

ATTACHMENT 3

**Laboratory Membership Application for EPA's
Environmental Response Laboratory Network (ERLN)**

Contact Information – Please provide the following address information and identify the points of contact you wish to specify for communicating with the ERLN

Laboratory Name:	
Shipping Address:	
City:	
State:	Zip Code:
Mailing Address:	
City:	
State:	Zip Code:

Points of Contact:

a. **Primary**

Title _____

E-Mail _____

Phone No. _____ Fax No. _____

Mobile Phone No. _____ Emergency Phone No. _____

b. **Secondary**

Title _____

E-Mail _____

Phone No. _____ Fax No. _____

Mobile Phone No. _____ Emergency Phone No. _____

c. **Other**

Title _____

E-Mail _____

Phone No. _____ Fax No. _____

Mobile Phone No. _____ Emergency Phone No. _____

1. **Accredited Quality System** – Please indicate if your laboratory maintains and operates a documented quality management system. Also indicate if this system has been accredited or certified by one of the listed organizations. (*Documentation required with the Application*)

<u>Accredited Quality System</u>	Yes	No	Comments
1.1. Does laboratory have a quality management system?			
1.2. Is laboratory certified by any EPA program?			
1.3. Is laboratory accredited by NELAP?			
1.4. Is laboratory accredited to ISO 17025 standard?			
1.5. Does laboratory agree to submit Quality Management Plan within thirty days of request?			

If your laboratory has a documented quality management system, but is not certified or accredited please complete Attachment 5, indicating the essential components of your current quality management system

2. **Plans and Procedures** – Please indicate if your laboratory has documented, comprehensive plans and procedures for the following

<u>Plans and Procedures</u>	Yes	No	Comments
2.1. Individual Standard Operating Procedures (SOPs) written for each major element listed in the laboratories quality assurance plan			
2.1.1. Are SOPs available at individual work stations?			
2.2. Health and Safety Plan that ensures the safety of the laboratory personnel as well as support the integrity and security of the samples			
2.3. Chemical Hygiene Plan			
2.4. Security Plan addressing physical security, personnel, policies, and procedures			
2.5. Waste Management Plan			
2.6. Radiation Protection Plan that satisfy all regulations applicable to radioactive materials licensing and radiation protection and which address safe receipt, handling, storage and disposition of radioactive materials and sources, if applicable.			
2.7. Does the laboratory conduct and document employee training for all of the above applicable plans?			

3. **Sample Management System** – Please indicate if your laboratory has documented procedures and systems that address the following aspects of sample management.

<u>Sample Management System</u>	Yes	No	Comments
3.1. Sample Receiving			
3.2. Sample Identification			
3.3. Sample Security			
3.4. Sample Storage			
3.5. Sample Tracking and Document Control			
3.6. Computer-Resident Sample Data Control			

<u>Sample Management System</u>	Yes	No	Comments
3.7. Report Organization, Assembly and Delivery			

4. Facilities for Sample Handling and Storage – Please indicate if your laboratory currently has the following sample handling and storage facilities.

<u>Facilities for Sample Handling and Storage</u>	Yes	No	Comments
4.1. Loading dock/designated sample receiving area			
4.2. Sample receipt area with an exhaust fume hood and sequestering area			
4.3. Screening process to identify and prevent potential laboratory contamination from contaminated samples that are received			
4.4. Remote or shielded sample storage available for samples containing elevated levels of radioactivity, if applicable.			
4.5. Secure/access controlled, refrigerated sample storage area with a minimum of 500 sq. ft storage to house samples awaiting analysis			
4.5.1. Temperature-controlled storage area for organic analyses (including Chemical Warfare Agent analysis)			
4.5.2. Separate temperature-controlled storage area for samples requiring volatile analyses			
4.5.3. Each temperature controlled storage area is monitored daily			
4.6. Chemical fume hoods for the preparation and analysis of samples			
4.7. A BSL 2 (or higher) facility or other certified biosafety cabinet, if applicable.			
4.8. Ultra pure (18 meg-ohm) water available for conducting analyses, if applicable.			
4.9. Separate area for samples awaiting final disposition and disposal, if applicable.			

5. Data Management and Exchange – Please indicate if your laboratory currently has any of the following data management and exchange systems and capabilities.

<u>Data Management and Exchange</u>	Yes	No	Comments
5.1. Systems in place to limit copying, and control distribution and access of secured methods to those individuals who are actively engaged in analysis of environmental samples in the ERLN?			
5.2. Systems to maintain integrity of data from tests (i.e., results cannot be changed)?			
5.3. Documented system for second party (e.g. second analyst, QA officer, etc) review of data?			
5.4. Operational automated laboratory information management system (LIMS)?			

<u>Data Management and Exchange</u>	Yes	No	Comments
5.5. Data system capable of generating an electronic data output meeting the ERLN's interim streamlined data format*			
5.6. Procedures to immediately report positive and suspect results to the established ERLN contact for your laboratory within 1 hour of generation of results			
5.7. Deliver electronic data and exchange of information with the established ERLN contact or other authorized personnel in a variety of report formats to a secure website			
5.8. Broadband internet connection (e.g., DSL, cable, T1, etc.)?			
5.9. Provide all calculated results and raw data used to generate results, including GC/MS tuning analyses, calibration analyses, and QC analyses?			
5.10. Long term archival (up to five years) of results and raw data, and ability to re-generate all results and raw data from archived data?			

* The ERLN EDD is expected to evolve to formats with the goal of facilitating the electronic assessment of data as well as provide final laboratory results.

6. Affiliation and Membership – Please indicate if your laboratory participates in any of the following Integrated Consortium of Laboratory Networks (ICLN) member networks:

<u>Affiliation and Membership</u>	Yes	No	Comments
6.1. Food Emergency Response Network (FERN)			
6.2. Laboratory Response Network (LRN) - Chemical			
6.3. Laboratory Response Network (LRN) - Biological			
6.4. National Animal Health Laboratory Network (NAHLN)			
6.5. National Plant Diagnostic Network (NPDN)			

7. Special Registrations, Approvals, or Licenses – Please indicate any special approvals your laboratory has received for the receipt, handling and analysis of agents or radioactive materials. Please provide copies of any of these licenses with your application. (*Documentation required with the Application*)

<u>Special Registrations, Approvals, or Licenses</u>	Yes	No	Comments
7.1. Select Agents			
7.2. Surety Agents			
7.3. NRC License for Radioactive Materials (other than instrument detector licenses)			
7.4. Others (specify)			

8. Clearances – Please indicate the number of staff associated with your laboratory who possess active clearance in each of the following categories:

Type of Clearance	Number of Personnel	Comments
8.1. Top Secret		
8.2. Secret		
8.3. Q		
8.4. L		

Responsibilities of Laboratory

By signing below, I recognize our responsibilities as an ERLN laboratory include the following (check all boxes):

<input type="checkbox"/>	Laboratory must maintain a documented Quality Management System such as by NELAP accreditation or an ISO 17025 equivalent accreditation program.
<input type="checkbox"/>	Laboratory must agree to on-site audits by ERLN representatives for the purposes of assessing qualifications for membership, capabilities, capacity, and quality.
<input type="checkbox"/>	Laboratory must have manuals and standard operating procedures which include, but are not limited to, a Quality Manual, Waste Management Plan, Health & Safety Plan, Chemical Hygiene Plan, and Radiation Protection Plan and associated standard operating procedures for radiation monitoring (if applicable). These documents and procedures will be made available to the authorized ERLN representatives upon request.
<input type="checkbox"/>	Laboratory will have sufficient personnel with necessary education, training, technical knowledge and experience to perform their assigned functions.
<input type="checkbox"/>	Laboratory will have a documented Sample Management System that addresses sample receiving, sample identification, sample security, sample storage, sample tracking and document control, computer-resident sample data control, and data deliverable organization and assembly.
<input type="checkbox"/>	Laboratory will have radioactive materials licensing and radiation safety plans and procedures as appropriate (radiological capabilities laboratories only).
<input type="checkbox"/>	Laboratory must have a designated emergency medical treatment center.
<input type="checkbox"/>	Laboratory will assure sufficient internal security to control access to ERLN materials.
<input type="checkbox"/>	Laboratory will accept responsibility for all risks associated with handling these materials and agents.
<input type="checkbox"/>	Laboratory will assure there will be no transfer of these materials to any third party.
<input type="checkbox"/>	Laboratory agrees to have system in place to limit copying, and control distribution and access of any method systems or procedures identified by ERLN as secure to those individuals who are actively engaged in analysis of environmental samples in the ERLN.
<input type="checkbox"/>	Laboratory will have the ability to share its data with the ERLN contact via an approved data system.
<input type="checkbox"/>	Laboratory will immediately report positive or suspect test results to authorized personnel only.
<input type="checkbox"/>	Laboratory will ensure data and information security system is in place to protect clients' confidential information and proprietary rights.
<input type="checkbox"/>	Laboratory will adhere to ERLN approved test methods when testing ERLN samples, as defined in <i>USEPA Standard Analytical Methods for Environmental Restoration following Homeland Security Events</i> . (www.epa.gov/sam)
<input type="checkbox"/>	Laboratory must have measurement and testing equipment to perform the applicable test as specified in the ERLN method.
<input type="checkbox"/>	Laboratory agrees to adhere to ERLN-approved testing protocols when testing and reporting results of ERLN samples.
<input type="checkbox"/>	Laboratory must be willing to participate in proficiency testing (PT) studies.
<input type="checkbox"/>	Laboratory agrees to meet the requirements listed in the ERLN Membership Application checklist.

I confirm that the preceding items have been diligently reviewed and assume responsibility for the accuracy of the responses contained herein.

Signature of Laboratory Director

Date

Printed Name, Title
