Memorandum of Agreement
for an
Integrated Consortium of Laboratory Networks (ICLN)

I. VISION

A U.S. homeland security infrastructure with a coordinated and operational system of laboratory networks that provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response.

II. STATEMENT OF NEED

The United States needs a system of laboratory networks capable of integrated and coordinated response to incidents involving:

- multiple types of agents (e.g., chemical, biologic, radiological) 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., 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 section 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, and forensic investigations).

The goals of early detection and integrated consequence management are heavily dependent on shared understanding of the reliability and accuracy of results. Jointly accepted performance standards for test methods, reagents, proficiency testing and quality assurance, laboratory accreditation, and results reporting are desirable wherever possible. Standard methods and procedures can serve the integration objectives of the ICLN (e.g., results that support action thresholds for both food safety and human health) by producing efficiencies of scale (e.g., stockpiling of reagents, triaging specimens for surge capacity) and by ensuring performance comparability when necessary performance data are not available or feasible.

An integrated nationwide consortium of laboratory networks is needed to support the delivery of timely, high quality, and interpretable results through:

- Inter-network communication and information sharing;
- Resource optimization;
- Resource coordination;
- Accountability; and
- Strategic planning.

Additionally, an integrated consortium of laboratory networks will create an inclusive forum for Federal leadership to share ideas, work collaboratively, and build relationships that will support a more effective integrated response during emergencies.

III. PURPOSE OF THIS AGREEMENT

The purpose of this Agreement is to set out the Federal relationships required to establish an ICLN by providing an information sharing structure and describing the commitments undertaken by the signatories. This Agreement acknowledges that significant national laboratory testing capacity derives from utilization of established laboratory networks such as the Food Emergency Response Network (FERN); the Laboratory Response Network (LRN); the National Animal Health Laboratory Network (NAHLN); the National Plant Diagnostic Network (NPDN); and networks within the Federal Agencies with responsibilities and authorities for laboratory preparedness and response (collectively referred to as the Networks). This agreement 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.

The signatories may have separate authorities and distinct laboratory missions, based in part upon the various types of samples they test (e.g., human, animal, plant, food, environment), the types of agents they test for (e.g., microbial, toxicological, radiological, and chemical), and the types of laboratories involved (e.g., screening/sentinel, confirmatory, definitive/reference, and forensic). Although the signatories recognize that participation in the ICLN does not require them to allow access to their respective facilities or expertise, this agreement reflects their intent to work cooperatively to optimize national laboratory preparedness and provide mutual support wherever possible, consistent with applicable authorities and funding restrictions, as noted below.

Additional departments and agencies may join this Agreement in the future.

IV. AUTHORITY AND LIMITATIONS

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

B. Establishing an ICLN to strengthen early detection and coordinated consequence management is consistent with the policy direction contained in Homeland Security Presidential Directives (HSPDs) 9 and 10.

C. This Agreement is an internal agreement among the signatories, including components of the signatories' organizations, and does not create or confer any right or benefit on any other person or party, private or public. Nothing in this agreement is intended to restrict the authority of any signatory to act as provided by law or regulation, or to restrict any agency from enforcing any laws within its authority or jurisdiction.

D. All commitments arising from this Agreement 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 utilize each other's Network capacity, they may enter into any further necessary agreements or arrangements. However, nothing in this Agreement 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.

E. Nothing in this Agreement supersedes information sharing requirements in U.S. law or regulation. If necessary and appropriate to further this Agreement, signatories or representatives of components of signatories' organizations may enter into information sharing agreements.

F. Nothing in this Agreement 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.

V. ORGANIZATION

A. The focal point of Network coordination is the Network Coordinating Group (NCG). The NCG answers to the Joint Leadership Council (JLC), is supported by an Executive Secretariat (ES), and receives input from a series of Technical Experts (TEs) (Appendix).

B. The ICLN comprises the following member organizations:
   1. Department of Agriculture
      i. Cooperative State Research, Education, and Extension Service
      ii. Food Safety and Inspection Service
      iii. Plant Protection and Quarantine, Animal and Plant Health Inspection Service (APHIS)
      iv. Veterinary Services, APHIS
   2. Department of Commerce
   3. Department of Defense
   4. Department of Energy
   5. Department of Health and Human Services
      i. Centers for Disease Control and Prevention
      ii. Food and Drug Administration
   6. Department of Homeland Security
   7. Department of the Interior
   8. Department of Justice

i. Federal Bureau of Investigation

9. Department of State
10. Environmental Protection Agency

C. The **Joint Leadership Council** (JLC) provides advice to senior Federal Government leaders with the objective of ensuring that the appropriate strategy and funding are in place for effective laboratory testing for detection and response to health and national security emergencies.

1. Each signatory will designate a single JLC representative for the respective organization with the ability to obtain decisions regarding budgets and policies rapidly. At the discretion of the JLC, additional senior representatives from a signatory organization may accompany the designee to JLC meetings.
2. The JLC will be chaired by the DHS representative to the JLC and will be supported by the Executive Secretariat.
3. The JLC:
   i. Guides the ICLN in system-wide strategic planning through the NCG;
   ii. Promotes coordinated initiatives and implementation thereof, consistent with applicable authorities and funding restrictions of signatory organizations;
   iii. Makes recommendations on issues elevated by the NCG in the best interest of the ICLN as a whole;
   iv. Approves inclusion of additional Networks into the ICLN and modifications to this Agreement; and
   v. Meets at least annually to review ICLN strategic plans and to support coordinated Federal budget development.

D. The **Network Coordinating Group** (NCG) develops and proposes policies and procedures and helps carry out the operations of the ICLN through a close and formal working relationship among the operational leadership of the individual Networks and the other involved parties.

1. Each of the signatories will designate one or more senior representatives who have:
   i. The authority to obtain rapidly Network decisions and decisions on the commitment of resources;
   ii. Knowledge of laboratory practices and testing capacity; network operations; policies and emergency response practices;
   iii. Knowledge of interagency government systems and stakeholder concerns;
   iv. Strong collaboration skills; and
   v. Sufficient technical support from their organization, including staff support, to execute their responsibilities effectively.
2. The NCG meetings will be chaired by DHS.

3. The NCG will operate by agreement among members. If agreement cannot be achieved, the issue may be presented to the JLC for consideration and resolution, when appropriate.
4. The NCG:
    i. Ensures timely communications among all member organizations.
    ii. Establishes the common operating procedures of the ICLN (e.g., notification and reporting guidance) for timely, high quality, and interpretable results.
    iii. Helps ensure 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; information management including data exchange and knowledge management; and refers legal and ethical issues relevant to the functioning of the Networks to appropriate legal and ethical advisors for advice.
    iv. Develops and proposes a comprehensive laboratory network strategic plan that identifies the resource and budgetary requirements of each individual Network and the integration of Networks.
    v. Establishes the agenda for and supports the effective operation of the Joint Leadership Council (JLC).
    vi. Gives direction to and supports the effective operation of the Technical Experts (TEs) and contacts TEs as needed.
    vii. Helps ensure the ICLN has appropriate relationships to and alignment with the National Response Plan.
5. The NCG may consult with other Federal organizations in support of its work.

E. The **Executive Secretariat** (ES) has dedicated staff to convene and support the organizational structure of the ICLN (JLC, NCG, and TEs). Oversight of the ES will be provided by the NCG. DHS will staff and support the ES. The size of the ES will be determined by DHS and should include a senior Executive Secretary and be sufficient to meet the administrative needs of the ICLN including inter-Network communications, convening meetings, facilitating actions approved during meetings, and serving as the point of contact for external outreach and communications.

F. Permanent and ad hoc **Technical Experts** (TEs) support decisions of the NCG by providing simultaneous individual consultation on matters before the NCG.
    1. Subject matter experts from government (state, local, and Federal), academia, professional organizations, and business may be Technical Experts as appropriate. The need for a TE will be determined by the NCG.

2. The TEs review key issues and requirements of the Networks (e.g., agent prioritization, methods development and standards, proficiency testing, quality assurance, accreditation, information management, forensic analysis, external outreach, etc.) and devise operational or policy choices.
3. The TEs may provide the inputs of individual members only. They will not provide collective recommendations or make decisions.

G. The **Responsible Federal Agencies** (RFAs), where they agree to be, and subject to their authorities and funding restrictions, ensure the operational capacity of the individual Networks to meet their testing requirements for surveillance, incident response, forensic analysis, and incident remediation and recovery. RFAs work through the existing laboratory Networks.
   1. Identification as an RFA is recommended by the NCG in accordance with Agency missions and authorities. This identification should cover all relevant agents (e.g., chemical, biologic, and radiological), specimen types (e.g., human clinical, environmental, food, animal, and plant), and operational phases (e.g., surveillance, incident response, forensic analysis, and incident remediation and recovery) for which the ICLN assumes responsibility.
   2. RFAs will make decisions in accordance with their existing authorities. Agreements between member organizations will be made operational by the RFA, where appropriate.
   3. RFA commitment for 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 specimen 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 or above the standards set by the ICLN;
      iv. Designing and implementing laboratory training and sampling guidance;
      v. Deploying information systems that meet ICLN and national standards (e.g., the National Biosurveillance Integration System) and support the timely exchange and appropriate management of information across Networks;
      vi. Addressing and ensuring compliance with legal, ethical, and safety standards appropriate for the agency, 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 Networks to carry out their assigned roles.
   4. RFAs will 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 funding restrictions.

5. The signatories recognize that not all of these capabilities exist for all Responsible Federal Agencies in all 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 funding restrictions.

VI. COMMITMENTS OF THE SIGNATORIES

A. To provide a representative with the ability to obtain decisions rapidly for the Joint Leadership Council.

B. To provide a representative with the ability to obtain decisions rapidly for the Network Coordinating Group and who is knowledgeable of laboratory practices and testing capacity; network operations; policies and emergency response practices, interagency government systems and stakeholder concerns.

C. To support the other signatories to this agreement in carrying out their Responsible Federal Agency requirements consistent with authorities and funding restrictions.

D. Furthermore, the Department of Homeland Security agrees to support the operations of the ICLN by staffing the Executive Secretariat, whose responsibilities are described herein.

VII. EXECUTION, MODIFICATION AND TERMINATION

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

Any participant in this Agreement may propose modifications to this Agreement. No modification will be effective until approved in writing by all members of the Joint Leadership Council. This Agreement, when signed by all signatories representing all of the organizations listed on the signature pages, will continue indefinitely as to such signatory. However, any participant in 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 participants. The ICLN will undergo performance review on a periodic basis set by the NCG and approved by the JLC.

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NOW THEREFORE, the undersigned agree to create and support an integrated system of laboratory networks to assist in responding to acts of terrorism and other events requiring an integrated laboratory response by fulfilling their responsibilities as part of the ICLN structure described in this Agreement.

Mike Johanns
Secretary
Department of Agriculture

Phillip J. Bond
Undersecretary of Commerce for Technology
Department of Commerce

5/9/05
Peter F. Verga
Deputy Assistant Secretary for Homeland Defense
Department of Defense

Department of Energy

Stewart Simonson
Assistant Secretary for Public Health Emergency Preparedness
Department of Health and Human Services

4/29/05
Charles E. McQueary, Ph.D.
Under Secretary for Science and Technology
Department of Homeland Security

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Gale A. Norton
Secretary
Department of the Interior

Dwight Adams, Ph.D.
Assistant Director for the FBI Laboratory Division
Department of Justice

John F. Turner
Assistant Secretary for the Bureau of Oceans and
International Environmental and Scientific Affairs
Department of State

Stephen L. Johnson
Administrator
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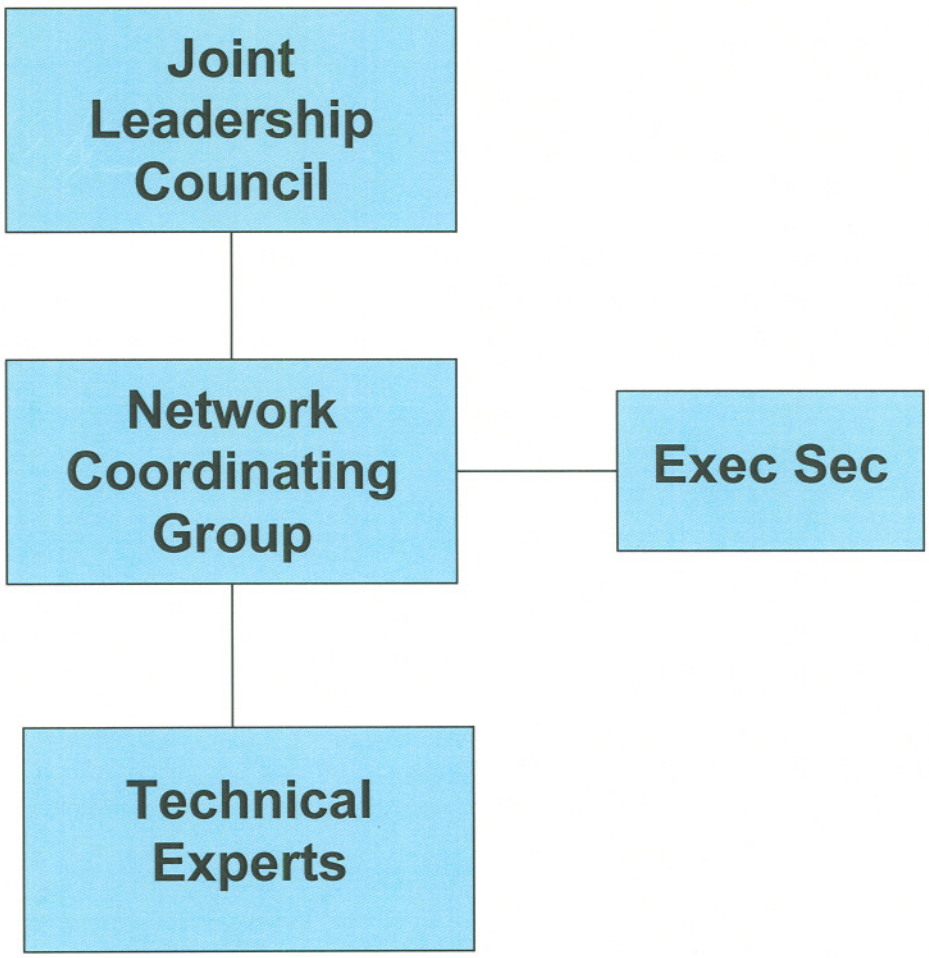
Appendix: ICLN Organizational Structure