

Appendix G: Preparedness and Response

Focus Area Name

Public Health Preparedness and Response

Focus Area Contact Information

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Approximate Average Annual Award: \$1,000,000

Funding Opportunity Description

1. Background

State and local public health laboratories (PHLs) play an indispensable role in protecting America's health from a broad spectrum of health threats. These threats include intentional and unintentional release of biological, chemical, radiological, and nuclear agents; exposures associated with natural and industrial disasters; and a range of public health threats and emergencies. The implicated agents may be well-known (e.g., anthrax, tularemia, or sarin), variations on known pathogens and chemicals, or entirely novel. In all cases, PHLs are critically important in performing primary and reference tests, providing surge capacity, interpreting test results, communicating test-related information to public health and emergency response authorities at the local, state, national, and international levels, and advising on effective emergency response.

The primary aim of the Laboratory Response Network (LRN) for chemical and biological threats and the Public Health Emergency Preparedness (PHEP) Cooperative Agreement is to set standards for laboratory preparedness and response, support an effective individual laboratory response to local events, and assure a coordinated national laboratory capacity that leverages the capabilities of member PHLs. To perform these functions effectively, PHLs must attain technical capabilities and resources as indicated in LRN membership policies (secure website) and the PHEP capabilities, specifically Public Health Laboratory Testing (PHLT) capability 12 (available at <https://www.cdc.gov/cpr/readiness/capabilities.htm>). Critical requirements include, but are not limited, to the following: a proficient workforce skilled in the safe use of LRN testing methods; availability and maintenance of state-of-the-art LRN equipment and instrumentation; and the ability to correctly interpret test results and exchange data with partners. Additionally, PHLs must exercise, test, and assure a robust operational laboratory system locally as well as nationally and establish/maintain effective partnerships and communication with other PHLs and with federal, clinical, and environmental laboratories. This may include providing input to proposed policies as well as formal agreements that authorize test referral and test service sharing during emergencies.

Healthy People 2020

This focus area supports the following Healthy People 2020 objectives:

Preparedness, Objective 3: Increase the proportion of Laboratory Response Network (LRN) laboratories that meet proficiency standards

Public Health Infrastructure, Objective 11: Increase the proportion of tribal and state public health agencies that provide or assure comprehensive laboratory services to support public health services

Public Health Infrastructure, Objective 12: (Developmental) Increase the proportion of public health laboratory systems (including State, Tribal, and local) which perform at a high level of quality in support of the 10 Essential Public Health Services

Other National Public Health Priorities and Strategies

- National Biodefense Strategy: <https://www.cdc.gov/cpr/readiness/capabilities.htm>
- National Health Security Strategy: <https://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx>
- Public Health and Medical Situational Awareness Strategy: <https://www.phe.gov/about/OPP/Documents/phm-sa-ip-sept2015.pdf>
- Global Health Security Agenda: <https://www.ghsagenda.org/>
- CDC Data Strategy (draft)
- Project Public Health Ready: <https://www.naccho.org/programs/public-health-preparedness/pphr>
- Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health: <https://www.cdc.gov/cpr/readiness/capabilities.htm>

2. CDC Project Description

a. Approach

I. Purpose

The overarching purpose of this program is to build and strengthen foundational capabilities needed by individual PHLs and the nation's PHL system to support every day effectiveness that can be scaled to meet the needs of a public health emergency. These capabilities are essential for rapid laboratory detection and characterization, diagnosis, and establishment of an evidence base to inform public health action. This program will also inform federal, state and local policies and agreements to reinforce and strengthen U.S. national testing capability and capacity.

II. Outcomes

Activities in this focus area should achieve or contribute to the following proximal outcomes (refer to section ii, "Outcomes," under Part II, A-2-a or the overall logic model in this NOFO for a full list of outcomes of this cooperative agreement):

PO-1. Improved collaboration and communication across public health laboratories and other stakeholders

- Improved communications systems with clinical and other laboratory partners and support networks among PHLs and with partners in other sectors; encourage laboratories to provide outreach to clinical laboratories



PO-2. Improved awareness and understanding of public health laboratories among public and other stakeholders

PO-3. Improved support among policy makers and other stakeholders

PO-7. Enhanced technical and non-technical knowledge, skills and abilities among public health laboratory professionals in diverse settings

PO-8. Improved understanding of data-related challenges and implementation of data-informatics solutions among laboratory professionals and other stakeholders

PO-13. Improved laboratory testing capability and surge capacity for emergency response through equipment procurement, competent staff and partnerships

Activities in this focus area should achieve or contribute to the following intermediate outcomes (refer to section ii, “Outcomes” under Part II, A-2-a or the overall logic model in this NOFO for a full list of outcomes of this cooperative agreement):

IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system

IO-6. Improved public health laboratory detection, surveillance, and response.

III. Funding Strategy

CDC funding strategy for this focus area is described in section iv, “Funding Strategy”, under Part II, A-2 (CDC Project Description; a. Approach) in this NOFO. Funds should be used for program activities, which could include personnel, travel, supplies, equipment, contractual, and consultant support for proposed activities.


Funded recipient is expected to adhere to the requirements of the cooperative agreement. This may include:

- Identifying a designated person with overall responsibility for all activities as well as personnel responsible for each activity;
- Participating in implementation, support, and monitoring efforts at least quarterly

Budgets should be submitted with sufficient level of detail so that the technical monitor, project officer, or the grants management officer can determine the necessity, reasonableness, and allocability of costs relative to the proposed grant activities, and their allowability pursuant to the applicable federal cost principles and requirements.

IV. Strategies and Activities

Activities under this focus area should be guided by strategies in the following categories: Policy, Partnership, and Communication (S2), Training and Capacity



Building (S3), and Laboratory Quality, Safety, and Informatics for Public Health Testing Services, Surveillance and Response (S4).

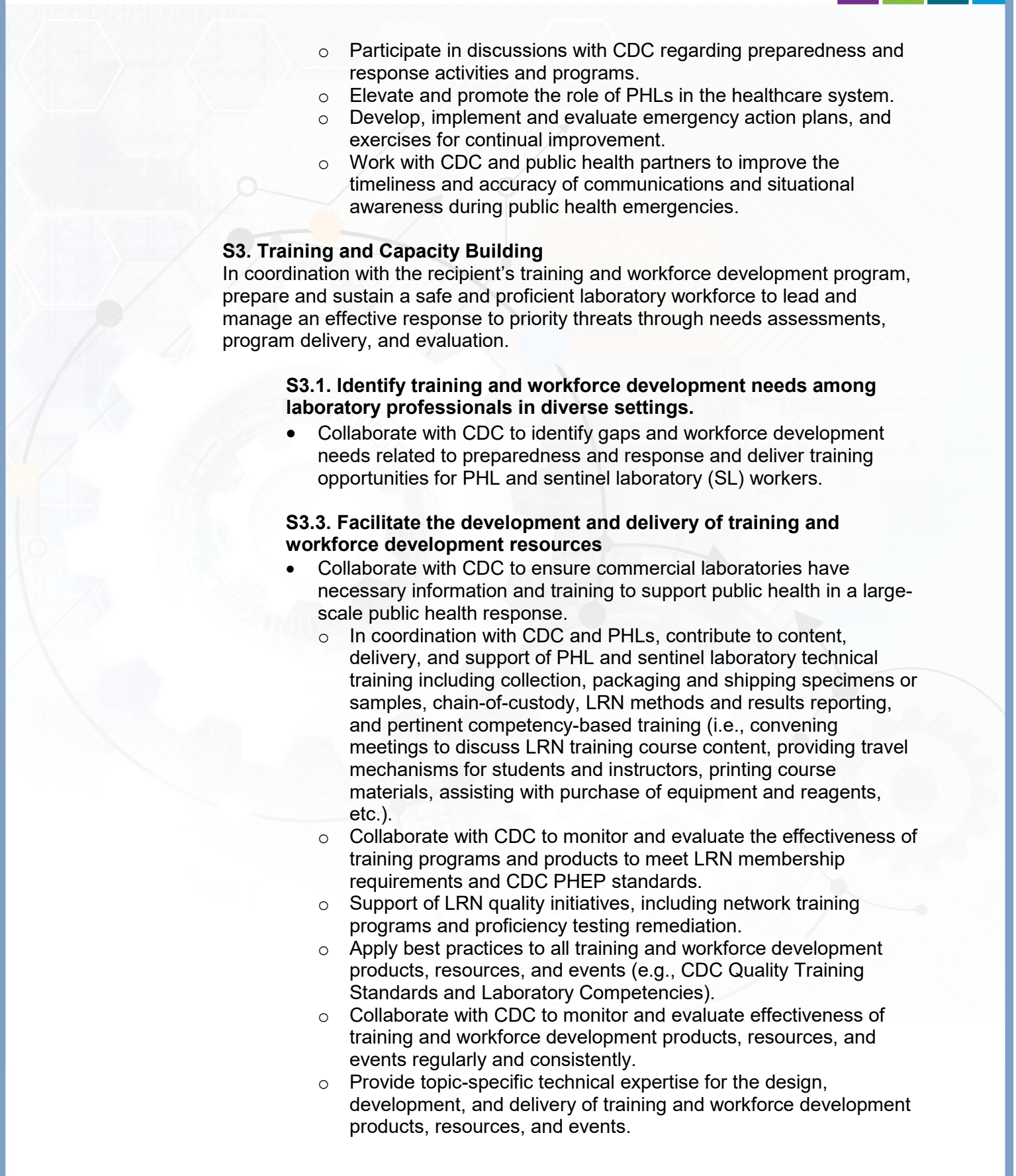
S2. Policy, Partnership, and Communication

S2.1. Provide policy and issues analysis to support public health laboratory interests

- Educate the public and other stakeholders about the role of the PHL system and LRN (including clinical laboratories, PHLs, and other stakeholders) and the data produced every day and in public health emergencies through newsletters, reports, social media, and other information dissemination modalities.
- Issue statements that provide the PHL perspective on pending legislation and regulations and disseminate educational materials on priority issues.
- Conduct policy analysis and identify gaps, challenges, and opportunities for advancing or improving PHL preparedness and response activities.
- Collect success stories and model practices to share with state and local PHLs to promote coordinated technical and biosafety outreach to sentinel clinical laboratories.
- Develop and communicate guidance about new and existing science and policy issues to ensure PHLs are informed and have the opportunity to provide a PHL perspective to proposed legislation or regulations.
- Develop communications or policy statements on issues pertinent to the PHL community to inform proposed policies or their interpretation.

S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare and beyond.

- Serve as a conduit of information between PHLs, state, local governments and federal agencies.
 - Develop activities that convene critical stakeholders to advise on priorities and promote information sharing and coordination between LRN-C and LRN-B activities within recipient, PHLs, FBI, DoD and CDC.
 - Provide input to the Department of Homeland Security (DHS) on the current BioWatch program and the Biodetection-21 program that is being evaluated at DHS.
 - Establish procedures or guidelines to help PHLs coordinate with relevant stakeholders (including, but not limited to, sentinel or clinical laboratories) during public health responses and engage with National Incident Management Systems (NIMS).
 - Develop relationships, facilitate strategic and operational communications, collaborate and convene with state, federal and international, healthcare, public health and other partners to ensure a coordinated and effective US laboratory response in public health emergencies.

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- Participate in discussions with CDC regarding preparedness and response activities and programs.
 - Elevate and promote the role of PHLs in the healthcare system.
 - Develop, implement and evaluate emergency action plans, and exercises for continual improvement.
 - Work with CDC and public health partners to improve the timeliness and accuracy of communications and situational awareness during public health emergencies.

S3. Training and Capacity Building


In coordination with the recipient's training and workforce development program, prepare and sustain a safe and proficient laboratory workforce to lead and manage an effective response to priority threats through needs assessments, program delivery, and evaluation.

S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings.

- Collaborate with CDC to identify gaps and workforce development needs related to preparedness and response and deliver training opportunities for PHL and sentinel laboratory (SL) workers.

S3.3. Facilitate the development and delivery of training and workforce development resources

- Collaborate with CDC to ensure commercial laboratories have necessary information and training to support public health in a large-scale public health response.
 - In coordination with CDC and PHLs, contribute to content, delivery, and support of PHL and sentinel laboratory technical training including collection, packaging and shipping specimens or samples, chain-of-custody, LRN methods and results reporting, and pertinent competency-based training (i.e., convening meetings to discuss LRN training course content, providing travel mechanisms for students and instructors, printing course materials, assisting with purchase of equipment and reagents, etc.).
 - Collaborate with CDC to monitor and evaluate the effectiveness of training programs and products to meet LRN membership requirements and CDC PHEP standards.
 - Support of LRN quality initiatives, including network training programs and proficiency testing remediation.
 - Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).
 - Collaborate with CDC to monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.
 - Provide topic-specific technical expertise for the design, development, and delivery of training and workforce development products, resources, and events.



Additional preparedness-related training and workforce development activities are detailed in Appendix I: Workforce Development.


S4. Laboratory Quality, Safety, Preparedness, and Informatics for Public Health Testing Services, Surveillance, and Response

S4.1. Develop and implement informatics-related solutions and standards to improve data exchange and interoperability

- In coordination with the CDC workgroup that provides governance for informatics projects accomplished through collaborations with CDC partners and the recipient's informatics program, convene partners and other stakeholders through committees, workgroups, and meetings to inform a laboratory data strategy and implementation plan that would support multilateral data exchange between public health, healthcare, and CDC and other partners, as appropriate, to support state, local, and national emergency response needs.
 - Work with the recipient's informatics program, LRN Program, CPR, PHLs, and other stakeholders to assess how to more effectively use LRN data in a public health emergency, align PHL and CDC laboratory informatics initiatives, and reduce the burden on PHLs. Recommendations should inform policies and programs for the following:
 - Collaborate with CDC to evaluate LRN data collection requirements and strategies to maximize the use of data collected in a response.
 - Collaborate with CDC and partners to prepare recommendations and guidance to help standardize data, message formats, and ensure needed data/metadata are shared between epidemiologists and laboratory scientists within state and local public health departments.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories: Coordinate with CDC and PHLs to decrease the time to accurately detect, characterize and report chemical, biological, radiological or emerging threats in clinical specimens, food, or environmental samples, as appropriate

- Identify gaps and implement solutions in coordination with CDC to ensure accurate, rapid detection and characterization of CBRN and emerging threats.
 - Implement committees, workgroups or programs to support active engagement of PHLs in the development and assessment of LRN strategies, policies, and programs.
 - Facilitate collaboration between CDC and PHLs to inform development, deployment and intended use of new methods.
 - Support participation of PHLs in method development, single and multicenter evaluations and the acquisition of samples/specimens necessary for method verification.
 - Partner with CDC, PHLs and state public health departments to develop strategies or plans that leverage use of LRN capabilities (e.g., proficient workforce and state-of-the art infrastructure) to



address high burden priority public health concerns (e.g., influenza).

S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and responds to public health threats.

Conduct needs assessments and collaborate with CDC to strengthen federal, state, and local public health infrastructure including assuring availability of up-to-date and properly maintained equipment and instrumentation that supports routine and surge testing needs:

- Assess the capacity and capability of U.S. PHLs for preparedness and response and disseminate findings through publications or reports.
- Coordinate development of guidelines or activities to improve PHL and SL preparedness to support critical emergency response operations that may include the following topics:
 - Receipt, recording, prioritization, and routing of specimens or samples
 - Testing using LRN methods
 - Accurate and timely reporting of presumptive or confirmed test results
 - Support PHL participation in emergency preparedness and response exercises and real emergency responses.
- Coordinate with CDC and state public health departments to develop recommendations or guidance to address challenges.
- Conduct needs assessments, produce reports, and develop products that improve compliance with federal regulations.
 - Identify and address quality, practice and safety issues in PHLs by convening committees, workgroups or other meetings and producing recommendations and reports.
 - Promote PHL adoption of, and compliance with, accreditation guidelines of government programs and professional societies (e.g., Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists accreditation programs (CAP), International Organization for Standardization (ISO), Clinical and Laboratory Standards Institute (CLSI), Federal Select Agent Program).
 - Identify and address quality, practice and safety issues in PHLs.
 - Develop tools and/or training to ensure the safe and secure storage, use and transfer of select agents and other high risk biological threats in compliance with the federal select agent program.
 - Monitor and provide guidance to state and local PHLs regarding the Federal Select Agent Program.
- Collaborate with CDC to convene experts within the agency, in other federal agencies, clinical and environmental laboratories, and nongovernmental partners to better address surge capacity testing needs.
 - Assist PHLs with development and implementation of programs, plans, or activities that ensure needed staff and equipment are in place to support laboratory emergency response activities.

- In coordination with CDC, assess needs, convene partners and develop strategies or plans to strengthen a national network of clinical, environmental and PHLs to improve surge testing capacity during a large scale response.
- Assess whether every state has continuity of operations (COOP) agreements in place and up-to-date plans that would allow routine laboratory testing needs to be maintained when normal operations are disrupted.

b. Evaluation and Performance Measurement

I. CDC Evaluation and Performance Measurement Strategy

The CDC Evaluation and Performance Measurement Strategy for this focus area uses the guidance from the overall CDC Evaluation and Performance Measurement Strategy described in this NOFO (Part II, A-2-b-i. CDC Evaluation and Performance Measurement Strategy), to address the following specific performance measures (including process measures and outcome measures) for this focus area.

Process measures for the strategies in this focus area may include:

Strategy and Activity	Process Measure
S2.1. Provide policy and issues analysis to support public health laboratory interests	<ul style="list-style-type: none"> ● Policy analyses that inform and positively influence preparedness and response programs or activities.
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare and beyond.	<ul style="list-style-type: none"> ● New partnerships, procedures, emergency action plans and/or guidelines that are needed for a coordinated national response.
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings.	<ul style="list-style-type: none"> ● Products, resources and events that enhance workforce development.
S3.3. Facilitate the development and delivery of training and workforce development resources	<ul style="list-style-type: none"> ● Number of related training and workforce development resources facilitated and/or delivered. ● Number and type of resources and delivery methods used to facilitate competency in public health preparedness and response.
S4.1. Develop and implement informatics-related solutions and standards to improve data exchange and interoperability	<ul style="list-style-type: none"> ● Strategy and implementation plan, in conjunction with the CDC Informatics Projects Governance Workgroup, for upgrading multilateral data exchange between public health, healthcare and CDC.



<p>S4.3. Identify and address emerging methodological and process improvements in public health laboratories</p>	<ul style="list-style-type: none"> Resources and products that assist LRN laboratories to conduct studies and implement new methods; produce and implement solutions to identified gaps in emergency response.
<p>S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and responds to public health threats.</p> <ul style="list-style-type: none"> Support PHL participation in emergency preparedness and response exercises and real emergency responses. 	<ul style="list-style-type: none"> Publications and reports that describe capability and capacity for PHLs to respond to public health emergencies. Guidance documents for emergency response that facilitate sample transport, accessioning, use of LRN methods and data reporting. LRN laboratory participation in exercises and responses events. Needs assessments, reports and products that improve compliance with federal regulations.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
<p>PO-1. Improved collaboration and communication across public health laboratories and other stakeholders</p>	<ul style="list-style-type: none"> Demonstrated increase and/or enhancement in LRN laboratories that have established active outreach programs with Sentinel laboratories.
<p>PO-2. Improved awareness and understanding of public health laboratories among public and other stakeholders</p>	<ul style="list-style-type: none"> Reports, articles or other informational documents that inform public, policy makers and government officials on LRN role in preparedness and response.
<p>PO-3. Improved support for public health laboratories among stakeholders</p>	<ul style="list-style-type: none"> Position papers that can inform development of policy documents related to federal laws and regulations that support emergency response and preparedness needs.
<p>PO-7. Enhanced technical and non-technical knowledge, skills and abilities among public health laboratory professionals in diverse settings.</p>	<ul style="list-style-type: none"> At least 95% of LRN PHLs meet requirements for DOT certification.
<p>PO-8. Improved understanding of data-related challenges and implementation of data-informatics solutions among laboratory professionals and other stakeholders</p>	<ul style="list-style-type: none"> Increase in the number of LRN laboratories that have ability to send results to CDC and other public health partners.



<p>PO-13. Improved laboratory testing capability and surge capacity for emergency response through equipment procurement, competent staff and partnerships</p>	<ul style="list-style-type: none"> • Increase in the number of PHLs with formal agreements for emergency-related testing sharing services and surge capacity support (e.g., COOP agreements). • Number of PHLs who have brought on assays for surge testing and emergency response.
<p>IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system</p>	<ul style="list-style-type: none"> • LRN laboratories can conduct new methods needed for emergency response.
<p>IO-6. Improved public health laboratory detection, surveillance, and response</p>	<ul style="list-style-type: none"> • Improved surveillance, detection, diagnostics, vaccine strain selection, pandemic preparedness and response capabilities.

II. Applicant Evaluation and Performance Measurement Plan

The recipient will be required to submit a detailed Evaluation and Performance Measurement plan within the first 6 months of award and work with CDC staff to ensure that the evaluation plan is feasible and consistent with proposed focus area activities, the intent of this NOFO, and CDC’s evaluation approach.

c. Collaborations

With CDC funded programs

General guidance for collaborations with CDC funded programs is described in section a, “With other CDC programs and CDC-funded organizations,” under Part II, A-2-iii-1 (Collaborations) in this NOFO.

The recipient is expected to strengthen existing public health preparedness and response collaborations with CPR, NCEZID, NCIRD, NCHHSTP, NCEH, CSELS, CSTLTS, CGH, NIOSH, OLSS and other relevant CDC offices and programs.


The recipient should explore and establish supportive new collaborations with CDC offices and programs.

With organizations external to CDC

General guidance for collaborations with organizations external to CDC is described in section b, “With organizations not funded by CDC,” under Part II, A-2-iii-1 (Collaborations) in this NOFO.

The recipient is encouraged to:

- Strengthen existing collaborations with federal agencies such as the DHHS Office of the Assistant Secretary for Preparedness and Response, the Department of Homeland Security, the Federal Bureau of Investigation, the Food and Drug Administration, the Department of Energy, the Department of Defense,



the Environmental Protection Agency, Department of Defense, and the Department of Agriculture.

- Explore and establish supportive new collaborations with state, federal, local, and international partners to advance public health priorities.
- Strengthen existing collaborations with supportive, nonfederal organizations such as the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the National Association of County and City Health Officials, American Clinical Laboratory Association and with appropriate professional/scientific organizations.
- Explore and establish supportive new collaborations with additional nonfederal organizations to advance public health priorities.

d. Target populations

In addition to PHLs and PHL professionals and epidemiologists supporting state, local, tribal, and territorial public health programs, the specific target population of this focus area also includes stakeholders of the PHL system, such as policy makers, clinical laboratories, healthcare organizations, professional organizations, as well as the general public.

e. Organizational Capacity

Refer to section c, “Organizational Capacity of Recipients to Implement the Approach” under Part II, A-2 (CDC Project Description) in this NOFO.

f. Work Plan

The recipient is required to provide a work plan for this focus area that provides both a high-level overview of the entire five-year period of performance and a detailed description of the first year of the award. The work plan should follow the general guidance provided in section d, “Work Plan” under Part II, A-2 (CDC Project Description) in this NOFO, and address the specific strategies, activities, outcomes, and performance measures of this focus area. After the award is made, the proposed work plan (including the evaluation and performance measurement plan) may be adjusted in collaboration with the CDC Technical Monitor(s) to ensure integration of the strategies and activities and achievement of the period of performance outcomes.

g. CDC Program Support to Recipient

CDC’s Center for Preparedness and Response, NCEZID/Division of Preparedness and Emerging Infections, NCEH/Division of Laboratory Sciences and CSELS/Division of Laboratory Systems will provide technical expertise, technical monitoring and program support (as appropriate) for this focus area as described in section f, “CDC Program Support to Recipients,” under Part II, A-2 (CDC Project Description) in this NOFO. In addition, CDC may participate in all relevant stakeholder and other meetings, either in-person or by teleconference.