strategic planning meetings were conducted 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 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.
- Seek to engage with international lab response entities to promote inclusion of the laboratory assets of other countries into similar integrated bodies, with an eventual goal of

ensuring an effective global laboratory response to any large CBRN incident across the world.

VI.Successes During the Year of Transition to Office of Health Affairs

In 2017, the ICLN was transitioned from research and development status under the DHS Science & Technology Directorate to operational status under the DHS OHA. This transition year shows that the successes of the ICLN continue. The following items were successes of the ICLN during Fiscal Years 2016-17:

- Updating and executing the 2016 ICLN MOA that encompasses the data sharing and information exchange procedures
- Resetting the objectives of the ICLN NCG technical subgroups
- Initiating monthly exercises of specific tools and functions of the ICLN Portal
- Conducting and participating in a confidence building competency test the Malathion (organophosphate insecticide) Exercise
- Finalizing the incident-specific data sharing agreement form
- Initiating revision of ICLN guidance documents by NCG subgroups
- Participating in planning and conduct of the radiological lab portion of interagency Northern Lights Full Scale Exercise 2016
- Initiating development of a Radiological Response Laboratory Network

VII. 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.

ICLN efforts over the last few years have solidified agreements and guidance documents that instill common laboratory methods and practices. Systems and processes to share knowledge and information relating to animal health, agriculture, the environment, and human health further contribute to the operational status of the ICLN. Laboratory network members have agreed on and instituted ways in which they can work cooperatively to optimize national laboratory preparedness and provide surge capacity during emergencies requiring the capabilities of more than one network. Finally, efforts to engage in ongoing dialogue and building of relationships have supported, and will continue to support, a more effective and integrated response during emergencies.

The important work of the ICLN will continue. Exercises to test existing and planned capabilities, as well as meetings to maintain the operational status of the ICLN, will continue to occur on a

regular basis. Most importantly, the ICLN is poised 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.