MEMORANDUM OF AGREEMENT for an INTEGRATED CONSORTIUM OF LABORATORY NETWORKS

August 1, 2016

1. MISSION

The mission of the Integrated Consortium of Laboratory Networks (ICLN) is to coordinate federally sponsored analytical laboratory services for chemical, biological, radiological, and nuclear incidents through planning, identification of resources, prescribing of key process steps, and information sharing. The ICLN is a U.S. homeland security infrastructure comprising a coordinated and interoperable system of laboratory networks for the provision of timely, credible, and interpretable data in support of surveillance, early detection, and effective consequence management of acts of terrorism and other incidents requiring an integrated laboratory response.

2. PARTIES

The parties to this Memorandum of Agreement (MOA) are the following departments and agencies of the U.S. Government:

- 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)
- Environmental Protection Agency (EPA)

3. PURPOSE

The purpose of this Memorandum of Agreement is to set out the Federal relationships within the ICLN to ensure an information-sharing structure, as well as to describe the commitments undertaken by the signatories. This MOA also describes the ICLN organizational structure, the roles and responsibilities of participating federal departments and agencies (D/As) within the ICLN, and the information-sharing process among members.

This Agreement immediately terminates and replaces the previous Agreement executed in full in December 2005 and updated in January 2012.

4. AUTHORITIES AND LIMITATIONS

• Each of the signatories will conduct activities under this MOA within the scope of, and to the extent authorized by, their existing statutory authorities.

- This MOA among Federal D/As, including components of the signatories' organizations, does not create or confer any right or benefit on any other person or party, private or public. Nothing in this MOA is intended to restrict the authority of any D/A to act as provided by law or regulation or to restrict any D/A from enforcing any laws within its authority or jurisdiction.
- All commitments arising from this MOA are subject to each signatory's budget priorities and the availability and limitations on the use of appropriated funds for such purposes. If any signatories, or representatives of components of signatories' organizations, determine it would be appropriate to use each other's network capacity, they may enter into any further necessary agreements or arrangements in accordance with the Economy Act or other applicable laws, regulations, and procedures. However, nothing in this MOA obligates any of the signatories to expend appropriations or to enter into any contract, assistance agreement, or interagency agreement or arrangement, or to incur other financial obligations.
- The ICLN contributes to stronger early detection and consequence management capabilities, consistent with the requirements of Homeland Security Presidential Directive (HSPD)-9 (Defense of United States Agriculture and Food), HSPD-10 (Biodefense for the 21st Century), HSPD-21 (Public Health and Medical Preparedness), HSPD-22 (Domestic Chemical Defense), and Presidential Policy Directive (PPD) 8 (National Preparedness).
- The statutory foundation for the ICLN was enacted into law by the 2011 Food and Safety Modernization Act (FSMA). The FSMA directs the Secretary of DHS, in coordination with the Secretaries of HHS, USDA, and the Department of Commerce and the Administrator of the EPA to maintain an agreement through which relevant laboratory network members can identify means by which laboratory network members could work cooperatively to optimize national laboratory preparedness, provide surge capacity during emergencies, and engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.
- Nothing in this MOA supersedes information-sharing requirements and/or restrictions/exclusions in U.S. laws or regulations. If necessary and appropriate to further the purposes of this MOA, signatories or representatives of components of signatories' organizations may enter into other information-sharing agreements.
- Nothing in this MOA impairs or otherwise affects the authority of the heads of the signatory
 organizations over the organizations, including, in the case of the Department of Defense, the
 chain of command for military forces from the President as Commander in Chief, to the
 Secretary of Defense, to the Combatant Commands and Military Departments, or military
 command and control procedures.
- Subject to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a, respectively), decisions on disclosure of D/A information to the public regarding projects and programs referenced in this MOA will be made by D/A following consultation among all affected parties.

5. BACKGROUND

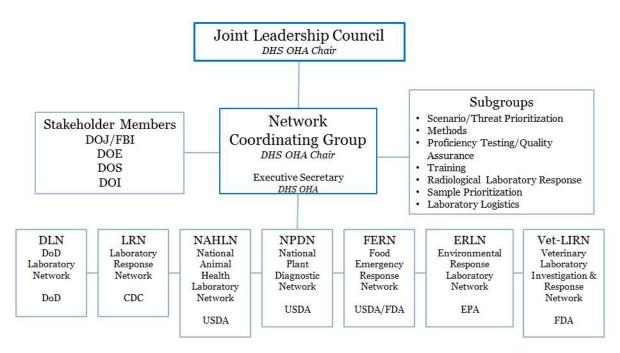
In 2005, the United States was in need of a system of laboratory networks capable of integrated and coordinated response to incidents involving:

- Multiple types of microbes (e.g., emerging infectious diseases), agents (e.g., chemical, biologic, radiological, and nuclear), or mixed or unknown agents, where sampling, testing, interpretation of results, and response must be closely coordinated;
- Multiple 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, and definitive reference); and
- Multiple phases of incident management (e.g., monitoring, emergency response, and remediation/recovery).

Understanding this need, ten D/As signed an MOA in 2005 establishing the ICLN.

6. ICLN ORGANIZATION STRUCTURE

The ICLN organization structure is as follows:



Joint Leadership Council (JLC)

At the strategic level, the Joint Leadership Council (JLC) is composed of senior leadership members from each of the signatory D/As and is charged with helping to ensure that the appropriate strategy is in place to support an effective all-hazard laboratory response capability. The JLC provides advice and advocacy to senior Federal Government leaders with the objective of aligning and supporting an appropriate strategy and requisite funding with appropriate

consideration of capability gaps in effective laboratory testing for detection and response to health and national security emergencies.

- The JLC is chaired by the DHS Office of Health Affairs (OHA) representative to the JLC and meets annually with the Network Coordinating Group (NCG). The JLC is administratively supported by DHS OHA.
- Each signatory from the member organizations designates a JLC representative or representatives for the respective organization with the ability to obtain decisions regarding budgets and policies. The JLC representative will make provisions for a responsible alternate designee to ensure continuity on issues and presence at all meetings. At the discretion of the JLC, additional senior leadership representatives from a signatory organization may accompany the signatory's representative/designee to JLC meetings.
- The JLC:
 - Guides the ICLN in system-wide strategic planning through the NCG;
 - Promotes coordinated initiatives and implementation thereof, consistent with applicable authorities and funding restrictions of signatory organizations;
 - o Reviews ICLN strategic plans and supports coordinated Federal budget development;
 - Makes recommendations on issues elevated by the NCG in the best interest of the ICLN as a whole; and
 - Approves inclusion of additional networks into the ICLN and modifications to this MOA.

Network Coordinating Group

At the operational level, the NCG is composed of representatives from signatory D/As and the operational leaders of the individual laboratory networks. The NCG is charged with promoting enhanced capability, capacity, and integration of network functions. The NCG is chaired by DHS OHA and meets monthly.

- Each of the signatories intend to support one or more senior representatives who have:
 - Authority to obtain network decisions and decisions on the commitment of resources rapidly;
 - Knowledge of laboratory practices and testing capacity, network operations, and policies and emergency response practices;
 - Knowledge of interagency government systems and stakeholder concerns; and
 - Sufficient technical support from their organization, including staff support, to execute his or her responsibilities effectively.
- The NCG is to operate by agreement among members. If agreement cannot be achieved, the issue may be presented to the JLC for consideration and resolution, when appropriate.
- The NCG:
 - Ensures timely communications among all member organizations;
 - Establishes the common operating procedures of the ICLN (e.g., notification and reporting guidance) for timely, high-quality, and interpretable results;
 - Promotes coordination for effective agent prioritization; appropriate analytic methods for high quality, timely, and interpretable results; proficiency testing, quality assurance, and accreditation of participating laboratory testing entities; training across

networks; and information management, including data exchange and knowledge management;

- Ensures legal and ethics issues relevant to the functioning of the networks are referred to appropriate legal and ethics advisors;
- Develops and proposes a comprehensive laboratory network strategic plan that enables the integration of the networks;
- Establishes the agenda for, and supports the effective operation of, the JLC; and
- Helps ensure the ICLN has appropriate relationships and alignment with the National Response Framework.
- The NCG is to establish and guide ICLN subgroups in support of its role to:
 - Create standardized and integrated approaches for the ICLN;
 - Promote organization, coordination and conservation of assets and resources;
 - Address critical issues affecting the reliability of data provided to decision makers;
 - Provide an initial analysis of an incident and ongoing advice and coordination;
 - Serve as a forum for the discussion and dissemination of information; and
 - Address any other relevant issues areas as deemed appropriate by the NCG Chair.
- The NCG may consult with other Federal organizations in support of its work.

Subgroups

Permanent and ad hoc Subgroups support decisions of the NCG by providing consultation on matters before the NCG.

- Subject matter experts from government (Federal, State, and local), academia, professional organizations, and business may provide technical support as appropriate and determined by the NCG. The need for subordinate groups is to be determined by the NCG. Subgroups are to be chaired by Federal staff within the response laboratory network system, who may be assisted by individuals enlisted via contract to provide specific technical support services to the Federal Government.
- The Subgroups review key issues and requirements of the networks (e.g., agent prioritization, methods development and standards, proficiency testing, quality assurance, accreditation, information management, and external outreach) and devise recommendations for operational or policy choices.
- Provision of technical input by non-Federal personnel will be conducted in a manner that will not require the establishment of a Federal advisory committee and that will comply with the Federal Advisory Committee Act and will otherwise be consistent with Federal practice on the solicitation and receipt of such input.

Responsible Federal Departments and Agencies

The Responsible Federal Departments and Agencies (RFDAs), where responsibility is agreed to, and subject to their authorities and funding restrictions, support the operational capacity of the individual networks to meet their testing requirements for monitoring, incident response, and incident remediation and recovery, including longer duration surge requirements for incidents with extended recovery periods. RFDAs work through the existing laboratory networks, whose laboratory members may be components of State, local, or other Federal D/A jurisdictions.

 Identification as an RFDA is recommended by the NCG in accordance with D/A missions and authorities. This identification should cover all relevant agents (e.g., chemical, biological, and radiological), sample types (e.g., human clinical, environmental, food, animal, and plant), and operational phases (e.g., monitoring, incident response, and incident remediation and recovery) for which the ICLN assumes responsibility.

- RFDAs are to make decisions in accordance with their existing authorities. Agreements among member organizations are to be made operational by the RFA, where appropriate.
- An RFDA's commitment to timely, high-quality, and interpretable laboratory results, in accordance with its authorities, is met through:
 - i. Prioritization of agents that will be tested for in a given sample type and operational phase;
 - ii. Sponsoring research and development of testing methods and promoting standardization where appropriate;
 - iii. Conducting proficiency testing, quality assurance, and laboratory accreditation at the standards set by RFDA policy and the ICLN;
 - iv. Designing and implementing laboratory training and sampling guidance;
 - v. Deploying information systems and supporting the timely exchange and appropriate management of information across networks;
 - vi. Addressing and ensuring compliance with legal, ethical, privacy, and safety standards appropriate for the RFA, network, and the ICLN; and
 - vii. Collaboration and written agreements with laboratories and other stakeholders to establish roles and relationships to meet testing requirements and help ensure there are adequate resources to support the network to carry out its assigned role.
- RFAs intend to use those RFA staff and resources routinely used to meet network responsibilities, to be directed through ICLN mechanisms where possible, and supplemental staff and resources for new integration activities, consistent with authorities and available funding.
- The signatories recognize that not all of these capabilities exist for all RFAs in all potential designated areas. Where they do not exist, the signatories commit to assist each other as appropriate in developing network coverage, consistent with existing authorities and available funding.

This MOA acknowledges that significant national laboratory testing capacity is derived from utilization of established laboratory networks such as the DoD Laboratory Network, Laboratory Response Network, National Animal Health Laboratory Network, National Plant Diagnostic Network, Food Emergency Response Network, Environmental Response Laboratory Network, and Veterinary Laboratory Investigation and Response Network within the Federal D/A with responsibilities and authorities for laboratory preparedness and response (collectively referred to as "the networks"). This MOA respects the existing relationships, policies, and operating procedures of these networks or any similar interconnected group of laboratories whose relationships involve Federal funding, direction, or other cooperative arrangements.

7. RESPONSIBILITIES/OPERATING PROCEDURES FOR DATA SHARING AND INFORMATION EXCHANGE

Incident-Specific Data Sharing Agreement (ISDSA)

The ISDSA applicable to each incident response will be developed and agreed upon by participating networks at the outset of a joint ICLN incident response. The ISDSA will address items such as analytical data elements to be shared, timeliness of the receipt of data, access to data by parties within the ICLN environment, release authorities, and data quality requirements. The ISDSA will be considered in force between and among D/As upon signature of individuals with delegated authority (e.g., network program office representative) to agree to the exchange of data and the conditions pertaining thereto.

The ISDSA template can be found at Attachment 1 to this MOA for illustrative purposes.

Data Format

All parties to this MOA will commit to acceptance of the Minimum Data Elements (MDE), a format developed and agreed to by the ICLN Network Coordinating Group, as a common format to enable transmission of data among network program offices, as necessary, during the conduct of a joint response within the ICLN environment. Decisions on the specific data to be exchanged via the MDE format will be determined by the parties to this MOA at the time of a joint incident response and documented in the ISDSA. The data exchanged will be in compliance with all applicable laws and regulations, especially those addressing privacy, and with policies of the D/As participating in the joint response. Any data exchanged under this MOA, where the transferring D/A does not own or possess unlimited intellectual property rights over such data, will be marked with appropriate restrictions prior to such transfer.

Data Quality

Reconciliation of data duplicates, discrepancies, or other quality issues will be in accordance with the process agreed upon and documented in the ISDSA.

Data Confidentiality

Access to data generated or received by any participant to the joint incident response will be limited to authorized users as agreed upon and documented in the ISDSA.

The level of access granted for an individual user or group of users will be limited to specific incidents as defined within the ISDSA.

Any support contractor providing personnel with access to any data via the ICLN Data Exchange System will be subject to legally binding confidentiality obligations (e.g., use and non-disclosure restrictions contained in the support contract, and contractor personnel having such access sign a Non-Disclosure Agreement (NDA) that is consistent with those restrictions) that permit the support contract to use and disclose the data only as authorized for the performance of its contract to support the participating D/A, and not for any other purpose. If the data transferred is considered proprietary to any company or organization other than the U.S. Government, the contractor NDA will also be executed with the owner of the data prior to such transfer.

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Data Distribution

All networks will obtain permission from any network that has provided data via the ICLN Data Exchange Utility before sharing such data outside the Data Exchange System, on an incident-specific basis. Such data includes, but is not limited to, reports at a detailed or summary level, screen captures, and downloads of data from the system. Any sharing of data beyond the Government employees of the D/A receiving such data will be only with the prior express authorization of the D/A transferring the data.

Data Retention

Subject to relevant law, all data posted to the ICLN Portal during an incident will be purged from the repository after conclusion of the incident response and at such time as requested by the lead network, with concurrence by any D/A or network that uploaded data.

8. EXECUTION, MODIFICATION, TERMINATION, AND FUNDING

This MOA may be signed in counterparts, each of which will be deemed to be an original, and all of which, taken together, will constitute one MOA. Upon signature and delivery of a counterpart signature page hereto by any entity indicated as a signatory on the signature pages of this MOA, such entity will become a party to this MOA. The signature and delivery of a counterpart signature page will not require the consent of any party that has already signed.

Any party that has already signed this MOA may propose modifications to this MOA. No modification will be effective until signed by all signatories to this MOA. However, any party to this MOA may terminate its participation herein at any time. If appropriate to do so, signatories will provide 90 days of written notice to the other parties.

The activities under this MOA are subject to the availability of funds. The MOA will terminate five years from the date of the last signature.

9. SIGNATURES

This Memorandum of Agreement is signed by all parties involved at the strategic and operational levels, and all parties acknowledge their responsibilities as identified in this MOA.

Department of Agriculture

ShortzE

Mr. Malcom Shorter Deputy Assistant Secretary Department of Agriculture

11/28/2016 Date

Department of Defense

Dr. Karen S. Guice Acting Assistant Secretary of Defense for Health Affairs Department of Defense

11/28/2014

JAN 1 1 2017

Date

Department of Energy

Dr. Elizabeth Sherwood-Randall Deputy Secretary Department of Energy

Department of Health and Human Services

Wollkerr

12/2/16

Date

Dr. Nicole Lurie Assistant Secretary for Preparedness and Response Department of Health and Human Services

Department of Homeland Security

the 15

Dr. Kathryn Brinsfield Assistant Secretary for Health Affairs Department of Homeland Security

11/14/16

Department of the Interior

Suzette M Kimball

11 29 2016 Date

Dr. Suzette Kimball Director U.S. Geological Survey Department of the Interior

Department of Justice

Mr. Christopher "Todd" Doss Director, FBI Laboratory Department of Justice

11 11 2016 Date

Department of State

In Della

<u>11/23/16</u> Date

Ms. Judith G. Garber Acting Assistant Secretary Bureau of Oceans and International Environmental and Scientific Affairs U.S. Department of State

Environmental Protection Agency

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Mr. Beggie Cheatham Director, Office of Emergency Management **Environmental Protection Agency**

Nov 28 20/6 Date

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ATTACHMENT 1 - ISDSA TEMPLATE

ALLERATED CONSORTING	INCIDENT-SPECIFIC DATA SHARING AGREEMENT (ISDSA) Please see Attachment 1 on Pg. 4 for instructions.
I. Incident Nan	ne:
II. Incident Star	rt Date:
III. Description of	of Incident:
IV. Phase of Inci □Notification □F	dent: First Response Characterization Decontamination Clearance
	ccupancy/Recovery/Monitoring/Post-incident
V. Lead Networ	46.
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X. Minimum Data Elements Data Fields:	
X. Minimum Data Elements Data Fields: ⊠Source Network	□ Sample Dimension
Testing Laboratory ID	□Sample Dimension Unit
· ·	□Sample Dimension Type
□Testing Laboratory Name □ICLN Incident Name/Identifier	Panel Battery
□ICLN Incident Name/Identifier	⊠Method
	⊠Analyte
Sample ID	□ Analyte Code
Sample Type	Analyte Coding System
Sample Matrix	Result Text/Nominal
Sample Location	Result Numeric
Sample Location Type	Unit of Measure –Result
Subject ID	□Result Qualifier
Subject Location	□Method Detection Limit
Subject Location Type	Unit of Measure – Method Detection Limit
Subject Species	□Reference Range
Sample Collected Data/Time	Uncertainty Value
Sample Collected End Date/Time	Uncertainty Level
Sample Collection Duration	□Uncertainty Type
□Sample Duration Unit	Result Annotation
	⊠Result Status
	⊠Result Date
XI. Additional Instructions:	
XII. Data Quality and Review:	ort of lead network agree to adhere to the following
XII. Data Quality and Review: Networks and laboratories providing data in supp parameter regarding quality: Primary data review will occur at the performer (1	ort of lead network agree to adhere to the following member laboratory) level. The secondary review will pload to the ICLN Portal. Any concerns with data will

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XIII. Data Confidentiality

Access to data generated or received by any party to this joint incident response is limited to authorized users as outlined below. The level of access granted for an individual user or group of users is limited to this specific event.

The lead network users identified above have access to all data provided under this agreement. The following supporting networks <u>may</u> view data other than that which they submitted.

□LRN-B □LRN-C □FERN □ERLN □NAHLN □NPDN □DLN □Vet-LIRN □DOE RRLN

The following caveats or exceptions apply: (fill-in)

XIV. Data Distribution

All networks sharing data will obtain permission from any network that has provided data via the ICLN before sharing such data outside the ICLN environment. Such data includes, but is not limited to, reports at detailed or summary level, screen captures, and downloads of data from the system.

XV. Data Retention

All data posted to the ICLN Data Exchange System during an incident will be purged from the repository after conclusion of the incident response and at such time as requested by the lead network with concurrence by any department or agency or network that uploaded data.

XVI. Approvals/Signatures :

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Attachment 1: ISDSA Instructions

Section	Instructions	
I. Incident Name	The incident name should match the name used for the incident on the ICLN Portal.	
II. Incident Start Date	Indicate the date on which the incident began.	
III. Description of Incident	Include all known information such as location, timing, and type of	
-	incident, consistent with incident description on the Portal.	
IV. Phase of the Incident	Select the phase that best fits the current state of the incident.	
V. Lead Network(s) and	Check the box of the lead network requesting assistance and point of	
POC	contact.	
VI. Supporting Networks	Check the appropriate box(es) for each network(s) providing	
and POC	assistance in sample analysis and point of contact.	
VII. Other	Include any networks or individual laboratories outside of the ICLN	
Supporting/Participating	that are involved in providing assistance in resolving the incident.	
Networks/Laboratories		
VIII. Types of Samples	If there are multiple sample types, a separate template should be filled out for each sample type.	
IX. Intended Purpose of the	Who would use the data for what purpose and what release of the data	
Data	is anticipated? Example: ERLN is using the data to verify that	
	decontamination of buildings is effective. Clearance testing is being	
	performed for re-occupancy of a previously contaminated area. Data	
	may be posted on a public website.	
X. Minimum Data Elements	Mandatory fields are noted in bold. Definitions for each data element	
Data Fields	can be found on the attached document.	
XI. Additional Instructions	Include any specific instructions outside what has already been stated.	
XII. Data Quality	List here the data reporting and data quality parameters beyond what	
-	is standardized in the method and in reporting with the ICLN	
	minimum data elements. Write in or refer to and attach the applicable	
	Quality Assurance Project Plan (QAPP) document when completing	
	this section.	
XIII. Data Confidentiality	In this section, include any caveats or exceptions that may apply to the	
~	shared data and their presentation format that might be routinely	
	provided to others in the lead department or agency responsible for	
	resolution of the incident. For example, EOCs, on-scene coordinators,	
	and policy staff.	
XIV. Data Distribution	The information in this section is standard language around Data	
	Distribution and is not negotiable.	
XV. Data Retention	The information in this section is standard language around Data	
	Retention and is not negotiable.	
XVI. Approvals/Signatures	The ISDSA will be considered in force between and among D/As	
	upon signature of individuals with delegated authority (eg - network	
	program office representative) to agree to the exchange of data and	
	the conditions pertaining thereto.	

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