CDC-RFA-OE20-2001: Enhancing Public Health Laboratory Capabilities and Increasing Capacity

Appendices

Appendix A: Foundational Leadership and Support

Focus Area Name
Foundational Leadership and Support

Focus Area Contact Information
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Approximate Average Annual Award: $2,000,000

Funding Opportunity Description

1. **Background**
    Public health laboratory (PHL) systems (including state, territorial, tribal, and local) play an indispensable role in protecting the health of Americans from new, emerging, and existing health threats by conducting laboratory testing and providing other science-based services. Public health professionals and policy makers use actionable information from PHLs daily to identify and prioritize these population health threats and to develop and implement effective interventions. In order to fulfill their critical public health mission, PHLs must be capable and effective at detecting and responding to a myriad of threats across a broad and expanding spectrum of health domains, including infectious and chronic diseases, chemical and radiological exposure, birth defects, foodborne and waterborne diseases, public health emergencies, and others.

    Despite their critical functions, PHLs face serious challenges in developing the capacities and capabilities to perform their role. These challenges include the rapid emergence of new disease threats, extensive restructuring of the nation's healthcare system, the accelerating evolution in testing and information that requires improvement in data exchange and interoperability, ensuring safe laboratory practices with existing and new technologies, and enhancing the infrastructure and capacity of the PHL workforce. In addition, PHLs often face persistent fiscal problems, workforce reductions, and other problems that threaten their development of needed capabilities to address public health issues and, in some cases, their ability to perform important testing services.

    Healthy People 2020
    This focus area supports the following Healthy People 2020 objectives:

    Public Health Infrastructure, Objective 11: Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential 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
- HHS Strategic Plan, 2018-2022: https://www.hhs.gov/about/strategic-plan/index.html
- CDC Strategic Framework, 2016-2020:
  https://www.cdc.gov/about/organization/strategic-framework/index.html

2. CDC Project Description
  a. Approach
  See Logic Model in Appendix J.

  I. Purpose
  The Foundational Leadership and Support focus area enables and empowers the recipient to achieve the goal of this cooperative agreement - improving the effectiveness of PHLs, both individually and as components of a national system. This cooperative agreement will support the implementation of two core strategies in this focus area: (1) science, management, and operations (2) policy, partnership, and communication. An integrated approach for ensuring organizational excellence is needed for achieving optimal outcomes for all strategic program activities included in this funding announcement.

  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

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

  PO-3. Improved support for public health laboratories among stakeholders

  PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders

  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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders

  IO-2. Established information sharing systems across public health laboratories and with key stakeholders

  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: Science, Management, and Operations (S1) and Policy, Partnership, and Communication (S2).
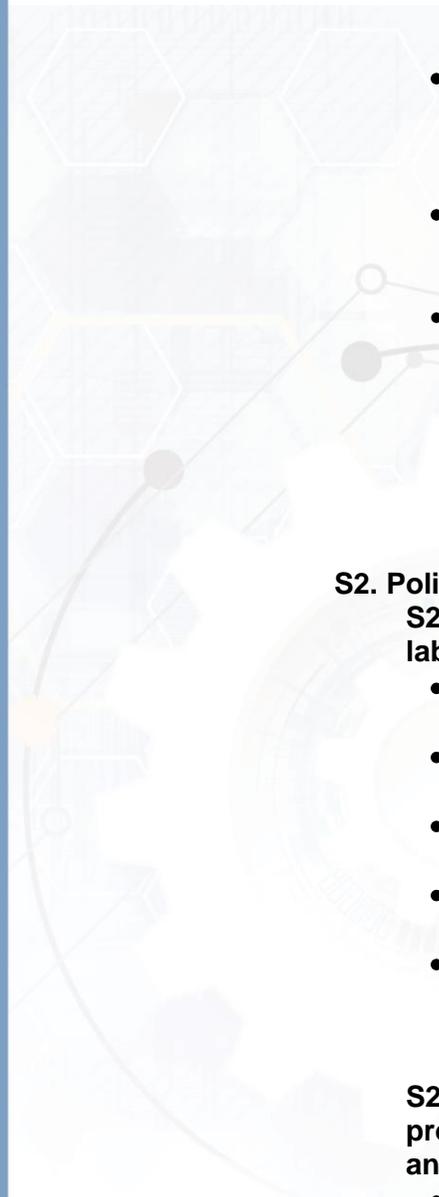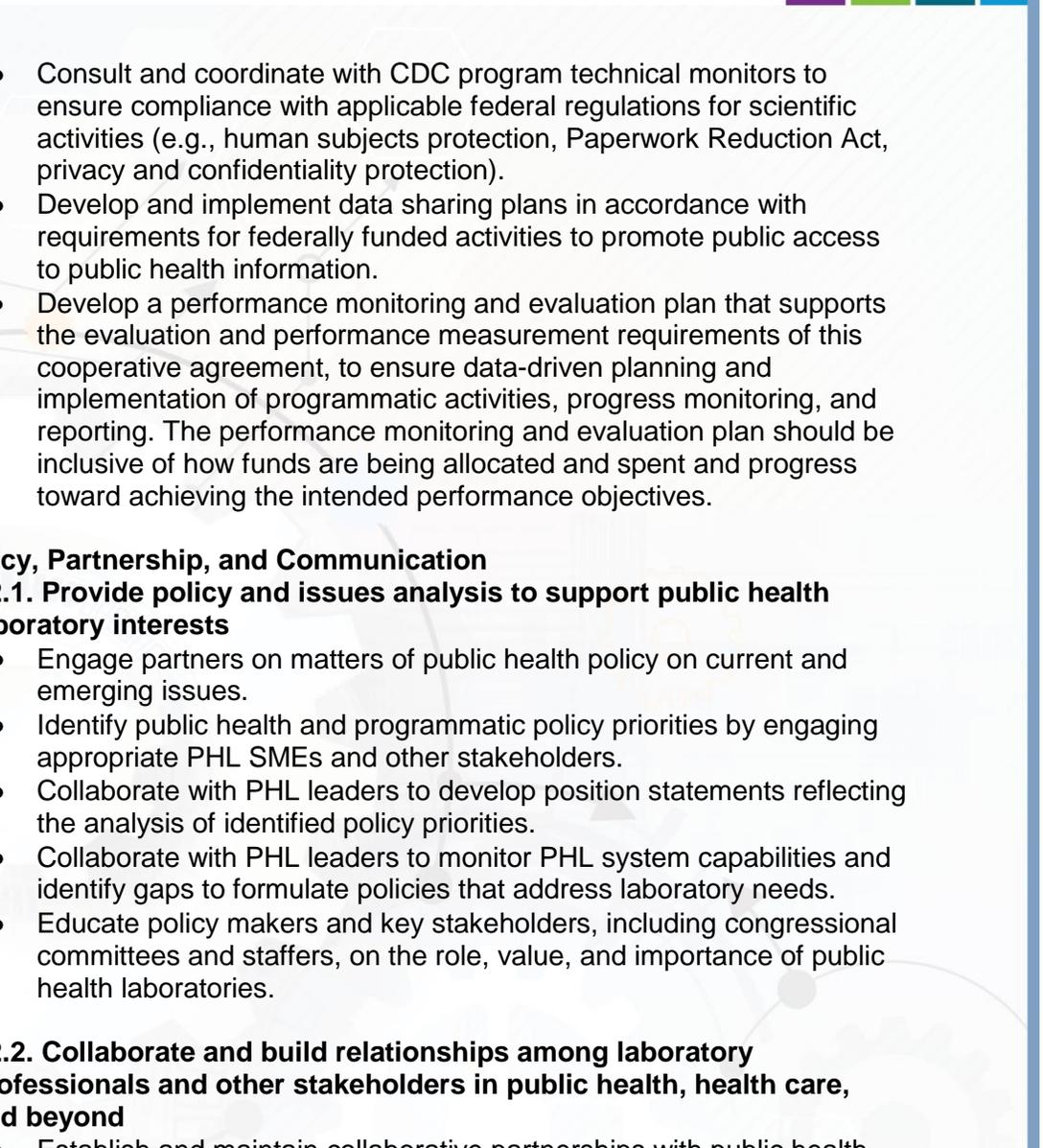
S1. Science, Management, and Operations

S1.1. Provide leadership and management approaches to ensure organizational efficiency and operational improvement
- Provide effective organizational leadership, coordination, and support to all focus areas under this cooperative agreement.
- Assess the performance of the overall organization to ensure quality of data, effective program implementation, information sharing, and accountability of funds.
- Develop and maintain reporting tools for the financial management of the cooperative agreement program areas that include detailed costs at the project level.
- Provide reoccurring reports on the utilization of funds across the cooperative agreement with high-level impacts of investment.
- Ensure that program and financial reporting support helps to minimize burden and reduces duplicate efforts across the projects within this cooperative agreement.
- Effectively manage project timelines within the scope of this cooperative agreement.
- Ensure all work is conducted in accordance with public health ethical standards.

S1.2. Provide appropriate monitoring, evaluation, and scientific services
- Promote quality, integrity, and innovation PHL science, practice, and services, and ensure science-based principles and/or best practices are used in all focus areas under this cooperative agreement.

- Consult and coordinate with CDC program technical monitors to ensure compliance with applicable federal regulations for scientific activities (e.g., human subjects protection, Paperwork Reduction Act, privacy and confidentiality protection).
- Develop and implement data sharing plans in accordance with requirements for federally funded activities to promote public access to public health information.
- Develop a performance monitoring and evaluation plan that supports the evaluation and performance measurement requirements of this cooperative agreement, to ensure data-driven planning and implementation of programmatic activities, progress monitoring, and reporting. The performance monitoring and evaluation plan should be inclusive of how funds are being allocated and spent and progress toward achieving the intended performance objectives.

S2. Policy, Partnership, and Communication
S2.1. Provide policy and issues analysis to support public health laboratory interests
- Engage partners on matters of public health policy on current and emerging issues.
- Identify public health and programmatic policy priorities by engaging appropriate PHL SMEs and other stakeholders.
- Collaborate with PHL leaders to develop position statements reflecting the analysis of identified policy priorities.
- Collaborate with PHL leaders to monitor PHL system capabilities and identify gaps to formulate policies that address laboratory needs.
- Educate policy makers and key stakeholders, including congressional committees and staffers, on the role, value, and importance of public health laboratories.

S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, health care, and beyond
- Establish and maintain collaborative partnerships with public health and clinical laboratories, health care organizations, government agencies, and other stakeholders to identify mutual goals and objectives within the scope of the cooperative agreement.
- Increase visibility of cooperative agreement projects, activities, financial investments, outcomes and accomplishments, in the nation's public health system (including state, territorial, local, and tribal) with stakeholder communities.
- Conduct partner outreach to promote work that is produced from the cooperative agreement.
- Evaluate the impact of collaborative partnerships on the advancement of mutual priorities.

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders

- Leverage policy, communication, and other networks to support information exchange and dissemination within and between laboratory and other stakeholder communities.
- Ensure that information sharing minimizes burden, increases access, reduces duplication, and is coordinated across organizations.
- Increase awareness of activities between CDC and recipient collaborative partnership priorities.

S2.4. Educate the public and other stakeholders about the role of public health laboratories

- Provide a leading voice and use multifaceted approaches (e.g., online publications, press releases, social media, and other mechanisms) to educate stakeholders and the general public on the critical roles, responsibilities, and needs of PHLs in the public health and health care systems.

S2.5. Promote and provide information about the tools and resources available to public health laboratories and stakeholders

- Deliver clear, compelling, targeted, and timely messages, using appropriate communication channels for relevant audiences and plain writing/plain language, as applicable.
- Establish an agreement for logo use (i.e., co-branding and logo licensing) and branding. Institute a protocol with CDC as it applies to products, services, communications materials, websites or other digital platform (e.g., social media, mobile apps), or any other resource in which CDC is engaged in with recipient as part of this cooperative agreement.
- Work with CDC to communicate information and distribute promotional materials and other resources for laboratory professionals, healthcare providers, public health professionals, and the general public.

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 each of the activities in this focus area may include:

Strategy and Activity	Process Measures
S1.1. Provide leadership and management approaches to ensure organizational efficiency and operational improvement	• Established and regularly reviewed organizational system and approaches to provide leadership, direction,

• Provide effective organizational leadership, coordination, and support to all focus areas under this cooperative agreement. • Assess the performance of the overall organization to ensure quality of data, effective program implementation, information sharing, and accountability of funds. • Develop and maintain reporting tools for the financial management of the cooperative agreement focus areas that include detailed costs at the project level. • Provide reoccurring reports on the utilization of funds across the cooperative agreement with high-level impacts of investment. • Ensure that program and financial reporting support helps to minimizes burden and reduces duplicate efforts across the projects within this cooperative agreement. • Effectively manage project timelines within the scope of this cooperative agreement. • Ensure all work is conducted in accordance with public health ethical standards.	management, coordination, and support to all focus areas. • System and approaches established and implemented to assess the performance of the overall organization to ensure quality of data, effective program implementation, timely information sharing, accountability of funds, and adherence to public health ethical standards. • Reporting tools developed and maintained for the financial management of the cooperative agreement focus areas to include detailed costs at the project level. • Reoccurring reports provided to CDC on the utilization of funds across the cooperative agreement with high-level impacts of investment. • Burden (e.g., time, effort, and resources involved) and duplicate efforts reduced or minimized across the projects through program and financial reporting support provided to all focus areas. • All activity and project timelines are monitored and managed effectively.
S1.2. Provide appropriate monitoring, evaluation, and scientific services • Promote quality, integrity, and innovation of PHL science, practice, and services, and ensure science-based principles and/or best practices are used in all focus areas under this cooperative agreement. • Consult and coordinate with CDC program technical monitors to ensure compliance with applicable federal regulations for scientific activities (e.g., human subjects protection, Paperwork Reduction Act, privacy and confidentiality protection). • Develop and implement data sharing plans in accordance with requirements for federally funded activities to promote public access to public health information. • Develop a monitoring and evaluation plan that supports the evaluation and performance measurement requirements of this cooperative agreement, to ensure data-	• Organizational systems, procedures, and processes established that ensure science-based principles and best practices are used in all focus areas under this cooperative agreement. • Processes and procedures established for ensuring quality and integrity of all scientific activities and compliance with applicable requirements. • Data sharing plan developed and implemented that enables public access to public health information generated under this cooperative agreement. • Monitoring and evaluation plan developed and implemented that meets the evaluation, performance measurement, and reporting requirements of this cooperative agreement.

driven planning and implementation of programmatic activities, progress monitoring, and reporting. The evaluation plan should be inclusive of how funds are being allocated and spent and progress toward achieving the intended performance objectives.	• Organizational systems established for ensuring appropriate training and competency assessment for all staff of the recipient involved in conducting or supporting this cooperative agreement.
S2.1. Provide policy and issues analysis to support public health laboratory interests • Engage partners on matters of public health policy on current and emerging issues. • Identify public health and programmatic policy priorities by engaging appropriate PHL SMEs and other stakeholders. • Collaborate with PHL leaders to develop position statements reflecting the analysis of identified policy priorities. • Collaborate with PHL leaders to monitor PHL system capabilities and identify gaps to formulate policies that address laboratory needs. • Educate policy makers and key stakeholders, including congressional committees and staffers, on the role, value, and importance of public health laboratories.	• Number and scope of recipient engagements with CDC, PHLs, clinical laboratories, professional organizations, and other stakeholders on current and emerging public health policy issues. • Number, frequency, and timeliness of policy and issues analysis conducted and provided to the PHL community, other stakeholders, and the public. • Number and scope of PHL leaders and SMEs engaged in policy/priority analyses. • Number and scope of engagements with policymakers, congressional committees and staffers, and other stakeholders to ensure awareness of information and assistance available from the PHL community.
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, health care, and beyond • Establish and maintain collaborative partnerships with public health and clinical laboratories, health care organizations, federal/state/local government agencies, and other stakeholders to identify mutual goals and objectives within the scope of the cooperative agreement. • Increase visibility of cooperative agreement projects, activities, financial investments, outcomes, and accomplishments in the nation's public health system (including state, territorial, local, and tribal) and stakeholder communities. • Conduct partner outreach to promote work that is produced from the cooperative agreement.	• Number and scope of recipient's outreach efforts to engage PHLs, clinical laboratories, professional organizations, and other stakeholders in partnerships or collaborations. • Number and variety of collaborative efforts or partnerships proposed or planned. • Number, frequency, and timeliness of recipient's communication or promotional efforts about projects, activities, outcomes and accomplishments of this cooperative agreement. • Number and scope of partners and other stakeholders reached or engaged to promote work produced from the cooperative agreement. • Number and frequency of evaluative efforts to assess the impact and effectiveness of the collaborative partnerships.

• Evaluate the impact of collaborative partnerships on the advancement of mutual priorities.	
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders • Leverage policy, communication, and other networks to support information exchange and dissemination within and between laboratory and other stakeholder communities. • Ensure that information sharing minimizes burden, increases access, reduces duplication, and is coordinated across organizations. • Increase awareness of CDC and recipient collaborative partnership priorities and activities.	• Number, frequency, and timeliness of recipient's efforts to support information exchange and dissemination within and between laboratory and other stakeholder communities. • Scope of networks, partners, and collaborators engaged to facilitate information exchange and dissemination. • Scope of practitioners and other stakeholders to be targeted or reached. • Number and scope of partners and other stakeholders reached or engaged to promote CDC and recipient collaborative partnership priorities and disseminate work produced from the cooperative agreement.
S2.4. Educate the public and other stakeholders about the role of public health laboratories • Provide a leading voice and use multifaceted approaches (e.g., online publications, press releases, social media, and other mechanisms) to educate stakeholders and the general public on the critical roles, responsibilities, and needs of PHLs in the public health and health care systems.	• Number and variety of target audience-appropriate educational materials developed on the critical roles, responsibilities, and needs of PHLs in the public health and health care systems. • Number and variety of audience-appropriate approaches employed for providing the educational messages and materials. • Frequency and timeliness of the educational efforts.
S2.5. Promote and provide information about the tools and resources available to public health laboratories and stakeholders • Deliver clear, compelling, targeted, and timely messages, using appropriate communication channel for relevant audiences and plain writing/plain language, as applicable. • Establish an agreement for logo use (i.e., co-branding and logo licensing) and branding. Institute a protocol with CDC as it applies to products, services, communications materials, websites or other digital platforms (e.g., social media, mobile apps), or any	• Number frequency, and/or timeliness of clear, compelling, and targeted messages and other information products developed by the recipient about the tools and resources available to PHLs and other stakeholders. • Number and frequency of communicated information products and distributed promotional materials and other resources. • Number and variety of communication channels used and audiences targeted (e.g., laboratory professionals, healthcare providers, public health professionals, general public).

other resource in which CDC is engaged in with recipient as part of this cooperative agreement. • Work with CDC to communicate information and distribute promotional materials and other resources for laboratory professionals, healthcare providers, public health professionals, and the general public.	• Agreement(s) and protocol on branding and logo use developed in collaboration with CDC.

Outcome measures for this focus area may include:

Outcome	Outcome Measures
PO-1. Improved collaboration and communication across public health laboratories and other stakeholders.	• Number and scope of recipient engagements with CDC, PHLs, clinical laboratories, professional organizations, and other stakeholders that advance mutual goals. • Number and % of state, territorial, and local PHL involved or participating in the collaboration and communication. • Number and extent of clinical laboratories, professional organizations, and other stakeholders involved or participating in the collaboration and communication.
PO-2. Improved awareness and understanding of public health laboratories among public and other stakeholders.	• Number and scope of marketing, communication and membership campaigns to promote the PHLs, CDC, and the products/resources developed by the recipient and CDC. • Frequency and extent of use or further dissemination among the public and other stakeholders (e.g., clinical laboratory communities, healthcare organizations, general public). • Number and variety of information products developed by recipient for the public and other stakeholders addressing the roles, responsibilities, and needs of PHLs.
PO-3. Improved support for public health laboratories among stakeholders.	• Number and scope of engagements with policymakers, professional organizations, and other stakeholders. • Number and scope of new or existing public health priorities reflected in federal, state, territorial, or local level policies.

PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders.	• Number, variety, frequency, and timeliness of evidence-based practices (e.g., best practices, scientific discoveries, innovative technologies) disseminated to PHLs and other stakeholders. • Number or percent of state, territorial, and local PHLs accessing the information products disseminated. • Number, type, and variety of stakeholders accessing the information products disseminated.
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders.	• Number of communities of practice and other collaborative relationships established among and between laboratories and other stakeholders that advance PHL roles. • Number of state, territorial, and local PHLs participating in these communities of practice or collaborative relationships. • Number and variety of public health topic areas that the communities of practice and collaborative relationships address.
IO-2. Established information sharing systems across public health laboratories and with other key stakeholders.	• Percent of state, territorial, and local PHLs using the information sharing systems. • Number, type, and variety of key stakeholders using the information sharing systems. • Feedback from PHL and other stakeholder communities on the usefulness of the information sharing systems.

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 collaborate with other CDC-funded programs to maximize the use of resources and improve the sustainability of the listed activities.

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 expected to provide leadership for enhancing existing and developing new strategic partnerships that best suit the needs of the nation's PHL system, at state, territorial, tribal, and local levels. Recipient is encouraged to explore opportunities for new collaborations with additional partners to advance public health priorities.

d. **Target populations**
In addition to PHLs and PHL professionals supporting state, local, tribal, and territorial public health programs, the specific target population of this focus area also includes other 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 Division of Laboratory Systems, in collaboration with subject matter experts across the agency, will provide technical monitoring and program support 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.

Appendix B: Environmental Health

Focus Area Name
Environmental Health (EH)

Focus Area Contact Information
Amy Mowbray, htm3@cdc.gov

Approximate Average Annual Award: $1,700,000

Funding Opportunity Description

1. **Background**
   Environmental health laboratories are essential to protecting the public's health from harmful exposures to environmental chemicals and in responding to diverse public health concerns. They apply advanced laboratory tests to determine people's exposure levels, assess disease risk, identify true hazards, assess the effectiveness of interventions, and respond to public health emergencies.

   Environmental health laboratories face unique challenges as they work to identify harmful exposures to people and in the environment. These laboratories must integrate tests for an ever-growing number of compounds, adopt new technologies, and operate effectively within a complicated system that includes public health officials, regulators, policymakers, advocacy groups, and others. In order to overcome these challenges, environmental health laboratories need a national forum to address laboratory practices and emerging issues across the environmental health laboratory and other public health systems.

   Healthy People 2020
   This focus area supports the following Healthy People 2020 objectives:

   Environmental Health, Objective 20: Reduce exposure to selected environmental chemicals in the population, as measured by blood and urine concentrations of the substances or their metabolites.

   Environmental Health, Objective 21: Improve quality, utility, awareness, and use of existing information systems for environmental health.

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

   Other National Public Health Priorities and Strategies
   - 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 purpose of the Environmental Health focus area is to improve national environmental health laboratory capability and practice and strengthen the role of environmental health laboratories within the environmental health and other public health systems. Competent, prepared, and well-integrated environmental health laboratories will improve the assessment of chemical and other exposures, helping to identify at-risk population groups and reduce or eliminate harm.

II. Outcomes
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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders
- Stronger roles for environmental health laboratories in the planning and response for public health threats

IO-2. Established information sharing across public health laboratories and with other key stakeholders
- More training for public health laboratories (PHLs) in biomonitoring methods for exposure assessment and other public health needs
- More guidance for PHLs on new policies and methods related to assessment of environmental exposures, emergency laboratory response, and other urgent public health needs

IO-3. Improved competence and engagement of public health laboratory workforce
- Larger PHL workforce skilled in conducting biomonitoring measurements for exposure assessment, emergency laboratory response, and other public health needs
- Improved national environmental health laboratory capability

IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system
- PHLs proficient in biomonitoring
- PHLs able to quickly detect and report human exposures to harmful chemicals, including chemical threat agents
- PHLs able to sustain environmental health laboratory testing during emergencies

IO-6. Improved public health laboratory detection, surveillance, and response
- Improved coordination of environmental health laboratory efforts among laboratories and partner organizations

- Better strategies to address emerging environmental exposures across the PHL system

IO-7. Improved quality and safety in public health laboratories
- High-quality and safe biomonitoring practices in PHLs

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, Preparedness, and Informatics for Public Health Testing Services, Surveillance, and Response (S4).

S2. Policy, Partnership, and Communication
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond
- Develop partnerships to build national, state, and community infrastructure to conduct biomonitoring for harmful chemicals, including chemical threat agents and other emerging chemicals of concern.
- Develop resources and partnerships to foster a coordinated national approach to biomonitoring, laboratory response to chemical threat agents, and other urgent public health needs.
- Facilitate partnerships and educate stakeholders to increase the use of biomonitoring data to reduce harmful exposures in people.
- Facilitate partnerships to improve the quality of tests conducted by environmental health laboratories for environmental chemicals, chemical threat agents, and other compounds of concern.

- Develop relationships and engage with partner organizations including policymakers and advocacy groups.

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders
- Disseminate guidance about policy, scientific, and management issues to PHL leadership and staff.
- Disseminate best practices for both routine and emergency environmental health laboratory operations.

S2.4. Educate the public and other stakeholders about the role of public health laboratories
- Facilitate communication among PHLs, health care providers, partners, and policy makers about environmental health laboratory science, policy, technology, regulation, and practice.

S3. Training and Capacity Building

S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings
- Conduct training and workforce development needs assessments to identify unique needs for environmental health laboratories.
- Use needs assessment results to inform the development and delivery of training and workforce development resources for environmental health staff and leadership.
- Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).
- Monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.

S3.3. Facilitate the development and delivery of training and workforce development resources
- Use needs assessment results and guidance from CDC to develop and deliver training opportunities and workforce development products for environmental health laboratory staff, including those on laboratory methods and/or emerging issues.
- Collaborate with CDC to review training and workforce development products, resources, and events.
- Collaborate with CDC to establish fellow and host site eligibility requirements and performance expectations
- Provide guidance and technical assistance to fellows and host sites.
- Manage operations and funds to support fellows.
- Coordinate with the recipient Training and Workforce Development Program regarding cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.

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

S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories
- Convene committees, workgroups, or other meetings to develop and communicate guidance about science and policy issues for environmental health laboratories.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories
- Develop guidance about policy, scientific, and management issues relevant to environmental health laboratories.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes
- Facilitate assessment and guidance for PHLs integrating new technologies or supporting new public health programs.
- Facilitate improvements in environmental health laboratory information technology and management infrastructure.

S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and respond to public health threats
- Monitor chemical threat and other emerging public health emergency capabilities in environmental health labs.
- Facilitate improvements in environmental health laboratory preparedness.
- Monitor trends in environmental health contingency planning.
- Collaborate with environmental health laboratories to develop contingency plans.

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 and activities in this focus area may include:

Strategy/Activity	Process Measure
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond - Develop partnerships to build national, state, and community infrastructure to conduct biomonitoring for harmful chemicals, including chemical threat agents and other emerging chemicals of concern.	- Number and type of partnerships to build to build national, state, and community infrastructure to conduct biomonitoring for harmful chemicals, including chemical threat agents and other emerging chemicals of concern. - Number and types of resources to foster a coordinated national approach to biomonitoring, laboratory response to

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• Develop resources and partnerships to foster a coordinated national approach to biomonitoring, laboratory response to chemical threat agents, and other urgent public health needs. • Facilitate partnerships and educate stakeholders to increase the use of biomonitoring data to reduce harmful exposures in people. • Facilitate partnerships to improve the quality of tests conducted by environmental health laboratories for environmental chemicals, chemical threat agents, and other compounds of concern. • Develop relationships and engage with partner organizations including policymakers and advocacy groups.	chemical threat agents, and other urgent public health needs. • Number of educational resources and events for partners and stakeholders that increase use of biomonitoring data to reduce harmful exposures in people. • Number of partners engaged in improving environmental health testing quality. • Number and diversity of new and existing partner organizations engaged in and familiar with environmental health laboratory issues.
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders • Disseminate guidance about policy, scientific, and management issues to PHL leadership and staff. • Disseminate best practices for both routine and emergency environmental health laboratory operations.	• Number of policy, science, and management guidance documents disseminated to environmental health laboratories. • Number of best practice documents for routine and emergency environmental health operations disseminated to PHLs.
S2.4. Educate the public and other stakeholders about the role of PHLs • Facilitate communication among PHLs, health care providers, partners, and policy makers about environmental health laboratory science, policy, technology, regulation, and practice.	• Number and breadth of connections made among diverse stakeholders regarding environmental health laboratory issues. • Number of educational resources disseminated to diverse stakeholders regarding environmental health laboratory issues.
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings • Conduct training and workforce development needs assessments to identify unique needs for environmental health laboratories. • Use needs assessment results to inform the development and delivery of training and workforce development resources for environmental health staff and leadership. • Apply best practices to all training and workforce development products,	• Number and type of training needs assessments that identify environmental health laboratory needs. • Number of trainings and workforce development products that apply best practices. • Number of evaluations of effectiveness of training products, resources, and events for environmental health laboratories.

resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies). • Monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.	
S3.3. Facilitate the development and delivery of training and workforce development resources • Use needs assessment results and guidance from CDC to develop and deliver training and workforce development opportunities for environmental health laboratory staff, including those on laboratory methods and/or emerging issues. • Collaborate with CDC to review training and workforce development products, resources, and events. • Collaborate with CDC to establish fellow and host site eligibility requirements and performance expectations. • Provide guidance and technical assistance to fellows and host sites. • Manage operations and funds to support fellows. • Coordinate with the recipient Training and Workforce Development Program regarding cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.	• Number and diversity of training opportunities for laboratory staff, including laboratory methods and/or emerging issues. • Number of trainee and/or fellowships for environmental health laboratories.
S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories • Convene committee, workgroups, or other meetings to develop and communicate guidance about science and policy issues.	• Number of committees, workgroups, and meetings to develop and communicate science and/or policy guidance for environmental health laboratories.
S4.3. Identify and address emerging methodological and process improvements in public health laboratories	• Number of guidance documents about policy, scientific, and management issues relevant to environmental health laboratories developed.

• Develop guidance about policy, scientific, and management issues relevant to environmental health laboratories.	
S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes • Facilitate assessment and guidance for PHLs integrating new technologies or supporting new public health programs. • Facilitate improvements in environmental health laboratory information technology and management infrastructure.	• Number of resources coalesced, developed, disseminated, and/or provided to assist environmental health laboratories in implementing new technologies or programs. • Number of resources coalesced, developed, disseminated, and/or provided to assist environmental health laboratories with improvements in information technology or management infrastructure.
S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and respond to public health threats • Monitor chemical threat and other emerging public health emergency capabilities in environmental health laboratories. • Facilitate improvements in environmental health laboratory preparedness. • Monitor trends in environmental health contingency planning. • Collaborate with environmental health laboratories to develop contingency plans.	• Number of resources coalesced, developed, disseminated, and/or provided to assist PHLs with improvements in chemical threat and other emerging public health emergency capabilities. • Number of resources coalesced, developed, disseminated, and/or provided to assist PHLs with improving or establishing environmental health laboratory contingency plans.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders	• Number of PHLs actively participating in a biomonitoring laboratory network and/or other environmental health-related networks and communities of practice. • Number of environmental health laboratories with active relationships with epidemiologists, policy makers, communicators, preparedness directors, and/or other environmental health system stakeholders. • Number and relevance of public health topics that networks, collaborative relationships, and/or communities of practice address.

IO-2. Established information sharing across public health laboratories and with other key stakeholders	• Number of PHLs participating in training in biomonitoring methods for exposure assessment and other public health needs. • Number of PHLs using or implementing guidance on new policies and methods related to assessment of environmental exposures, emergency laboratory response, and other urgent public health needs. • Number of environmental health stakeholders using or implementing guidance.
IO-3. Improved competence and engagement of public health laboratory workforce	• Number of PHL staff able to conduct biomonitoring measurements for exposure assessment, emergency laboratory response, and other public health needs in accordance with established standards for competence and quality. • Percent of PHLs with expanded analytical capability for exposure assessment, emergency laboratory response, and other public health needs.
IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system	• Number of PHLs with expanded laboratory and programmatic capability and capacity for biomonitoring. • Number of PHLs able to more rapidly and accurately detect and report human exposures to harmful chemicals, including chemical threat agents. • Number of PHLs with established and exercised protocols to sustain environmental health laboratory testing during emergencies.
IO-6. Improved public health laboratory detection, surveillance, and response	• Number of environmental health laboratory initiatives that incorporate environmental health stakeholder and other partner organizations. • Number of emerging environmental exposure assessments that integrate PHLs into the environmental health response.
IO-7. Improved quality and safety in public health laboratories	• Percent increase in the number of PHLs conducting high-quality and safe biomonitoring practices.

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**
The recipient is expected to use or develop strategic partnerships that best suit their needs in order to maximize the use of resources and improve the sustainability of the listed activities.

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 collaborate with CDC's National Center for Environmental Health and Division of Laboratory Sciences, Center for Preparedness and Response, Division of State and Local Readiness, and other relevant programs to establish program priorities and activities. The recipient may consider collaboration with state programs previously or currently funded by CDC to share expertise, challenges, and successes related to environmental health and related public health systems, including those funded by CDC to conduct state-based biomonitoring, build and strengthen the ability to respond to public health incidents (Public Health Emergency Preparedness and Chemical Laboratory programs), assess and develop a state network to track and report environmental hazards and related health problems (Environmental Health Tracking Program), and prevent opioid overdoses. The recipient may also consider collaborating with state programs that receive funding through the Agency for Toxic Substances and Disease Registry's (ATSDR) State Cooperative Agreement Program to build capacity to assess and respond to site-specific issues involving human exposure to hazardous substances in communities in the United States.

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 may also consider collaboration with PHLs not currently funded by CDC to share expertise, challenges, and successes related to environmental health, biomonitoring, emergency laboratory response, and opioid overdose prevention. The recipient may also consider appropriate collaboration with and support from environmental health and other public health stakeholders to accomplish diverse activities. Potential collaborators may include, but are not limited to other federal or state agencies, academic institutions, professional organizations, non-profit organizations, advocacy groups, community groups, public health or environmental officials, and health care providers.

d. **Target populations**
The primary target population of this focus area is environmental health laboratory professionals supporting state, local, and territorial public health programs. The secondary target population is stakeholders in environmental health and related public
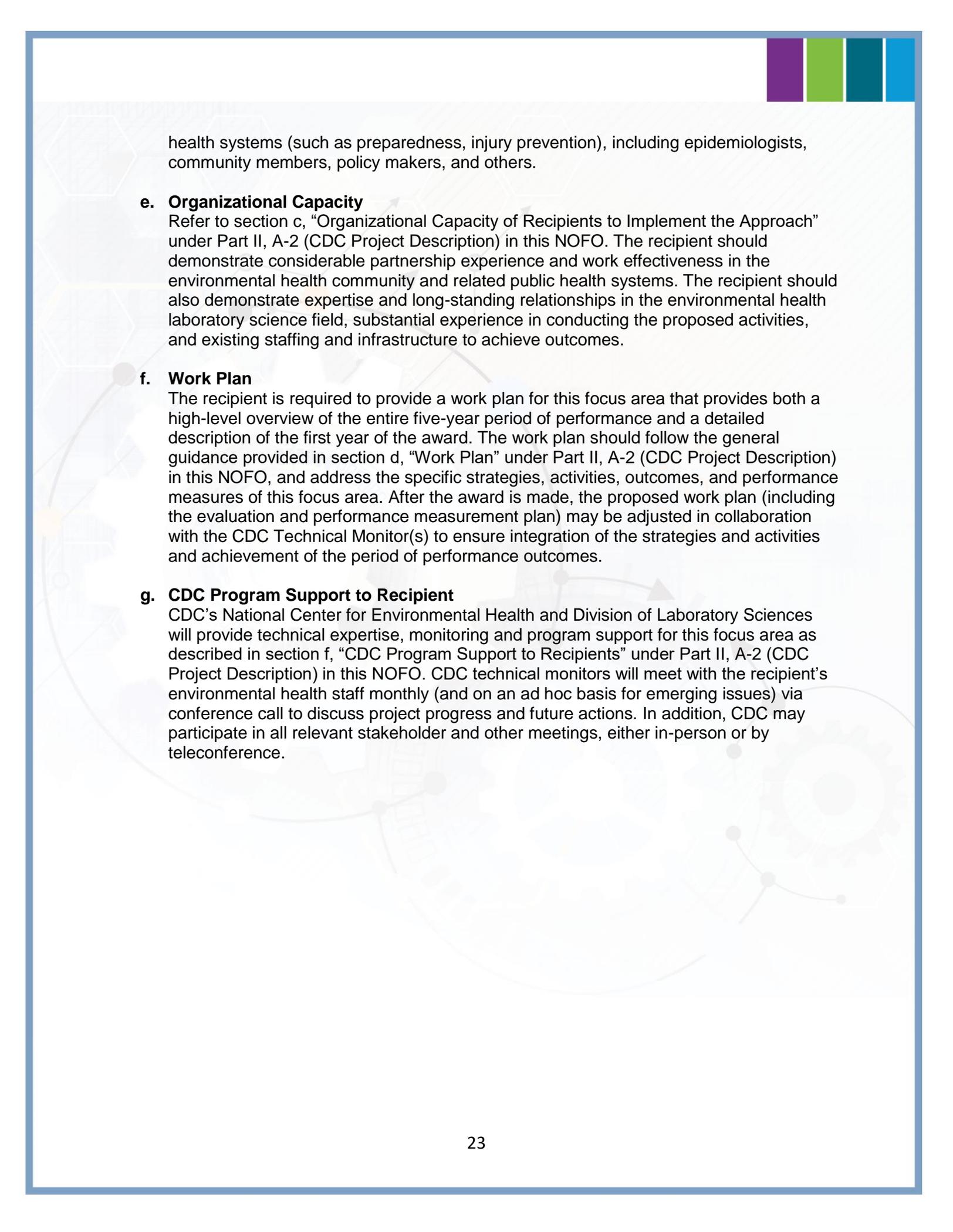
health systems (such as preparedness, injury prevention), including epidemiologists, community members, policy makers, and others.

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. The recipient should demonstrate considerable partnership experience and work effectiveness in the environmental health community and related public health systems. The recipient should also demonstrate expertise and long-standing relationships in the environmental health laboratory science field, substantial experience in conducting the proposed activities, and existing staffing and infrastructure to achieve outcomes.

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 National Center for Environmental Health and Division of Laboratory Sciences will provide technical expertise, monitoring and program support 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. CDC technical monitors will meet with the recipient's environmental health staff monthly (and on an ad hoc basis for emerging issues) via conference call to discuss project progress and future actions. In addition, CDC may participate in all relevant stakeholder and other meetings, either in-person or by teleconference.

Appendix C: Foodborne, Waterborne, and Environmentally Transmitted Diseases

Focus Area Name
Foodborne, Waterborne, and Environmentally Transmitted Diseases

Focus Area Contact Information:
Racquel Williams, iic3@cdc.gov
Donald Sharp, das8@cdc.gov

Approximate Average Annual Award: $2,000,000

Funding Opportunity Description

1. **Background**
   Each year, approximately 48 million foodborne illnesses occur in the United States (1 in 6 Americans are affected), which results in an estimated 128,000 hospitalizations and 3,000 deaths. In addition to human impact, foodborne illnesses cost billions of dollars in health care, industry, and personal/income losses. In the United States, the estimated annual burden of waterborne disease is approximately 7.2 million cases and 7,000 deaths, and $3.3 billion in direct healthcare costs. To address these important public health problems, improvements in the capacity of public health agencies to efficiently detect, control and establish more efficient prevention and control measures are necessary. Local and state PHLs play a role in routine surveillance of foodborne and waterborne disease, in detecting outbreaks of foodborne and waterborne illness, and in a wide variety of testing activities during investigations of outbreaks of foodborne and waterborne disease.

   Healthy People 2020
   This focus area supports the following Healthy People 2020 objectives:

   Food Safety, Objective 1: Reduce infections caused by pathogens transmitted commonly through food.

   Food Safety, Objective 2: Reduce the number of outbreak-associated infections due to Shiga toxin-producing *E. coli* O157, or *Campylobacter*, *Listeria*, or *Salmonella* species associated with food commodity groups.

   Environmental Health, Objective 5: Reduce waterborne disease outbreaks from water intended for drinking among persons served by community water systems.

   Other National Public Health Priorities and Strategies:
   - Public Health Emergency Preparedness (PHEP) Cooperative Agreement https://www.cdc.gov/cpr/readiness/phep.htm
   - 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
   - HHS Strategic Plan, 2018-2022: https://www.hhs.gov/about/strategic-plan/index.html

- CDC Strategic Framework, 2016-2020: cdc.gov/about/organization/strategic-framework/index.html
- U.S. Government Global Water Strategy: https://www.usaid.gov/sites/default/files/documents/1865/Global_Water_Strategy_2017_final_508v2.pdf

2. CDC Project Description
a. Approach

I. Purpose

Building state and local laboratory capacity is necessary to have a strong national foodborne and waterborne disease outbreak detection and investigation system. CDC is committed to helping improve local and state laboratory capacity by funding the recipient to work on a variety of related issues and projects. The overall purpose is to improve collaboration between laboratories, between laboratorians and epidemiologists and environmental health specialists, and to improve a variety of laboratory detection, investigation, and reporting systems.

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

PO-4. Improved awareness of new tools and resources for public health laboratories and other stakeholders

PO-5. Improved awareness and understanding of public health laboratory workforce development needs and opportunities

PO-6. Improved access to training opportunities among laboratory professionals

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 data-informatics solutions among laboratory professionals and other stakeholders

PO-9. Improved implementation of quality and safety systems and practices in public health laboratories

PO-11. Improved awareness and understanding among laboratory professionals of emerging methods and processes in public health laboratories

PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders

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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders
- Improved collaboration and coordination between laboratories, and between laboratorians, epidemiologists, environmental health specialists and bioinformaticians at local, state, federal, and international levels

IO-3. Improved competence and engagement of public health laboratory workforce
- Improved laboratory workforce competency in foodborne, waterborne, and environmentally transmitted disease detection and response

IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system
- Improved laboratory methods for detection, investigation, and reporting foodborne, waterborne, and environmentally transmitted illnesses

IO-6. Improved public health laboratory detection, surveillance, and response
- Improved laboratory systems for detection, investigation, and reporting foodborne, waterborne, and environmentally transmitted illnesses

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).

S.2. Policy, Partnership, and Communication

S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond
- Support the Council to Improve Foodborne Outbreak Response (CIFOR) in identifying barriers to rapid and accurate foodborne disease outbreak detection and investigation.
- Support CIFOR's efforts to develop and implement solutions to these identified barriers.
- Support global food safety activities (e.g. PulseNet International (PNI)).

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders
- Help improve methods to rapidly obtain, collate, analyze, and disseminate combined food and water safety epidemiologic and laboratory information.
- Support the compilation, dissemination, discussion, and professional exchange of information about various aspects of foodborne, waterborne, and environmentally transmitted disease among the laboratory, epidemiology, and environmental health disciplines through conferences, webinars, and meetings.

S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders
- Support and assist state and local authorities in the use and adoption of recommendations contained in the *CIFOR Guidelines for Foodborne Disease Outbreak Response, Third Edition,* 2019 and the *CIFOR Guidelines Toolkit.*

S3. Training and Capacity Building

S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings
- Identify training needs and provide training opportunities for PHL staff and executive leadership.
- Use needs assessment results to inform the development and delivery of training and workforce development resources for PHL staff and leadership.

S3.3. Facilitate the development and delivery of training and workforce development resources
- Support foodborne and waterborne disease outbreak response training of laboratorians and other local and state officials through

various training opportunities, including the Epi-Ready Team Training Courses.

- Support training of laboratorians in the detection, categorization and identification of foodborne, waterborne, and environmentally transmitted organisms, and the diagnosis of foodborne, waterborne, and environmentally transmitted disease.
- Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).
  - o Monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.
  - o Provide topic-specific technical expertise for the design, development, and delivery of training and workforce development products, resources, and events.
  - o Collaborate with CDC to review training and workforce development products, resources, and events.

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 collaborative CDC workgroup that provides governance for informatics projects accomplished through collaborations with CDC partners governance workgroup and the recipient's informatics program:

- Develop and maintain secure communication systems for information exchanges and transfers.
- Support development of improved methods to electronically disseminate laboratory results.

S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories

- Develop best practices, and performance and quality standards.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories

- Evaluate and improve existing laboratory workflows to better implement new technologies [e.g., whole genome sequencing (WGS)], including guidance for changes to PHL practice.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes

- Increase laboratory workforce capacity to more rapidly and efficiently identify agents of foodborne, waterborne, and environmentally transmitted disease, including capability to recognize new pathogens as well as known pathogens in new food and environmental vehicles, and effectively respond to the challenges of culture-independent diagnostic testing.

- Support environmental health, science and microbiology activities related to waterborne investigations.

    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 each of the activities in this focus area may include:

Strategy and Activity	Process Measure
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond • Support the Council to Improve Foodborne Outbreak Response (CIFOR) in identifying barriers to rapid and accurate foodborne disease outbreak detection and investigation. • Support CIFOR's efforts to develop and implement solutions to these identified barriers. • Support global food safety activities (e.g., PNI).	• Number of staff and number of members who participate on the CIFOR Council, Governance Team, and Development Teams. • Number of CIFOR products supported, including 3rd edition of the CIFOR Guidelines, the CIFOR Toolkit, and other CIFOR materials. • Number of PNI regional and PNI steering committee meetings and calls organized. • Number of trainings and proficiency testing supported in PNI regions.
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders • Help improve methods to rapidly obtain, collate, analyze, and disseminate combined food and water safety epidemiologic and laboratory information. • Support the compilation, dissemination, discussion, and professional exchange of information about various aspects of foodborne, waterborne, and environmentally transmitted disease among the laboratory, epidemiology, and environmental health disciplines through conferences, webinars, and meetings.	• Number of InFORM Conference/Regional Meeting bimonthly Executive Committee and sub-committees calls attended. • Number of staff and laboratorians supported for travel to InFORM/Regional Meetings. • ≥90% of attendees rate InFORM 2020 sessions and trainings as tools that help increase job performance. • CaliciNet SharePoint site maintained and accessible on recipient's website. • Number of PulseNet Steering Committee calls coordinated. • Number of in-person meetings at InFORM/Regional Meetings coordinated.

	• Number of training activities conducted for PulseNET WGS and analysis workflows. • Number of CryptoNet training and reporting activities conducted.
S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders • Support and assist state and local authorities in the use and adoption of recommendations contained in the CIFOR Guidelines for Foodborne Disease Outbreak Response, Third Edition, 2019 and the CIFOR Guidelines Toolkit.	• Number of communication mechanisms and messages promoting the use of the CIFOR Guidelines for Foodborne Disease Outbreak Response, Third Edition, 2019 and the CIFOR Guidelines Toolkit.
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings • Identify training needs and provide training opportunities for PHL staff and executive leadership.	• Report summarizing recommendations, including prioritization of training needs in the PulseNet network. • Number of new and emerging training needs identified for PulseNet network • Number of trainings conducted in coordination with CDC.
S3.3. Facilitate the development and delivery of training and workforce development resources • Support foodborne and waterborne disease outbreak response training of laboratorians and other local and state officials through various training opportunities, including the Epi-Ready Team Training Courses. • Support training of laboratorians in the detection, categorization and identification of foodborne, waterborne, and environmentally transmitted organisms, and the diagnosis of foodborne, waterborne, and environmentally transmitted disease. • Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).	• Number of laboratory professionals participating in foodborne and waterborne disease outbreak response training (e.g., Epi Ready), and CaliciNet, PulseNet and CryptoNet trainings. • CaliciNet users meeting held annually. • CaliciNet training workshop held annually. • Number of PulseNet trainings developed and implemented, including coordination of continuing education credits if needed. • Number of CryptoNet trainings developed and implemented.
S4.1. Develop and implement informatics-related solutions and standards to improve data exchange and interoperability	• Number and types of informatics approaches and improvements for data

• Develop and maintain secure communication systems for information exchanges and transfers. • Support development of improved methods to electronically disseminate laboratory results.	exchange between laboratory and epi databases. • Number and types of informatics approaches for linking case patient ID in laboratory databases for more efficient data linking at local, state, and national level.
S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories • Develop best practices and performance and quality standards.	• Number and types of Quality Management System (QMS) laboratory good practice documents provided to PHLs for PulseNet related workflows. • Supported coordination and maintenance of PulseNet's quality management system, including certification of annual proficiency testing.
S4.3. Identify and address emerging methodological and process improvements in public health laboratories • Evaluate and improve existing laboratory workflows to better implement new technologies [e.g., whole genome sequencing (WGS)], including guidance for changes to PHL practice.	• Number of process improvement evaluations conducted, such as LEAN, to aid PHLs in integrating WGS into routine workflows. • Number of process improvement evaluations conducted as new technologies are integrated into PulseNet. • Evaluated workflows to incorporate parasite WGS (e.g., Cryptosporidium) into PulseNet workflows.
S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes • Increase laboratory workforce capacity to more rapidly and efficiently identify agents of foodborne, waterborne, and environmentally transmitted disease, including capability to recognize new pathogens as well as known pathogens in new food and environmental vehicles, and effectively respond to the challenges of culture-independent diagnostic testing. • Support environmental health, science and microbiology activities related to waterborne investigations.	• Support work performed by at least 5 CaliciNet-Outbreak Support Centers (CN-OSCs). • Support work performed by at least 2 CaliciNet-Unexplained Viral Diarrheal Centers (CN-UVDs). • Number and types of workflows developed and implemented in response to changing clinical and diagnostic laboratory practice, such as CIDTs. • Conference calls and one in- person meeting supported for workflow development. • Validation of workflow improvements with no less than 2 PHLs for laboratory approaches including isolate recovery.

	• Coordination of processing and testing workflows for environmental samples.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders • Improved collaboration and coordination between laboratories, and between laboratorians, epidemiologists, environmental health specialists and bioinformaticians at local, state, federal, and international levels	• Increased number of communication and collaborative efforts among public health scientists, laboratorians, epidemiologists, bioinformaticians, and environmental health scientists. • Increased number of collaborative efforts among global public health partners.
IO-3. Improved competence and engagement of public health laboratory workforce • Improved laboratory workforce competency in foodborne, waterborne, and environmentally transmitted disease detection and response	• Increased number of state and local health departments and laboratories that are prepared to respond to current and emerging foodborne, waterborne, and/or environmentally transmitted public health threats. • Increased number of frontline public health workers at the state and local level who are competent and prepared to respond to foodborne, waterborne, and/or environmentally transmitted disease outbreaks, threats, and emergencies. • Increased number of trainings to improve the effectiveness, preparedness, and sustainability of the PHL workforce to meet emerging public health challenges related to foodborne, waterborne, and/or environmentally transmitted pathogens.
IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system • Improved laboratory methods for detection, investigation, and reporting foodborne, waterborne, and environmentally transmitted illnesses	• Increased number of PHLs capable of performing and evaluating new technologies and changes in clinical laboratory practice (e.g., next-generation sequencing (NGS) and culture-independent diagnostic testing). • Decreased state and local health department time to identify causes, risk factors, and appropriate interventions for those affected by foodborne,

	waterborne, and/or environmentally transmitted threats to public health.
IO-6. Improved public health laboratory detection, surveillance, and response • Improved laboratory systems for detection, investigation, and reporting foodborne, waterborne, and environmentally transmitted illnesses	• Decreased PHL time to detect and report foodborne, waterborne, and/or environmentally transmitted agents in tissue, food, water, or other environmental samples.

    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 work effectively with the CDC Food Safety Office, Enteric Diseases Laboratory Branch, the Outbreak Prevention and Response Branch, and Waterborne Disease Prevention Branch within NCEZID/DFWED, as well as the Viral Gastroenteritis Branch in NCIRD/DVD, the Parasitic Diseases Branch in CGH/DPDM, and the Water, Food and Environmental Health Services Branch in NCEH/DEHSP.

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 must demonstrate the capacity to work effectively with state agencies, federal agencies [Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA),Environmental Protection Agency (EPA)], and national associations [Association of Food and Drug Officials (AFDO), Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), the National Environmental Health Association (NEHA), National Association of County and City Health Officials (NACCHO), the National Association of State Departments of Agriculture (NASDA), the National Association of State Public Health Veterinarians (NASPHV), the Association of State Drinking Water Administrators (ASDWA)]. The recipient should also have experience in working with agricultural, environmental and chemical laboratories.

The recipient is expected to provide leadership for enhancing existing and developing new strategic partnerships that best suit the needs of the nation's PHL system, at state, territorial, tribal, and local levels. Recipient is encouraged to explore opportunities for new collaborations with additional partners to advance public health priorities.
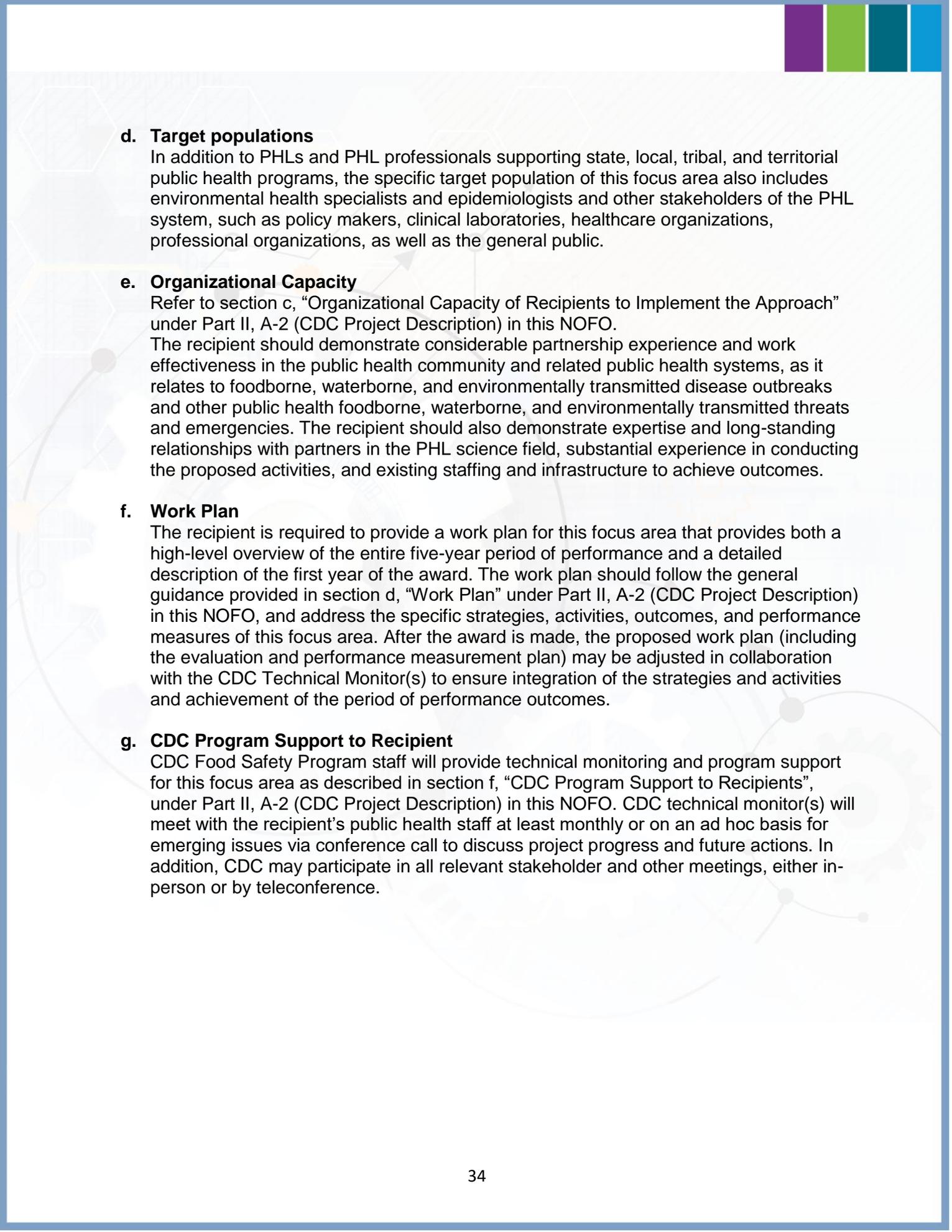
d. Target populations

In addition to PHLs and PHL professionals supporting state, local, tribal, and territorial public health programs, the specific target population of this focus area also includes environmental health specialists and epidemiologists and other 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.

The recipient should demonstrate considerable partnership experience and work effectiveness in the public health community and related public health systems, as it relates to foodborne, waterborne, and environmentally transmitted disease outbreaks and other public health foodborne, waterborne, and environmentally transmitted threats and emergencies. The recipient should also demonstrate expertise and long-standing relationships with partners in the PHL science field, substantial experience in conducting the proposed activities, and existing staffing and infrastructure to achieve outcomes.

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 Food Safety Program staff will provide technical monitoring and program support 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. CDC technical monitor(s) will meet with the recipient's public health staff at least monthly or on an ad hoc basis for emerging issues via conference call to discuss project progress and future actions. In addition, CDC may participate in all relevant stakeholder and other meetings, either in-person or by teleconference.

Appendix D: Infectious Diseases

Focus Area Name
Infectious Diseases

Focus Area Contact Information
Wendi Kuhnert-Tallman, Senior Advisor for Laboratory Science to DDID, wdk1@cdc.gov
Brandi Limbago, bbl7@cdc.gov
Serena Carroll, awx6@cdc.gov
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Approximate Average Annual Award: $11,200,000

Funding Opportunity Description

1. **Background**
   Infectious diseases remain an important public health problem both globally and in the United States. Public health laboratories (PHLs) work closely with their program and epidemiology counterparts to develop and improve strategies for disease detection, control and prevention, many of which include sustaining and constantly improving specialized testing capabilities. One challenge for PHLs is ensuring access to the many varied infectious disease testing services that share infrastructure in the form of equipment, staffing, disease reporting and close linkage with epidemiology, but at the same time supporting the unique strategies needed for different programmatic approaches. The specialized testing services for diseases such as Influenza, tuberculosis (TB), HIV, enteric diseases, sexually transmitted infections (STIs), Viral Hepatitis, antibiotic-resistant (AR) infections, and vaccine-preventable diseases (VPD) often share the same testing platforms. However, they may differ in the programmatic priorities related to surveillance strategies (e.g., "right sizing" for Influenza), coordination with clinical laboratories for rapid referral and confirmation (e.g., TB), and ensuring access to low-volume testing services related to sporadic focused outbreaks (e.g., VPD). PHLs must sustain and strengthen these specialized services in an environment of funding constraints, changes in technology, and shifts in workforce expertise.

   Control of infectious disease in the United States also involves both public and clinical laboratories with coordination of different levels of service for screening, detection, referral, and confirmatory testing. This partnership requires a PHL leadership role for continual outreach and communication with the clinical laboratories that serve as sentinel laboratories for suspecting and referring specimens for infectious disease testing. Without excellent coordination and communication between public and private sector laboratories, diagnosis and treatment of patients and steps to interrupt disease transmission may be delayed.

   Access to specialized public health testing is increasingly provided through establishment of regional networks, designated referral centers, and test sharing between state and local PHLs. Therefore, the individual PHL must establish mechanisms and relationships to ensure access to testing services through participation in these networks as either a receiving or referring laboratory. Effective interstate referral of samples for testing will require further
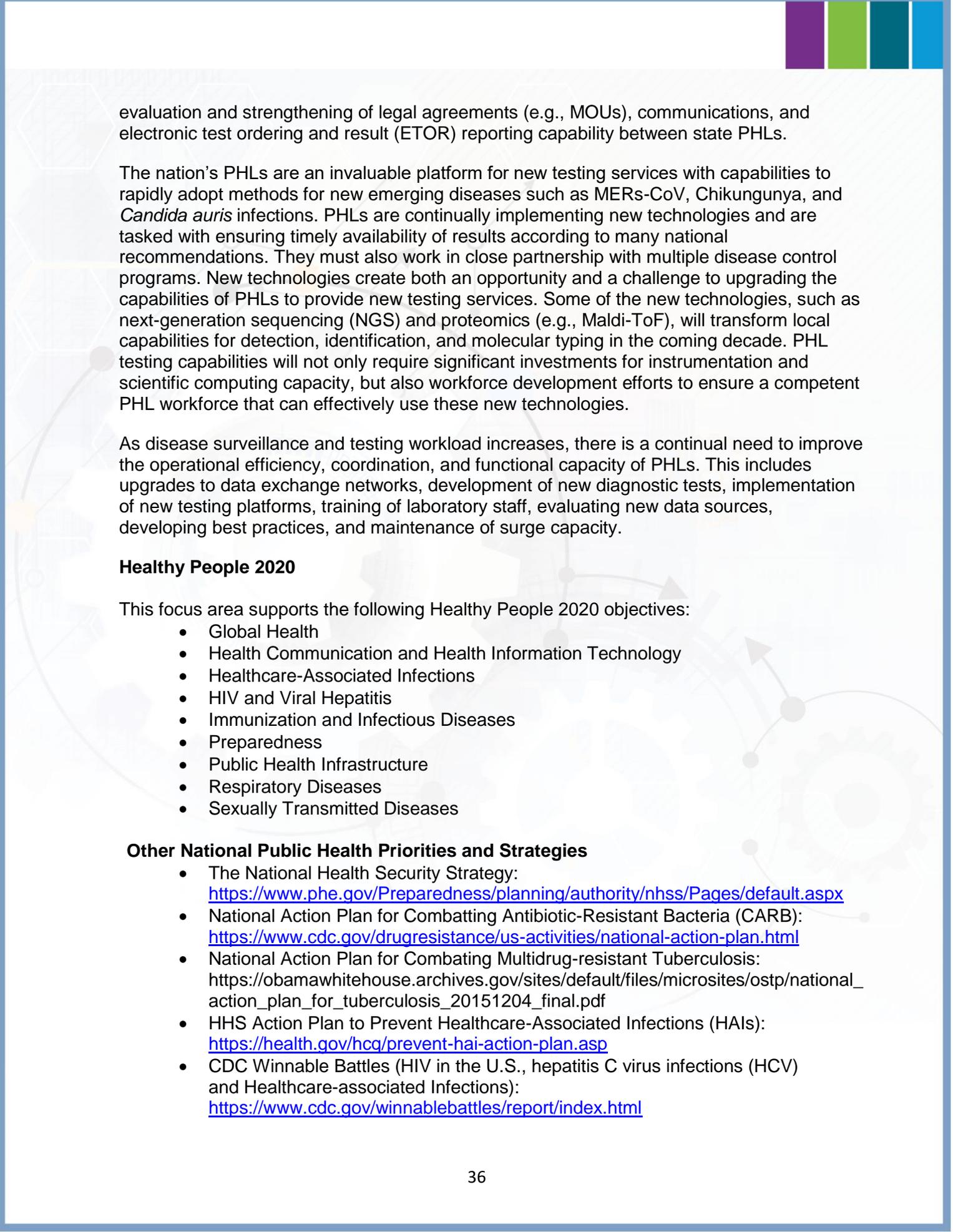
evaluation and strengthening of legal agreements (e.g., MOUs), communications, and electronic test ordering and result (ETOR) reporting capability between state PHLs.

The nation's PHLs are an invaluable platform for new testing services with capabilities to rapidly adopt methods for new emerging diseases such as MERs-CoV, Chikungunya, and *Candida auris* infections. PHLs are continually implementing new technologies and are tasked with ensuring timely availability of results according to many national recommendations. They must also work in close partnership with multiple disease control programs. New technologies create both an opportunity and a challenge to upgrading the capabilities of PHLs to provide new testing services. Some of the new technologies, such as next-generation sequencing (NGS) and proteomics (e.g., Maldi-ToF), will transform local capabilities for detection, identification, and molecular typing in the coming decade. PHL testing capabilities will not only require significant investments for instrumentation and scientific computing capacity, but also workforce development efforts to ensure a competent PHL workforce that can effectively use these new technologies.

As disease surveillance and testing workload increases, there is a continual need to improve the operational efficiency, coordination, and functional capacity of PHLs. This includes upgrades to data exchange networks, development of new diagnostic tests, implementation of new testing platforms, training of laboratory staff, evaluating new data sources, developing best practices, and maintenance of surge capacity.

Healthy People 2020

This focus area supports the following Healthy People 2020 objectives:
- Global Health
- Health Communication and Health Information Technology
- Healthcare-Associated Infections
- HIV and Viral Hepatitis
- Immunization and Infectious Diseases
- Preparedness
- Public Health Infrastructure
- Respiratory Diseases
- Sexually Transmitted Diseases

Other National Public Health Priorities and Strategies
- The National Health Security Strategy: https://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx
- National Action Plan for Combatting Antibiotic-Resistant Bacteria (CARB): https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html
- National Action Plan for Combating Multidrug-resistant Tuberculosis: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_action_plan_for_tuberculosis_20151204_final.pdf
- HHS Action Plan to Prevent Healthcare-Associated Infections (HAIs): https://health.gov/hcq/prevent-hai-action-plan.asp
- CDC Winnable Battles (HIV in the U.S., hepatitis C virus infections (HCV) and Healthcare-associated Infections): https://www.cdc.gov/winnablebattles/report/index.html

- CDC Surveillance Strategy: https://www.cdc.gov/surveillance/improving-surveillance/index.html
- Ending the HIV Epidemic: A Plan for America: https://www.cdc.gov/endhiv/index.html
- 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
- 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

Public health laboratories (PHLs) work closely with their program and epidemiology counterparts using systems-based strategies for disease detection, control and prevention in the U.S. and globally, including sustaining and improving specialized testing capabilities. CDC is committed to helping improve local and state laboratory capacity in areas such as upgrades to data exchange networks, development of new diagnostic tests, implementation of new testing platforms, training of laboratory staff, evaluating new data sources, developing best practices, and maintenance of surge 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

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

PO-11. Improved awareness and understanding among laboratory professionals of emerging methods and processes in public health laboratories

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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders

IO-2. Established information sharing systems across public health laboratories and with other key stakeholders

IO-3. Improved competence and engagement of public health laboratory workforce

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

IO-5. Improved data exchange and interoperability among public health laboratories and their partners

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: Science, Management and Operations (S1), Policy, Partnership, and Communication (S2), Training and Capacity Building (S3), and Laboratory Quality, Safety, Preparedness, and Informatics for Public Health Testing Services, Surveillance, and Response (S4).
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S.2. Policy, Partnership, and Communication
　　S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond
- Convene workgroups to develop or review guidelines and recommendations on PHL infectious disease capacity and quality laboratory practice and to promote quality infectious disease testing practices and control efforts.
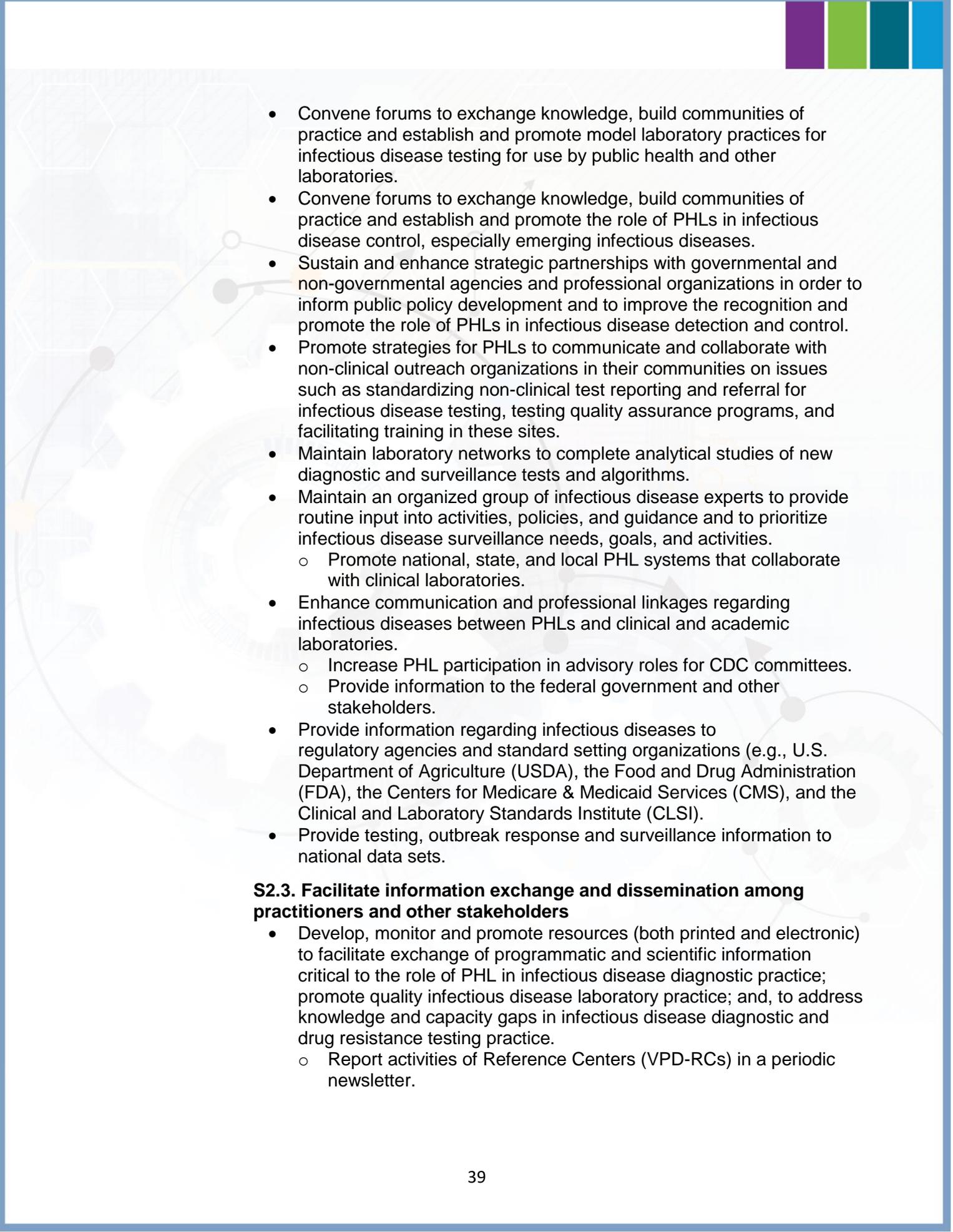
- Convene forums to exchange knowledge, build communities of practice and establish and promote model laboratory practices for infectious disease testing for use by public health and other laboratories.
- Convene forums to exchange knowledge, build communities of practice and establish and promote the role of PHLs in infectious disease control, especially emerging infectious diseases.
- Sustain and enhance strategic partnerships with governmental and non-governmental agencies and professional organizations in order to inform public policy development and to improve the recognition and promote the role of PHLs in infectious disease detection and control.
- Promote strategies for PHLs to communicate and collaborate with non-clinical outreach organizations in their communities on issues such as standardizing non-clinical test reporting and referral for infectious disease testing, testing quality assurance programs, and facilitating training in these sites.
- Maintain laboratory networks to complete analytical studies of new diagnostic and surveillance tests and algorithms.
- Maintain an organized group of infectious disease experts to provide routine input into activities, policies, and guidance and to prioritize infectious disease surveillance needs, goals, and activities.
  - Promote national, state, and local PHL systems that collaborate with clinical laboratories.
- Enhance communication and professional linkages regarding infectious diseases between PHLs and clinical and academic laboratories.
  - Increase PHL participation in advisory roles for CDC committees.
  - Provide information to the federal government and other stakeholders.
- Provide information regarding infectious diseases to regulatory agencies and standard setting organizations (e.g., U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and the Clinical and Laboratory Standards Institute (CLSI).
- Provide testing, outbreak response and surveillance information to national data sets.

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders
- Develop, monitor and promote resources (both printed and electronic) to facilitate exchange of programmatic and scientific information critical to the role of PHL in infectious disease diagnostic practice; promote quality infectious disease laboratory practice; and, to address knowledge and capacity gaps in infectious disease diagnostic and drug resistance testing practice.
  - Report activities of Reference Centers (VPD-RCs) in a periodic newsletter.

- Serve as principal point of contact to distribute information to PHLs on infectious disease activities via email, issue briefs, newsletters, list serves, webinars and other relevant communication venues.
- Coordinate and share data on new tests and algorithm performance.
- Coordinate information sharing on PHL testing services through the PHLSD, National Electronic Reporting Systems, and other mechanisms.
  - Coordinate conferences and meetings.
  - Facilitate member and staff participation in steering committees and convene sessions in meetings and conferences relevant to infectious disease diagnostic issues and issues related to drug resistance identification and control.
  - Conduct telephone conferences between state PHLs and the CDC to coordinate seasonal and emergency laboratory diagnostic and surveillance activities.

S2.4. Educate the public and other stakeholders about the role of public health laboratories
- Develop materials to assist PHL with communication of the PHL role in infectious disease detection, control, and prevention.
- Educate leadership at decision making positions across states for infectious diseases that require greater attention and resources to build state/local laboratory and epi capacity.

S3. Training and Capacity Building
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings
- Assess PHL capabilities and capacities in infectious disease and antimicrobial resistance testing by conducting and analyzing formal and informal surveys and other evaluation methodologies.

S3.3. Facilitate the development and delivery of training and workforce development resources
- Use needs assessment results to inform the development and delivery of training and workforce development resources for PHL staff, PHL-hosted fellows, and leadership to address infectious disease knowledge and capacity gaps.
  - Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).
  - 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.
  - Collaborate with CDC to review training and workforce development products, resources, and events.
- Support training fellowships to strengthen and increase competency of PHL workforce.

- o Collaborate with CDC to establish fellow and host site eligibility requirements and performance expectations.
- o Provide guidance and technical assistance to fellows and host sites.
- o Manage operations and funds to support fellows.
- o Coordinate with the recipient Training and Workforce Development Program regarding cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.
- Provide training to public health, clinical, and commercial laboratories to promote quality assurance practices, adoption of new and recommended testing technology and algorithms, and best practices in the laboratories (including waived testing sites under the Clinical Laboratory Improvement Amendments (CLIA).
  - o Improve diversity of non-traditional laboratory training (e.g., informatics, bioinformatics, safety) for laboratory professionals.

Additional 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:

- Develop and implement integrated information systems and networks for the exchange of surveillance data between government agencies and partners
  - o Support and expand data exchange between PHLs, and CDC via HL7 messaging.
- Maintain secure communication systems with interoperability between CDC, PHLs and surveillance stakeholders.
- Promote and support health systems-oriented laboratory informatics practice, use of new technologies, and standards-based interoperability
  - o Promote the reporting and communication of laboratory results to providers and programs as soon as they become available using more efficient reporting protocols and technologies.
- Conduct activities with state PHLs to evaluate the use of alternative data sources for infectious disease surveillance.

Additional Informatics activities are detailed in Appendix E: Informatics.

   S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories
- Conduct program performance evaluations of PHLs by analyzing metrics data.

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- Develop and implement best practices to improve infectious disease laboratory surveillance (e.g., turn-around time for reporting, accuracy, appropriate use of resources)
  - o Manage and support external quality control programs.
  - o Manage and support the availability of validations panels to support assay validation at PHLs.
  - o Develop analytical tools to guide infectious disease testing, outbreak response, and surveillance decision-making
  - o Assess the state of PHL safety using surveys, evaluations, risk assessment or other methods.

Additional Quality and Safety systems activities are detailed in Appendix H: Quality and Safety Systems.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories
- Systematic review of new commercial assays and assays and tools developed at CDC intended for deployment to PHLs to ensure efficient test implementation and maximum testing utility.
- Contribute to development, evaluation and validation of new technologies and procedures, products, and alternative testing algorithms in collaboration with CDC.
- Promote and provide support for the role of PHLs in test development, validation, and evaluation studies.
- Develop and promote technology transfer
  - o Ensure and enhance technology transfer from CDC and other agencies' PHLs.
  - o Ensure appropriate quality control when technology is transferred to community-based organizations involved in infectious disease testing.
- Develop strategies for the federal, state, and local level to overcome barriers to implementation of new infectious disease diagnostics and resistance testing technology and protocols.
  - o Develop testing strategies for infectious diseases by working with laboratories, state and local epidemiologists and primary health care providers.
- Provide leadership and management approaches to develop timely and accessible laboratory testing for infectious diseases by PHLs
  - o Provide leadership and management for designated PHLs to serve as Reference Centers based on a shared service model.
  - o Support PHLs to have broad access to Legionella testing with standard procedures, and reporting, with high quality results.
  - o Manage and support Reference Centers to provide broad access to infectious disease testing with high quality, uniform testing, short turnaround times and electronic reporting, and facilitate the introduction of new testing assays and algorithms.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes

- Provide expert consultation to CDC, PHLs, other public health partners, and regulatory and standard setting organizations on relevant infectious disease issues.
  - Conduct periodic teleconferences with Reference Centers, CDC, PHLs and state epidemiologists to maximize the public health benefits from Reference Center testing.
- Promote the implementation of the new infectious disease testing guidelines in public health and clinical laboratories in the United States.
- Assist in developing laboratory services and assist in control efforts for infectious disease diagnostics and detection of antimicrobial resistance.
- Provide leadership for framework and support of alternate service delivery models (e.g., Reference Centers and Regional Testing Centers) to ensure access to core infectious disease laboratory services (e.g., conventional drug susceptibility testing, and molecular testing).
- Provide support for PHL studies.
- Provide services that support uptake of CDC testing guidance.

S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and respond to public health threats
- Communicate to PHLs regarding pandemic preparedness and response.
- Address technical assistance requests in response to seasonal, variant and pandemic influenza outbreak responses and variant influenza outbreak responses in a timely way.

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 each strategy in this focus area may include:

Strategy and Activity	Process Measure
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, health care, and beyond	• Number and scope of recipient outreach efforts to engage PHLs, and other stakeholders in partnerships and collaborations. • Number of times infectious disease committees and subcommittees meet per year to collaborate and build relationships among laboratory professionals and other

	stakeholders in public health, healthcare, and beyond.
	• Number of speakers recruited by the Infectious Disease Subcommittees for recipient's workshops and meetings to collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond.
	• Integration of Influenza Subcommittee's expanded charge by ID Committee and the recipient's Board of Directors to include other respiratory pathogens of public health concern to collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond.
	• Number of subcommittee engagements and products shared with stakeholders (e.g FDA, PHLs) regarding pending over-the-counter infectious disease diagnostics to collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond.
	• Number of partnerships to build regional, state, and local infrastructure to detect and report AR threats in the AR Laboratory Network.
	• Number of partner organizations engaged to raise awareness of and participation in the AR Lab Network and other Reference Centers.
	• Educational material developed and disseminated, number of webinars or other discussions focused on improving turn-around time and accuracy of testing.
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders	• Number, frequency, and timeliness of recipient's efforts to support information exchange and dissemination within and between laboratory and other stakeholder communities. • Number of times recipient provided technical assistance and connected states with appropriate CDC staff in response to Right Size questions.

	• Number of national calls facilitated to provide information exchange and dissemination of testing and surveillance guidance among practitioners and other stakeholders. • Number of resources and types of resources to foster a coordinated approach to detection of and response to AR threats. • Number of education sessions and mix of attendees at stakeholder sessions to increase awareness of and participation in AR Lab Network. • webpage developed to provide real-time data around testing volumes and results • Number, timeliness and accuracy of products developed and disseminated to promote testing guidance.
S2.4. Educate the public and other stakeholders about the role of public health laboratories	• Number and type of target audience-appropriate educational materials developed. • Number, frequency and type of target audience-appropriate informational materials developed and disseminated, such as VPD-RC's newsletter. • Frequency and timeliness of the educational efforts. • Number of education sessions and mix of attendees at stakeholder sessions to increase awareness of the role of PHLs in the detection and response to AR threats and the activities included in the AR Lab Network.
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings	• Number of surveys conducted to identify training and workforce development needs among laboratory professionals in diverse settings. • Response rate for needs assessments (Percent of invitees who responded) – which is an indicator of a well-defined target audience and quality of survey design. • Number of prioritized needs based on results from needs assessments • Number of recommendations to address identified needs. • Number of education sessions to address training and workforce development needs.

S3.3. Facilitate the development and delivery of training and workforce development resources	• Number of infectious diseases training and workforce development resources facilitated and/or delivered. • Number of national technical and informational webinars hosted. • Number and type of resources and delivery methods used to facilitate workforce development.
S4.1. Develop and implement informatics-related solutions and standards to improve data exchange and interoperability	• Number of public health labs using new data solutions (e.g., HL7 messaging; ETOR) to enhance timely data reporting.
S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories	• Describe types of systems and services implemented to improve lab quality among PHLs. • Number of performance evaluations of PHLs performed to assess capacity to detect and report on infectious disease threats. • Number of PT panels provided for testing and number of laboratories successfully completing PT. • Number and type of validation panels requested by PHLs.
S4.3. Identify and address emerging methodological and process improvements in public health laboratories	• Number of specimens tested per infectious disease Reference Center supported by the recipient. • Number of pilot and reproducibility studies conducted leading to increased surveillance efficiency and/or FDA clearance submissions. • Number of contracts awarded for pilot and reproducibility studies • Increase usage of WGS methods on Legionella testing. • Number and type of process improvements identified and implemented in PHLs. • Number of routine tests performed, turnaround time, and quality indicators at supported Reference Centers. • Number of laboratories designated as Reference Centers to maximize coverage, and catchment. • Number of PHLs submitting samples to established Reference Centers.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes	• Number and type of technical assistance provided to PHLs for AR related activities. • Number of teleconferences and webinars that engage key partners. • Number of contracts awarded. • Number of contracts maintained. • Number of monthly calls facilitated between recipient and CDC SMEs. • Number of technical assistance requests addressed. • Number of states tracked for meeting influenza surveillance goals established by right sizing. • Describe leadership and management approaches provided to support PHLs and ensure access to AR lab services for detection of AR.
S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and respond to public health threats	• Number of communications provided to PHLs regarding pandemic preparedness and response. • Number of technical assistance requests addressed in response to seasonal influenza outbreak responses. • Number of technical assistance requests addressed in response to variant outbreak responses. • Number of technical assistance requests addressed in infectious disease outbreak responses.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
PO-1. Improved collaboration and communication across public health laboratories and other stakeholders	• Number of PHLs who are enrolled to the supported Reference Centers. • Percent of resource materials/ reference documents on partner website that are up to date. • Number of webinars, calls, and other outreach activities conducted.

PO-8. Improved understanding of data-related challenges and data-informatics solutions among laboratory professionals and other stakeholders	• Number of surveys assessing laboratory informatics and data transfer capacities and needs. • Number of informatics-related trainings offered annually for PHL partners.
PO-11. Improved awareness and understanding among laboratory professionals of emerging methods and processes in public health laboratories	• Number of surveys assessing laboratory testing capacity. • Number of trainings in emerging methods and processes.
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders	• Number of annual or bi-annual assessments of targeted infectious diseases prevalence in the United States.
IO-2. Established information sharing systems across public health laboratories and with other key stakeholders	• Increased number of sequences that resulted from confirmed outbreaks and isolates not associated with the respective outbreaks. • Percent of complete, accurate and relevant meta data submitted (e.g., state, year, outbreak facility, source, species).
IO-3. Improved competence and engagement of public health laboratory workforce	• Improved identified training and workforce development gaps in PHL practice and established competencies in the PHL workforce. • Workforce capable of transitioning to, and implementing, new molecular technologies. • Enhanced infectious disease capacity among laboratorians and other public health officials. • Convened subcommittee calls with at least 90% member attendance for 10 of 12 months per year. • Percent responsiveness to all ID committee and sub-committee and CDC Division requests. • Increased capabilities of laboratory workforce as a result of workshop attendance, trainings, and webinars.

	• Number/percent of fellows that successfully complete the fellowship program. • Number of testing personnel who are CLIA competent for diagnostic tests reported. • Improve PHL usage and knowledge base of CDC's bioinformatics toolset.
IO-4. Enhanced practices, methods, and technical capabilities within the public health laboratory system	• PHLs have improved interoperable electronic data reporting systems that facilitate data exchange and rapid dissemination of diagnostic results. • PHLs are proficient in testing and have knowledge of laboratory practices of infectious diseases. • Introduced new assays and improved PHL capacity for pathogen genetic characterization. • Improved efficiency of laboratory capabilities supporting surveillance. • Number of PHLs capable of providing testing for both environmental and clinical specimens. • Number of PHLs reporting genetic data to CDC and public databases. • Number of PHLs submitting either isolates or positive specimens for genetic characterization.
IO-5. Improved data exchange and interoperability among public health laboratories and their partners	• Number/percent of PHLs that implement standardized electronic messaging of data to and from CDC. • States meeting or exceeding CDC-defined surveillance goals.
IO-6. Improved public health laboratory detection, surveillance and response	• Number of documented improvements in infectious disease testing and prevention programs. • Number of implemented and improved methods to respond to, and detect, disease outbreaks and emerging infectious diseases. • Improved influenza surveillance, detection, diagnostics, antiviral assessment, vaccine strain selection, pandemic preparedness and response capabilities as a result of information

| | exchange and dissemination as result of national calls. |
| | • Number/percent of PHLs that implement and are proficient in CDC-supported testing. |

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 collaborate with other CDC-funded programs to maximize the use of resources and improve the sustainability of the listed activities.

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. Recipient is encouraged to explore opportunities for new collaborations with additional partners to advance public health priorities, for example:
- State and local PHLs and public health departments
- Federal agencies and programs:
  - CMS (including the CLIA implementation program)
  - FDA (including the Bloodborne Pathogens Advisory Committee)
  - Indian Health Service (IHS)
  - National Institutes of Health (NIH)
  - Office of the National Coordinator for Health Information Technology (ONC)
  - The Substance Abuse and Mental Health Services Administration (SAMHSA)
  - U.S. Department of Defense
- Accreditation and standards-setting organizations, for example:
  - College of American Pathologists (CAP)
  - The Joint Commission
- Professional organizations/Public health partners, for example:
  - American Association for the Study of Liver Diseases (AASLD)
  - American Association for Clinical Chemistry (AACC)
  - American Society for Clinical Pathology (ASCP)
  - American Society for Microbiology (ASM)
  - Association of State and Territorial Health Officials (ASTHO)
  - Clinical Laboratory Management Association (CLMA)

- o Council of State and Territorial Epidemiologists (CSTE)
- o Infectious Disease Society of America (IDSA)
- o Joint Public Health Informatics Taskforce (JPHIT)
- o National Alliance of State and Territorial AIDS Directors (NASTAD)
- o National Association of County & City Health Officials (NACCHO)
- o National Coalition of STD Directors (NCSD)
- o National Tuberculosis Controllers Association (NTCA)
- Advisory Council for the Elimination of Tuberculosis (ACET)
- Health Information Technology Policy Committee (HITPC)
- Pan American Health Organization (PAHO)
- Public Health Data Standards Consortium (PHDSC)
- World Health Organization (WHO)
- National Influenza Centers funded by CDC's Influenza Division Cooperative Agreements with Ministries of Health
- Other organizations and agencies that could assist in improving public health infrastructure through the development of programs to promote PHL leadership.

d. **Target populations**
In addition to PHLs and PHL professionals 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 National Center for Immunization and Respiratory Diseases (NCIRD), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and the Deputy Director for Infectious Diseases (DDID) will provide technical monitoring and program support 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.

Appendix E: Informatics

Focus Area Name
Informatics

Focus Area Contact Information
Jasmine Chaitram, zoa6@cdc.gov
Jason Hall, zfr9@cdc.gov

Approximate Average Annual Award: $9,000,000

Funding Opportunity Description

1. **Background**
   Laboratory data are critical to patient care and for informing the decisions public health agencies make for the prevention, detection, and response to health threats. Laboratory data are also ubiquitous, with a growing volume and variety of data sources from both within and outside of traditional partners. Public health laboratories (PHLs) and agencies have the unique opportunity to harness this data in a collaborative way to make more timely and insight-driven decisions to inform public health programs, policies, and investments. To fully use laboratory data requires a robust health information systems infrastructure.

   PHLs and other laboratories that serve public health face increasing challenges to their ability to enhance, develop, and sustain the laboratory informatics capabilities they need to meet existing and emerging public health challenges. For instance, some clinical and laboratory partners are still exchanging data that are not standardized or via labor-intensive, paper-based methods. Additionally, the linking of epidemiological data with laboratory results remains a challenge for public health response. Furthermore, laboratory staff have taken on more responsibilities for maintaining informatics without any formal training.

   Healthy People 2020
   This focus area supports the following Healthy People 2020 objective:

   Health Communication and Health Information Technology, Objective 11:
   (Developmental) Increase the proportion of meaningful users of health information technology (HIT) (Developmental)

   Other National Public Health Priorities and Strategies
   - CDC's public health data strategy and IT transformation efforts:
     https://www.cdc.gov/surveillance/surveillance-data-strategies/data-IT-transformation.html
   - Centers for Medicare & Medicaid Services Promoting Interoperability (PI) Programs:
     https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html
   - LRN 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 purpose of this program is to maximize PHL adoption and use of interoperable, standards-based data exchange and information systems to communicate test orders and results and provide electronic reporting to public health. This program will strengthen PHL's ability to benefit from and contribute to the CDC data strategy drafted in 2018. Within this overarching purpose, the program will help improve coordination within and among jurisdictions; advance electronic data exchange; and promote the reuse of existing data systems rather than creating new solutions.

   II. **Outcomes**
   Activities in this focus area should achieve or contribute to the following proximal and 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):

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

   IO-5. Improved data exchange and interoperability among public health laboratories and their partners
   - Data are increasingly available to CDC and states for case investigations and surveillance through improved integration of epidemiologic and laboratory data.
   - Public health networks and systems function better to provide surge capacity or reference testing.
     - Improve laboratory operations and functionality for data collection and transmission to states and CDC.
   - Interoperability between information systems and entities is increased; quality of data is improved; more timely data are collected and reported; existing resources are better leveraged.
     - Improved and increased standards-based data exchange.
     - Increased use of resources.
   - Data are used for public health practice, policy, program, 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) and Laboratory Quality, Safety, Preparedness, and Informatics for Public Health Testing Services, Surveillance, and Response (S4). Specific training and workforce development activities are detailed in Appendix I: Workforce Development.

S2. Policy, Partnership, and Communication
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare and beyond:
- Enhance coordination within a jurisdiction across laboratory, epidemiology and health information technology personnel and practices.
  - o Continue to create and maintain relationships with epidemiologists, Health Information Technology (HIT), clinical care, and laboratory staff.
  - o Participate in laboratory-epidemiology collaboration efforts to identify and implement a universal case identifiers (or similar linking variables) to include with laboratory and case data transmission (e.g., patient identifier that links data from health systems; identifier to link PulseNet data to case reports).
- Strengthen laboratory coordination among state health departments
  - o Help develop policies that advance PHL capabilities through adoption and use of informatics and interoperable information technology.
  - o Continue to expand, coordinate, and support communities of practice around laboratory information management systems and public health informatics.
  - o Use existing state consortiums and CDC-defined laboratory networks to promote policies and best practices for improved data collection and transmission.

S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders

- Conduct annual assessments and develop action plans for improvement of a tool that can be used by PHLs to self-assess their informatics capabilities and maturity.

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:

- Advance and modernize electronic information exchange:
  - o Develop a vision and recommendations for PHL informatics, information systems, and integration with partner organizations that aligns with CDC Data Strategy.
  - o Provide technical assistance and technical solutions to support public health agencies implementations of standards-based data exchange such as electronic laboratory reporting (ELR), electronic test orders and results reporting (ETOR), electronic case reports (eCR), and surveillance, referrals and survey data.
  - o Participate in and support national standards development efforts and efforts to standardize data transmissions.
  - o Assess and provide recommendations for current information systems to support data exchange with partners like CDC with increasingly large data exchange needs (e.g., WGS).
- Reuse existing data systems, services and software solutions:
  - o Create, maintain and provide a catalog of shared services, technical solutions, and software as a service (SaaS) available through recipient to public health agencies.
    - Maintain and enhance data transport capacity that serves as cloud-based public health infrastructure, including transport protocols and software, message validators, dashboards and tools for monitoring data transmissions, and web access to data files.
    - Enhance and modernize cloud-based public health infrastructure as a service (IaaS) to improve performance and efficiency for the projects that use it.
  - o Maintain and enhance a laboratory web portal to support test ordering from submitter and reporting from PHLs.
  - o Contribute code for software solutions to CDC's open code repository.
- Provide quantitative measures and metrics, showcasing the economies of scale through year-over-year comparisons.
- Maintain and enhance core services and functions on cloud-based public health infrastructure, including help desk services and tools to support all projects, security, liability protection, and legal services, agreements, and documentation.
- Consult with CDC on architecture, function and evolution (e.g. capacity planning) of public health informatics infrastructure and activities.
- Maintain up to date documentation of public health informatics infrastructure and processes following CDC and/or industry templates for these artifacts (e.g., architecture diagrams)

- Make code base of software solutions, apps and other tools developed as part of funded projects available through agreed upon mechanisms. Include build and deployment instructions for the software solutions and components.

   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 each of the activities in this focus area may include:

Strategy and Activity	Process Measure
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare and beyond • Enhance coordination within a jurisdiction across laboratory, epidemiology and clinical care. • Strengthen laboratory coordination among state health departments.	• Number of partnerships formed to improve integration/linking of epidemiological and laboratory data in health departments.
S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders • Conduct annual assessments and develop action plans for improvement of a tool that can be used by PHLs to self-assess their informatics capabilities and maturity.	• Number of PHLs that have completed entering or updating data into a tool to assess informatics capabilities and maturity. • Number of PHLs that have used a tool to assess informatics capabilities and obtain additional resources or implement informatics modernization activities.
S4.1 Develop and implement informatics-related solutions and standards to improve data exchange and interoperability: • Advance and modernize electronic information exchange. • Reuse existing data systems, services and software solutions.	• Number of laboratories that use common dashboard to monitor transmission of data. • Gather level-of-effort (LOE) estimates across offerings (example: TA, solution development etc.) and actuals to build a knowledge repository for capacity planning and optimization. • Number of CDC programs and projects using common, modernized components of the cloud-based public health infrastructure (e.g., data lake, containers, native cloud functionality).

Outcome measures for this focus area include:

Outcome	Outcome Measure
PO-8. Improved understanding of data-related challenges and data-informatics solutions among laboratory professionals and other stakeholders	• Increase the number of public health programs and partners within states that contribute to implementation of informatics solutions.
IO-5. Improved data exchange and interoperability among public health laboratories and their partners • Data are increasingly available to CDC and states for case investigations and surveillance through improved integration of epidemiologic and laboratory data. • Public health networks and systems function better to provide surge capacity or reference testing. • Interoperability between information systems and entities is increased; quality of data is improved; more timely data are collected and reported; existing resources are better leveraged.	• Number of new laboratories sending standard cancer reports using HL7 electronic pathology standard to cloud-based public health infrastructure for use by cancer registry jurisdictions. • Number of new laboratories sending Rabies ELR to cloud-based public health infrastructure for use by CDC. • Percent of ARLN laboratory results sent to cloud-based public health infrastructure using HL7. • Number of technical assistance projects with states in progress and completed. • Number of state PHLs that have set up new electronic test orders and results (ETOR) for newborn screening with at least one large hospital system in their state. • Number of CDC programs and projects using common, modernized, components of the cloud-base public health infrastructure (e.g., data lake, containers, native cloud functionality).Number of message senders receiving notifications about transmissions. • Number of clinical care and public health partners in production, testing and queued for sending and receiving eCR (eICRs and RRs). • Reduced cost per message routed through cloud-based public health infrastructure resulting from synergies and optimization o Provide baseline cost per message routed through cloud-based public health infrastructure.

		o Identify incremental costs, if any, for each data exchange scenario / use case.

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 informatics-related collaborations with OPHSS/CSELS, CPR, CGH, OID, and the Advanced Molecular Detection (AMD) initiative, the Antimicrobial Resistance initiative, and the TB and vaccine-preventable diseases (VPD) programs, and with non-infectious programs such as cancer and other chronic conditions, newborn screening, among others.

Recipient should also explore opportunities for new collaboration with and across CDC programs and initiatives and develop collaborations to advance public health priorities.

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. Recipient is encouraged to participate with public health partners in planning, development, implementation, and assessment efforts related to electronic data exchange and information systems. These partners include, among others, the Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), the National Association of County and City Health Officials (NACCHO), the Public Health Informatics Institute (PHII), and the Office of the National Coordinator (ONC).

Recipient should also explore opportunities for new collaborations with additional partners and develop collaborations as appropriate to advance public health priorities.

d. **Target populations**
In addition to PHLs and PHL professionals 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 CSELS, NCEZID, NCIRD, NCEH and NCCDPHP will provide technical monitoring and program support 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. CDC support also includes facilitating a governance workgroup to 1) assist recipient to manage growth of public health informatics infrastructure; 2) advise recipient on architecture, function and evolution of public health informatics infrastructure; and 3) advise recipient on prioritization of funded informatics projects and activities. In addition, CDC may participate in all relevant stakeholder and other meetings, either in-person or by teleconference.

Appendix F: Newborn Screening and Genetics

Focus Area Name
Newborn Screening and Genetics

Focus Area Contact Information
Amy Mowbray, htm3@cdc.gov

Approximate Average Annual Award: $2,300,000

Funding Opportunity Description

1. **Background**
   State and territorial newborn screening (NBS) programs test infants for diseases that require immediate medical treatment but are not apparent at birth. Nearly 4 million newborns are tested annually in the United States, and thousands of infants and children are saved from severe disability and death through early detection and treatment. Newborn screening laboratories face unique challenges as they implement new tests and conduct ongoing screening to rapidly and accurately identify infants affected by harmful or fatal diseases. Laboratories must rapidly integrate tests for an ever-growing number of diseases, adopt new technologies, manage and interpret increasingly complex newborn screening data, and operate effectively within an NBS community that includes policymakers, advocacy groups, and health care providers. In order to overcome these challenges, NBS laboratories need a national forum to address laboratory practice issues and other emerging issues across the newborn screening system.

   Healthy People 2020
   This focus area supports the Healthy People 2020 Maternal, Infant, and Child Health Objectives:

   Maternal, Infant, and Child Health, Objective 1: Reduce the rate of fetal and infant deaths.

   Maternal, Infant, and Child Health, Objective 3: Reduce the rate of child deaths.

   Maternal, Infant, and Child Health, Objective 32: Increase appropriate newborn blood-spot screening and follow-up testing.

   Other National Public Health Priorities and Strategies
   N/A

2. **CDC Project Description**
   a. **Approach**

      I. **Purpose**
         The purpose of the Newborn Screening focus area is to improve national NBS laboratory capability and practice and strengthen the role of NBS laboratories within the newborn screening system. Competent and well-integrated NBS

laboratories will increase the number of newborns screened for harmful or deadly diseases, as well as those identified and referred for life-saving medical treatment.

II. Outcomes

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-1. Enhanced communities of practice and other collaborative relationships among and between laboratories and other stakeholders
- Stronger roles for public health laboratories (PHLs) in state NBS programs and the NBS system

IO-2. Established information sharing systems across public health laboratories and with other key stakeholders
- More training for PHLs in existing and emerging NBS testing methods and data interpretation approaches, such as molecular detection, next-generation sequencing (NGS), and bioinformatics
- More guidance for PHLs on emerging NBS techniques and new diseases

IO-3. Improved competence and engagement of public health laboratory workforce
- Larger PHL workforce skilled in newborn screening
- Improved national NBS laboratory capability

IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system
- PHLs proficient in NBS testing, including new testing technologies
- PHLs able to rapidly conduct and report newborn screening results
- PHLs able to quickly implement new screening tests and sustain NBS laboratory testing during emergencies

IO-6. Improved public health laboratory detection, surveillance, and response
- Improved coordination of newborn screening laboratory efforts in the newborn screening system.
- Better strategies to address emerging issues across the NBS system

IO-7. Improved quality and safety in public health laboratories
- High-quality and safe NBS laboratory practices in PHLs
- Efficient, interoperable PHL data exchange, transfer, and use for NBS

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 resources which could include:

personnel, travel, supplies, equipment, contractual, and consultant support for proposed activities.

The 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

S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond
- Develop relationships and engage with partner organizations, including policymakers and advocacy groups.
- Develop partnerships to improve screening test performance, test result interpretation, quality assurance approaches, and training, and technology transfer.

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders
- Communicate with PHLs, federal partners, and others about NBS policy, technology, regulation, and practice.
- Disseminate guidance to PHL leadership and staff.
- Disseminate best practices for both routine and emergency laboratory operations.

S2.4. Educate the public and other stakeholders about the role of PHLs
- Identify and address communication and information needs of parents and advocacy groups, including the use of plain writing/plan language in communications.
- Facilitate communication among PHLs, parents, health care providers, partners, and policy makers about NBS science, policy, technology, regulation, and practice.

S3. Training and Capacity Building

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

- Conduct training and workforce development needs assessments to identify unique needs for NBS laboratories.
- Use needs assessment results to inform the development and delivery of training and workforce development resources for newborn screening staff and leadership.
- Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies).
- Monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.

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

- Use needs assessment results and guidance from CDC to develop and deliver training and workforce development opportunities for NBS laboratory staff, including those on laboratory methods and emerging issues in NBS.
- Collaborate with CDC to review training and workforce development products, resources, and events.
- Collaborate with CDC to establish fellow and host site eligibility requirements and performance expectations
- Provide guidance and technical assistance to fellows and host sites.
- Manage operations and funds to support fellows.
- Coordinate with the recipient Training and Workforce Development Program regarding cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.

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

S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories

- Convene committees, workgroups, or other meetings to develop and communicate guidance about NBS science and policy issues.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories

- Develop guidance about policy, scientific, and management issues in NBS.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes

- Facilitate on-site assessment and guidance for PHLs integrating new technologies and implementing systems to modernize screening.

- Facilitate improvements in newborn screening laboratory information technology and management infrastructure.

S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and respond to public health threats.
- Distribute NBS filter paper from emergency stockpile to PHLs experiencing shortages.
- Monitor trends in NBS contingency planning.
- Collaborate with PHLs to develop state NBS contingency plans.

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
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, healthcare, and beyond • Develop relationships and engage with partner organizations, including policymakers and advocacy groups. • Develop partnerships to improve screening test performance, test result interpretation, quality assurance approaches, and training, and technology transfer.	• Number and diversity of new and existing partner organizations engaged in and familiar with newborn screening laboratory issues. • Number of partners engaged in screening test performance, test result interpretation, quality assurance approaches, and training, and technology transfer.
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders • Communicate with PHLs, federal partners, and others about NBS policy, technology, regulation, and practice. • Disseminate guidance to PHL leadership and staff. • Disseminate best practices for both routine and emergency laboratory operations.	• Number of policy, science, and management guidance documents disseminated to newborn screening laboratories. • Number of educational resources and events for partners and stakeholders that increase awareness of newborn screening laboratory capabilities and issues. • Number of best practice documents for routine and emergency newborn screening laboratory operations disseminated to PHLs.

S2.4. Educate the public and other stakeholders about the role of PHLs • Identify and address communication and information needs of parents and advocacy groups, including the use of plain writing/plan language in communications. • Facilitate communication among PHLs, parents, health care providers, partners, and policy makers about NBS science, policy, technology, regulation, and practice.	• Number of educational resources, including those in plain language, disseminated to diverse stakeholders, such as parent and advocacy groups, regarding newborn screening laboratory issues. • Number and breadth of connections made among diverse stakeholders regarding newborn screening laboratory and system issues.
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings • Conduct training and workforce development needs assessments to identify unique needs for NBS laboratories. • Use needs assessment results to inform the development and delivery of training and workforce development resources for newborn screening staff and leadership. • Apply best practices to all training and workforce development products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies). • Monitor and evaluate effectiveness of training and workforce development products, resources, and events regularly and consistently.	• Number and type of training needs assessments that identify NBS laboratory needs. • Number of trainings and workforce development products that apply best practices. • Number of evaluations of effectiveness of training products, resources, and events for newborn screening laboratories.
S3.3. Facilitate the development and delivery of training and workforce development resources • Use needs assessment results and guidance from CDC to develop and deliver training and workforce development opportunities for NBS laboratory staff, including those on laboratory methods and/or emerging issues in NBS. • Collaborate with CDC to review training and workforce development products, resources, and events.	• Number and diversity of training opportunities for newborn screening laboratory staff, including laboratory methods and/or emerging issues. • Number of trainee and/or fellowships for newborn screening laboratories.

• Collaborate with CDC to establish fellow and host site eligibility requirements and performance expectations. • Provide guidance and technical assistance to fellows and host sites. • Manage operations and funds to support fellows. • Coordinate with the recipient Training and Workforce Development Program regarding cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.	
S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories • Convene committees, workgroups, or other meetings to develop and communicate guidance about NBS science and policy issues.	• Number of committees, workgroups, and meetings to develop and communicate science and/or policy guidance for newborn screening laboratories.
S4.3. Identify and address emerging methodological and process improvements in public health laboratories • Develop guidance about policy, scientific, and management issues in NBS.	• Number of guidance documents about policy, scientific, and management issues relevant to newborn screening laboratories developed.
S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes • Facilitate on-site assessment and guidance for PHLs integrating new technologies and implementing systems to modernize screening. • Facilitate improvements in newborn screening laboratory information technology and management infrastructure.	• Number of on-site assessments of newborn screening laboratories to improve implementation of new technologies and operations. • Number of resources coalesced, developed, disseminated, and provided to assist newborn screening laboratories in implementing new technologies, approaches, or programs. • Number of resources coalesced, developed, disseminated, and/or provided to assist newborn screening laboratories with improvements in information technology or management infrastructure.
S4.5. Identify and address gaps in laboratory infrastructure and capability to	• Number of newborn screening laboratories that received and

prepare and respond to public health threats.	successfully used NBS filter paper from emergency stockpile during shortages.
• Distribute NBS filter paper from emergency stockpile to PHLs experiencing shortages. • Monitor trends in NBS contingency planning. • Collaborate with PHLs to develop state NBS contingency plans.	• Number of resources coalesced, developed, disseminated, and/or provided to assist PHLs with continuous, high-quality newborn screening during an emergency. • Number of resources coalesced, developed, disseminated, and/or provided to assist PHLs with improving or establishing newborn screening contingency plans.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders	• Number of PHLs participating in NBS laboratories and/or NBS system networks and communities of practice. • Number of NBS laboratories with active relationships with hospitals, follow-up coordinators, policy makers, communicator and other NBS system stakeholders. • Number and relevance of newborn screening topics that networks, collaborative relationships, and/or communities of practice address.
IO-2. Established information sharing across public health laboratories and with other key stakeholders	• Number of PHLs participating in training for existing and emerging NBS testing methods and data interpretation approaches, such as molecular detection, NGS, and bioinformatics. • Number of PHLs using or implementing guidance on new policies and methods related to emerging NBS techniques or new diseases. • Number of newborn screening system stakeholders using or implementing guidance.
IO-3. Improved competence and engagement of public health laboratory workforce	• Number of PHL staff able to conduct newborn screening for existing and emerging conditions. • Percent of PHLs with expanded newborn screening laboratory capability.

IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system	• Number of PHLs with expanded newborn screening laboratory capacity. • Percent of PHLs that implement new testing technologies. • Number of PHLs able to more rapidly and accurately detect and report newborn screening results. • Number of PHLs with established and exercised protocols to sustain newborn screening laboratory testing during emergencies.
IO-6. Improved public health laboratory detection, surveillance, and response	• Number of newborn screening laboratory initiatives that incorporate newborn screening system stakeholders and other partner organizations. • Number of newborn screening laboratories implementing best practices to address emerging NBS issues.
IO-7. Improved quality and safety in public health laboratories	• Percent increase in the number of PHLs conducting high-quality and safe NBS practices. • Percent increase in the number of newborn screening laboratories effectively utilizing PHL data exchange, transfer, and analytics for NBS.

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**
The recipient is expected to use or develop strategic partnerships that best suit their needs in order to maximize the use of resources and improve the sustainability of the NBS project activities.

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 collaborate with CDC's Division of Laboratory Sciences, Newborn Screening and Molecular Biology Branch, and other relevant programs to establish program priorities and activities. The recipient may also consider collaborations with NBS laboratories previously or currently funded by CDC to share expertise, challenges, and successes related to the newborn screening system.

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 may also consider collaboration with NBS laboratories not currently funded by CDC to share expertise, challenges, and successes related to the NBS system. The recipient should establish appropriate collaboration with and support from NBS stakeholders to accomplish diverse activities. Potential collaborators include, but are not limited to: other federal or state agencies involved in newborn screening, national advisory committees, academic institutions, professional organizations, non-profit organizations, advocacy groups, parent support groups, community groups, public health officials, and health care providers.

d. Target populations

The primary target population of this project is PHL professionals supporting state and territorial newborn screening programs. The secondary target population is stakeholders in the newborn screening system, including parents, policy makers, care providers, and others.

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. The recipient should demonstrate a well-established and trusted role with newborn screening laboratories and among the newborn screening community as a whole. The recipient should also demonstrate broad expertise in the newborn screening field, experience executing the proposed activities, and existing staffing and infrastructure to support the work plan.

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 Monitors to ensure integration of the strategies and activities and achievement of the period of performance outcomes.

g. CDC Program Support to Recipient

CDC's Division of Laboratory Sciences and Newborn Screening and Molecular Biology Branch will provide technical expertise in support of project activities and will meet with the recipient's newborn screening and genetics staff monthly (and on an ad hoc basis for emerging issues) via conference call to discuss project progress and future actions. In addition, CDC will participate in all relevant stakeholder and other meetings, either in-person or by teleconference.

Appendix G: Preparedness and Response

Focus Area Name
Public Health Preparedness and Response

Focus Area Contact Information
Jasmine Chaitram, zoa6@cdc.gov
Joanne D. Andreadis, jsa9@cdc.gov

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.
    o 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.
    o 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.
    o 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).
    o 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.

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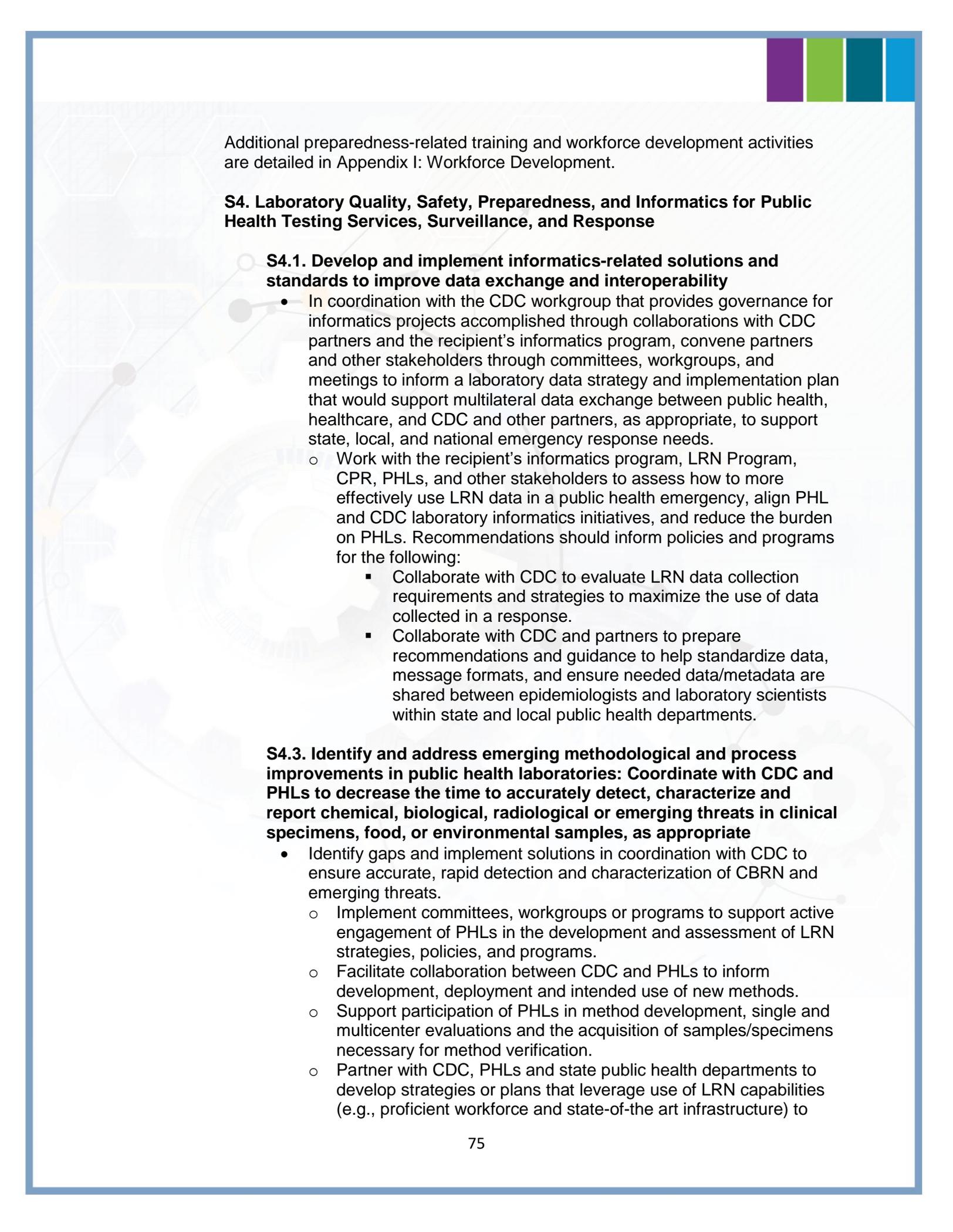
Additional preparedness-related training and workforce development activities are detailed in Appendix I: Workforce Development.

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	• 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.	• 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.	• Products, resources and events that enhance workforce development.
S3.3. Facilitate the development and delivery of training and workforce development resources	• 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 heath preparedness and response.
S4.1. Develop and implement informatics-related solutions and standards to improve data exchange and interoperability	• Strategy and implementation plan, in conjunction with the CDC Informatics Projects Governance Workgroup, for upgrading multilateral data exchange between public health, healthcare and CDC.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories	• Resources and products that assist LRN laboratories to conduct studies and implement new methods; produce and implement solutions to identified gaps in emergency response.
S4.5. Identify and address gaps in laboratory infrastructure and capability to prepare and responds to public health threats. • Support PHL participation in emergency preparedness and response exercises and real emergency responses.	• 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
PO-1. Improved collaboration and communication across public health laboratories and other stakeholders	• Demonstrated increase and/or enhancement in LRN laboratories that have established active outreach programs with Sentinel laboratories.
PO-2. Improved awareness and understanding of public health laboratories among public and other stakeholders	• Reports, articles or other informational documents that inform public, policy makers and government officials on LRN role in preparedness and response.
PO-3. Improved support for public health laboratories among stakeholders	• Position papers that can inform development of policy documents related to federal laws and regulations that support emergency response and preparedness needs.
PO-7. Enhanced technical and non-technical knowledge, skills and abilities among public health laboratory professionals in diverse settings.	• At least 95% of LRN PHLs meet requirements for DOT certification.
PO-8. Improved understanding of data-related challenges and implementation of data-informatics solutions among laboratory professionals and other stakeholders	• Increase in the number of LRN laboratories that have ability to send results to CDC and other public health partners.

PO-13. Improved laboratory testing capability and surge capacity for emergency response through equipment procurement, competent staff and partnerships	• 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.
IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system	• LRN laboratories can conduct new methods needed for emergency response.
IO-6. Improved public health laboratory detection, surveillance, and response	• 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.

Appendix H: Quality and Safety Systems

Focus Area Name
Quality and Safety Systems

Focus Area Contact Information
Nancy Anderson, nla0@cdc.gov
Natasha Griffith, njv0@cdc.gov

Approximate Average Annual Award: $1,500,000

Funding Opportunity Description

1. **Background**
   Public health laboratories (PHLs) play an indispensable role in protecting the health of Americans from new, emerging, and existing health threats by conducting laboratory testing and providing other science-based services. PHLs have to work as part of an interconnected system of state and local PHLs working with clinical laboratories and other stakeholders, including national agencies such as Centers for Disease Control and Prevention (CDC). A functional national PHL system requires constant efforts to reach out to clinical and public health partners while adopting new technologies and providing a safe environment and quality testing. This requires a focus on quality and safety standards for unique PHL testing, outreach and coordination with clinical laboratories and other stakeholders, and adapting to constantly evolving best practices identified through PHL peers and collaboration with CDC.

Healthy People 2020
This focus area supports the following Healthy People 2020 objectives:

Public Health Infrastructure, Objective 11: Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential 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
- The National Health Security Strategy:
  https://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx
- National Biodefense Strategy: https://www.phe.gov/Preparedness/biodefense-strategy/Pages/default.aspx
- Global Health Security Agenda (GHSA) https://www.ghsagenda.org
- WHO International Health regulations (IHR)
  https://www.who.int/topics/international_health_regulations/en/
- ISO 35001 Laboratory biorisk management system – Requirements
  https://www.iso.org/standard/66154.html
- HHS Strategic Plan, 2018—2022: hhs.gov/about/strategic-plan/index.html

- HHS Action Plan to Prevent Healthcare-Associated Infections (HAIs): https://www.cdc.gov/hai/prevent/prevention.html
- CDC Strategic Framework, 2016-2020: https://www.cdc.gov/about/organization/strategic-framework/index.html
- Centers for Medicare & Medicaid Services Promoting Interoperability (PI) Programs: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html
- Public Health and Medical Situational Awareness Strategy: https://www.phe.gov/about/OPP/Documents/phm-sa-ip-sept2015.pdf
- Project Public Health Ready: https://www.naccho.org/programs/public-health-preparedness/pphr
- Clinical Laboratory Improvement Amendments of 1988: https://www.cdc.gov/clia/law-regulations.html

2. **CDC Project Description**
   a. **Approach**

   I. **Purpose**
   The overarching purpose of this focus area is to improve quality and safety in PHLs national, state, territorial, and local levels. PHLs require consistent guidance for implementing quality and safety standards to ensure the quality of testing services and to promote safety in laboratories. The effectiveness of these standards, and guidance provided should be evaluated by the recipient to ensure improvements in public health and health outcomes. The recipient should encourage PHLs to establish collaborations and communicate results of evaluations to promote quality and safety best practices.

   II. **Outcomes**
   Activities in this focus area should achieve or contribute to the following proximal outcomes (PO) (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

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

   PO-9. Improved implementation of quality and safety systems and practices in public health laboratories

   PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders

   Activities in this focus area should achieve or contribute to the following intermediate outcomes (IO) (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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders

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

IO-7. Improved quality and safety in public health laboratories

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**

The recipient enhances laboratory quality and safety systems by supporting PHLs and clinical laboratories in regular and continual needs assessment, identifying laboratory quality and safety gaps, identifying laboratory quality and safety training needs aligned with laboratory competencies, fostering the development of future laboratory system leaders, improving access to a variety of quality and safety resources, and leading or contributing to other PHL system initiatives. Furthermore, the recipient works with partners to build the foundation for quality testing, comprehensive standards, and integrated public health laboratory systems.

Activities under this focus area should be guided by strategies in the following categories: Policy, Partnership, and Communication (S2) and Laboratory Quality, Safety, and Informatics for Public Health Testing Services, Surveillance and Response (S4). Specific training and workforce development activities are detailed in Appendix I: Workforce Development, of this NOFO.

S2. Policy, Partnership, and Communication

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

- Develop, maintain, and share educational and related resources for quality and safety systems improvements in collaboration with CDC and other relevant stakeholders.
- Promote active communication, coordination, and connectivity between public health and clinical laboratories, and other stakeholders in the laboratory system.
- Foster and support collaborations for sharing of best practices in laboratory quality and safety management among and between public health and clinical laboratories and other relevant stakeholders.

S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders

- Share information with public health and clinical laboratories, and relevant partners about the effectiveness of continual quality and safety improvement strategies.

S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders

- Promote quality and safety standards, guidelines, and good laboratory practices.

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

S4.2. Identify and address systems to improve the practice of laboratory quality and safety in public health laboratories

- Identify and address challenges and gaps in knowledge, understanding, and competencies regarding quality and safety standards, guidelines, and good laboratory practices.
- Facilitate consistent implementation of laboratory quality and safety management systems.
- Support evidence-based studies to characterize and mitigate both novel and known quality and safety issues of concern in the PHL and clinical laboratory settings.
- Evaluate implementation and impact of quality and safety standards, guidelines, and good laboratory practices for public health and clinical laboratories.

S4.3. Identify and address emerging methodological and process improvements in public health laboratories

- Develop tools and guidance that assist public health and clinical laboratories with implementation of laboratory quality management and safety systems for emerging technologies.

S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes

- Coordinate with CDC to provide technical assistance to public health and clinical laboratories related to compliance with CLIA regulations, other applicable quality standards, guidelines and quality management systems.
- Coordinate with CDC to provide technical assistance to public health and clinical laboratories related to safety and biosafety standards, guidelines and other applicable risk management systems.

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 each strategy in this focus area may include:

Strategy and Activity	Process Measure
S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, health care, and beyond	• Number of partnerships formed and partner organizations engaged to strengthen quality and safety systems within public health and clinical laboratories. • Number and types of quality and safety resources developed and/or shared with CDC and other relevant stakeholders.
S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders	• Number, frequency, and timeliness of recipient's efforts to support quality and safety information exchange and dissemination within and between laboratory and other stakeholder communities. • Scope of networks, partners, and collaborators engaged to facilitate quality and safety information exchange and dissemination.
S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders	• Number and types of resources related to quality and safety made available to public health and clinical laboratories and other relevant stakeholders.
S4.2. Identify an address systems to improve the practice of laboratory quality and safety in public health laboratories	• Number of quality and safety needs assessments completed by the recipient. • Number of challenges identified in interpretation and implementation of CLIA requirements by public health and clinical laboratories and other relevant stakeholders.

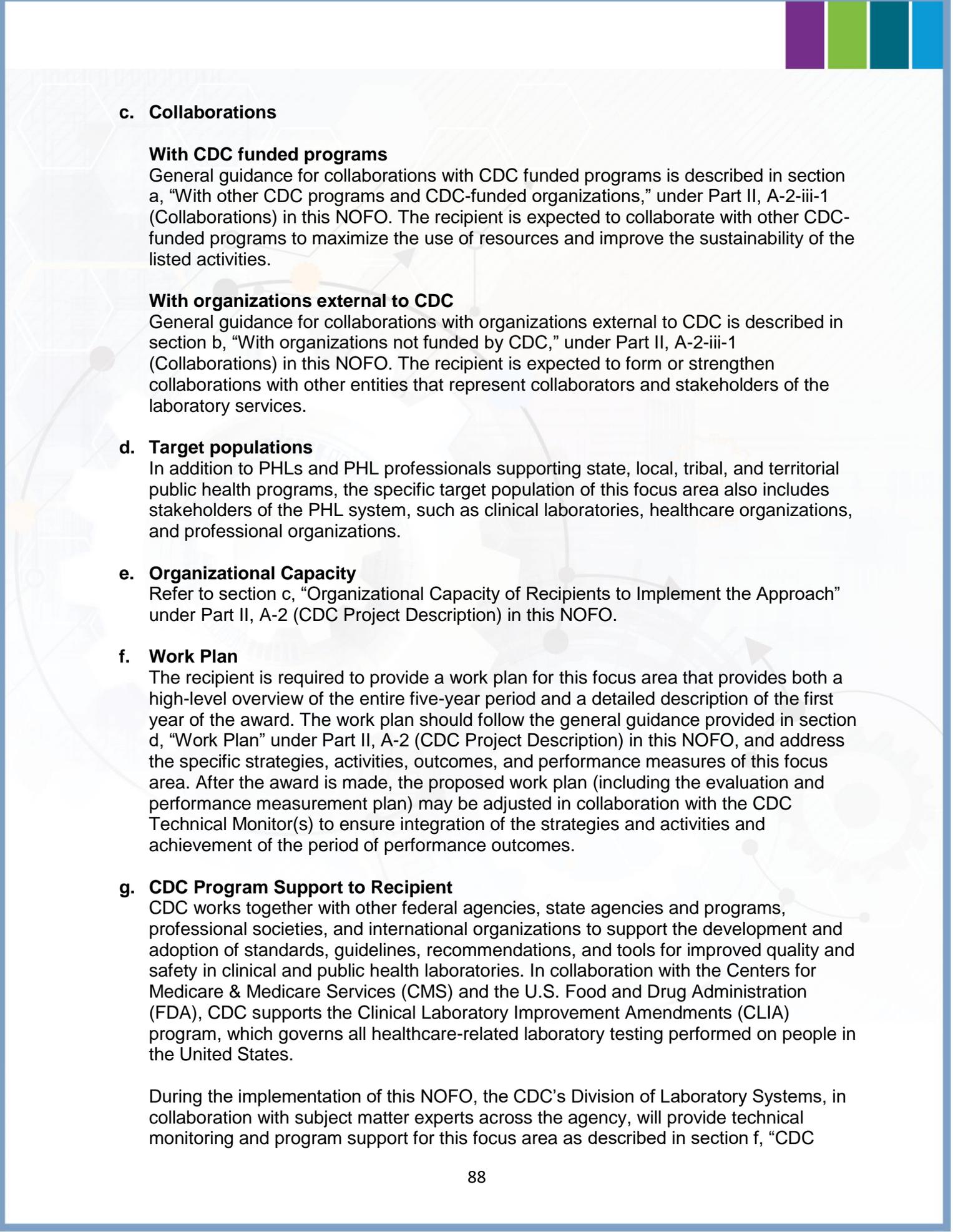|	• Number and types of resources developed to address challenges in interpretation and implementation of CLIA requirements. • Number and types of engagements with public health and clinical laboratory to identify safety gaps and needs. • Number and types of resources developed to address safety gaps and needs.
S4.3. Identify and address emerging methodological and process improvements in public health laboratories	• Number and type of methodological and process improvements related to quality and safety, made by public health and clinical laboratories and other relevant stakeholders.
S4.4. Provide technical assistance to state and local public health laboratories to support improvements in public health outcomes	• Number of times technical assistance related to quality and safety was provided to public health and clinical laboratories and other relevant stakeholders.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
PO-1. Improved collaboration and communication across public health laboratories and other stakeholders	• Number and scope of engagements of PHLs with CDC, clinical laboratories, professional organizations, and other stakeholders that advance mutual goals in both quality and safety. • Measurable increase in effective and efficient communication between public health and clinical laboratories to coordinate testing and reporting needed to support public health needs.
PO-7. Enhanced technical and non-technical knowledge, skills, and abilities among public health laboratory professionals in diverse settings	• Measurable increase in technical and non-technical knowledge, skills and abilities among PHL professionals. • Number and scope of PHLs' engagements with clinical laboratories to enhance technical and non-technical knowledge, skills and abilities among clinical laboratory professionals. • Measurable increase in PHLs that are meeting quality and safety standards for testing services, including those that require special controls and validation approaches for low frequency events (e.g., pathogens, environmental contaminants).
PO-9. Improved implementation of quality and safety systems and practices in public health laboratories	• Measurable increase in PHLs that are establishing quality and safety management systems.

	• Number of public health and clinical laboratories conducting quality and safety assessments • Type and scope of quality and safety systems and practices implemented in PHLs. • Number and type of system improvements related to quality and safety, made by public health and clinical laboratories and other relevant stakeholders.
PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders	• Number and scope of evidence-based practices (including publications, presentations, etc.) disseminated supporting laboratory quality and safety.
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders	• Number and scope PHLs engagements with clinical laboratories that advance quality and safety systems and practices. • Number of shared resources. • Number of relevant communities of practice. • Number of members of relevant communities of practice.
IO-4. Enhanced practices, methods, technical capabilities, and infrastructure within the public health laboratory system	• Measured increase in enhanced practices, methods technical capabilities, and infrastructure within the PHL system for both: quality and safety. • Number of laboratories that have adopted a comprehensive risk management approach to laboratory safety.
IO-7. Improved quality and safety in public health laboratories	• Percent of PHLs that have adopted QMS, safety systems based on accepted standards and guidelines at state, territorial, tribal, and local levels. • Measured increased number of quality and safety internal audits in state, territorial, and local PHLs. • Measured decrease of incidents and accidents in laboratories. • Measured decreased number of quality and/or safety deficiencies.

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 collaborate with other CDC-funded programs to maximize the use of resources and improve the sustainability of the listed activities.

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 expected to form or strengthen collaborations with other entities that represent collaborators and stakeholders of the laboratory services.

d. Target populations

In addition to PHLs and PHL professionals 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 clinical laboratories, healthcare organizations, and professional organizations.

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 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 works together with other federal agencies, state agencies and programs, professional societies, and international organizations to support the development and adoption of standards, guidelines, recommendations, and tools for improved quality and safety in clinical and public health laboratories. In collaboration with the Centers for Medicare & Medicare Services (CMS) and the U.S. Food and Drug Administration (FDA), CDC supports the Clinical Laboratory Improvement Amendments (CLIA) program, which governs all healthcare-related laboratory testing performed on people in the United States.

During the implementation of this NOFO, the CDC's Division of Laboratory Systems, in collaboration with subject matter experts across the agency, will provide technical monitoring and program support 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.

Appendix I: Workforce Development

Focus Area Name
Workforce Development

Focus Area Contact Information
Yescenia Wilkins, exq6@cdc.gov
Renee Ned-Sykes, rin1@cdc.gov
Kelly Winter, yec4@cdc.gov

Approximate Average Annual Award: $2,000,000

Funding Opportunity Description

1. **Background**
   The public health system is dependent on competent, prepared, and sustainable public health laboratory (PHL) and clinical laboratory workforces. However, these workforces are aging rapidly and face numerous challenges in the recruitment and retention of qualified personnel, creating skill and capacity gaps that extend from the laboratory bench to management and leadership positions. These gaps have affected the ability of laboratories to provide the critical public health services expected of them and threaten the future of the PHL system in the United States. Current laboratory professionals need effective training to address established and emerging needs. New technologies continue to replace or supplement existing testing procedures, emphasizing the need for laboratory professionals to stay current with the newest standards and technologies. In addition, emerging and re-emerging health threats require PHLs to strengthen their capacity to respond effectively.

   To maintain the critical services that PHLs provide, multi-tiered workforce development strategies are needed to strengthen the competence and engagement of the PHL workforce. Any training and workforce development resources created must be data-driven in order to be directly and immediately relevant to the priorities and needs of the PHL workforce. Only then will successful transfer of knowledge occur in real-life settings to create necessary change and help strengthen the laboratory workforce.

   Healthy People 2020
   This focus area supports the following Healthy People 2020 objectives:

   Public Health Infrastructure, Objective 11: Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential 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
   - HHS Strategic Plan, 2018—2022: https://www.hhs.gov/about/strategic-plan/index.html

2. CDC Project Description
a. Approach

I. Purpose
The Workforce Development (WD) focus area is intended to strengthen the competence and engagement of the public health and clinical laboratory workforce. The multi-tiered WD approach (Figure A) broadly depicts the recipient's roles and responsibilities at each tier and provides a common approach to all WD programs, products, resources, and events in this cooperative agreement. The recipient will implement a data-driven WD portfolio (Figure B), with a special emphasis on foundational needs such as basic laboratory skills, informatics, quality and safety, regulations, and leadership.

Figure A: Workforce Development: A Multi-Tiered Approach for Recipient Strategies and Activities
(Collaborate with CDC on identifying all programs, products, resources, and events)

AD HOC
Just-in-time trainings for emergency responses or other sensitive situations

Population Level

Individual Level

Training of Trainers — Create and maintain Train the Trainer programs
Effective training for adult learners, BT, packaging & shipping, etc.

ROLE-SPECIFIC — Implement programs and committees, design and develop training, and enlist pilot testers
Role-specific programs and resources for current/future leaders, mentors, etc.

TOPIC-SPECIFIC — Administer fellowships; recruit pilot testers; enlist SMEs and/or provide content as needed
Described in Appendices B-D, F (e.g., NB screening, infectious diseases, environmental health, etc.)

REGULATORY — Recruit pilot testers and enlist SMEs and/or provide content as needed
CLIA, packaging & shipping, biothreat rule-out-or-refer, etc.

FOUNDATIONAL — Design and develop training, recruit pilot testers
Basic laboratory skills, quality and safety, informatics, preparedness, etc.

All workforce development resources are informed by competency guidelines

**Figure B: Data-driven Decision Process
for Workforce Development (WD) Programs & Activities**
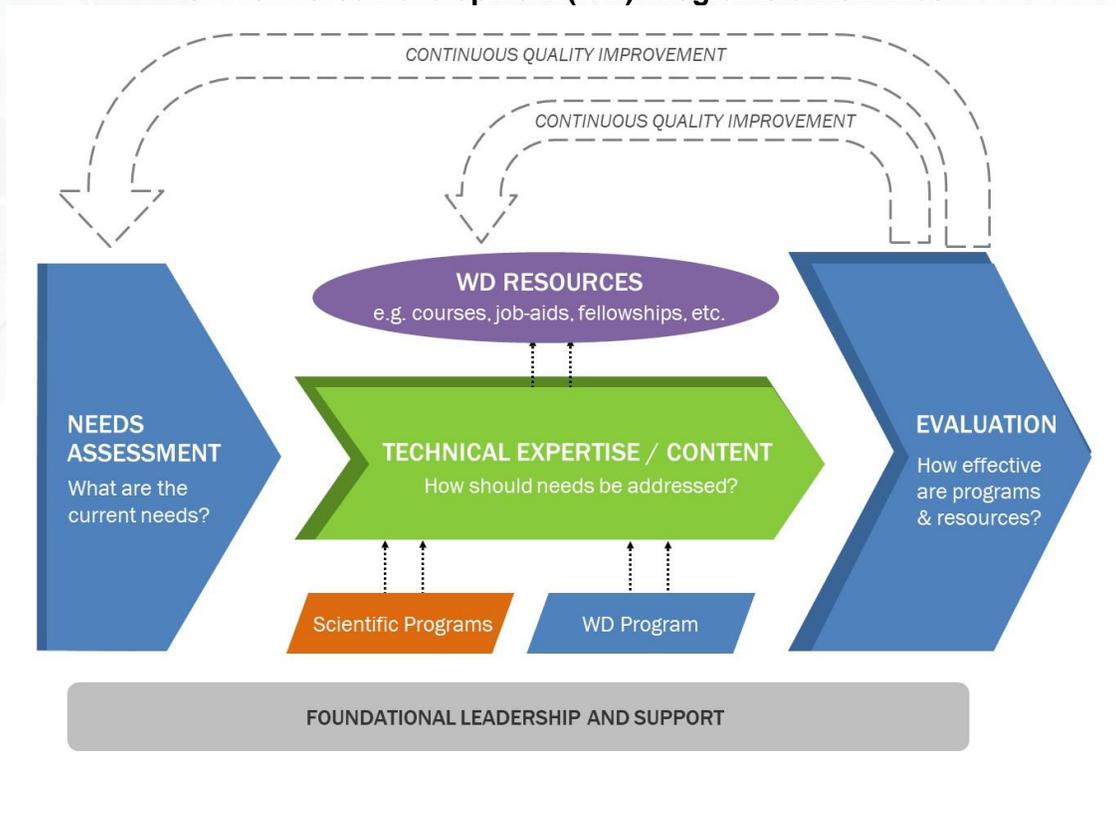
II. Outcomes

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-4. Improved awareness of new tools and resources for public health laboratories and other stakeholders

PO-5. Improved awareness and understanding of public health laboratory workforce development needs and opportunities

PO-6. Improved access to training opportunities among laboratory professionals

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

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-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders

IO-3. Improved competence and engagement of public health laboratory workforce

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

The recipient enhances laboratory workforce development by supporting its members in the recruitment, development, and retention of the next generation of laboratory professionals; providing laboratory training aligned with laboratory competencies; fostering the development of future laboratory system leaders; and improving access to a variety of learning resources. Activities in this focus area are expected to reinforce and further CDC efforts to enhance knowledge, skills, and abilities among laboratory professionals in diverse settings. While other focus areas in this cooperative agreement may include training and workforce development activities, the WD focus area intends for the recipient to implement a variety of training and workforce development programs, products, resources, and events with a special emphasis on foundational needs such as basic laboratory skills, informatics, quality and safety, and regulations. All workforce development resources across the cooperative agreement are expected to be informed by competency guidelines and be data-driven. All training-specific resources are expected to follow the CDC Quality Training Standards.

The recipient is not permitted to charge fees for any training and workforce development programs, products, resources, or events developed as part of this cooperative agreement.

Activities under this focus area should be guided by the Training and Capacity Building strategies (S3):

S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings
- Identify training and workforce development needs by conducting regular needs assessments on a schedule determined in collaboration with CDC.
- Generate and communicate reports on results of needs assessments and recommendations to address identified training and workforce development needs.
- Develop training plans and/or modify existing ones to reflect current needs, with emphasis on basic laboratory skills, informatics, quality and safety, and regulatory topic areas.
  - Training plans should include recommendations for training products to be developed, updated, or retired and which organization should have primary responsibility (i.e., CDC, recipient, or CDC and recipient collaboratively).
  - Collaborate with CDC and the recipient's other scientific programs to determine yearly training calendars and promotion/distribution plans as needed.
- Coordinate across the recipient's individual scientific programs and evaluation program to use needs assessment results to inform the development and delivery of training and workforce development resources for PHL staff and leadership.

S3.2. Implement leadership development programs
- Support the next generation of laboratory leaders by conducting programs that build leadership and management competencies, facilitate networking opportunities, and provide development opportunities for emerging and current leaders.
- Develop and distribute tools and resources to support leadership development in the PHL community.

S3.3. Facilitate the development and delivery of training and workforce development resources
- Coordinate with the recipient's evaluation program and other scientific programs to
  - Apply best practices to all training and workforce development programs, products, resources, and events (e.g., CDC Quality Training Standards and Laboratory Competencies), and findings from needs assessments.
  - Monitor and evaluate the effectiveness of training and workforce development programs, products, resources, and events regularly and consistently.
- Provide instructional design expertise for the design, development, and delivery of training and workforce development programs, products, resources, and events.
- Collaborate with CDC to review training and workforce development programs, products, resources, and events.
- Provide technical assistance to laboratory training partners to develop and disseminate their own PHL education and training activities.
- Provide opportunities for laboratory training partners to share knowledge, build skills, and enhance collaboration.
- Foster communities of practice to advance the development of strategies, programs, and activities that address identified training and workforce development needs and challenges.
- Collaborate with CDC to hold joint biennial conferences for laboratory training partners to
  - Share CDC and recipient guidance and best practices for training and workforce development.
  - Deliver training on critical topics as identified by needs assessments.
  - Improve awareness and access to CDC and recipient programs, products, resources, and events.
  - Foster an environment for networking and sharing of lessons learned.
- Develop and implement a communication plan for established communities of practice and to reach target audiences.
- Create and implement innovative solutions for the recruitment and retention of PHL scientists to increase the pipeline of PHL leaders, managers, and scientists.
- Provide programs and resources that support new laboratory directors:

- o Provide ongoing training and support through the design and delivery of a curriculum, in collaboration with CDC, that 1) helps familiarize new laboratory directors to CDC's and the recipient's mission, programs, priorities, and resources, and 2) helps equip new directors with knowledge and skills useful to their positions. Curriculum is to be administered over the course of multiple didactic sessions (e.g., an in-person orientation and follow-up virtual sessions).
  - o Develop and disseminate resources and programs (e.g., skill building activities; mentoring program) to support new laboratory directors.
  - o Coordinate and facilitate a community of practice for new and existing laboratory directors.
- Provide fellowship program administration and develop a strategy for continuous improvement. (Note: The listed sub-activities relate only to the administration of fellowship programs. Funding support for fellows, as well as program-specific monitoring and evaluation activities and metrics, are included in the respective Appendices of this NOFO.)
  - o Conduct program administration including, but not limited to, recruitment, fellow and host laboratory selection, onboarding, and tracking progress of the fellows.
  - o Coordinate with the recipient's other scientific programs and evaluation program on cross-cutting and program-specific data generation to contribute to fellowship program monitoring and evaluation activities.
    - Monitor and evaluate the administration of the fellowship programs in terms of efficiency and quality of the recruiting, matching, and onboarding processes.
    - Monitor and evaluate the fellowship programs in terms of common metrics (across programs) related to fellow and host laboratory satisfaction, quality of the fellowship experience, and effectiveness as a recruitment and training tool.
  - o Generate and implement recommendations to improve fellowship program administration based on monitoring and evaluation findings.
- Provide management and logistical support for training and workforce development offerings.
- Increase access to and awareness of available CDC and CDC/Recipient training and workforce development opportunities among target audiences.
- Enlist subject matter experts, and recruit pilot testers for CDC and CDC/Recipient training and workforce development resources.
- In Year 1, develop a Continuity of Operations Plan (COOP) for training and workforce development programs and activities to prepare for public health emergencies.
- Facilitate just-in-time training during time-sensitive situations (e.g., public health emergency responses) by quickly mobilizing resources, providing logistical support, and communicating with target audiences.

- Develop promotion and distribution plans for training and workforce development programs, products, resources, and events tailored to target audiences with the goal of increasing reach.
  - Training and workforce development products and resources developed in support of this cooperative agreement should be made publicly available as determined by CDC and the recipient.
- Monitor the uptake and implementation of laboratory competency guidelines among PHL audiences and identify ways to support further adoption.
- Facilitate the application of laboratory competency guidelines through practical workshops and developing guidance and other resources.
- Engage subject matter experts (SMEs) to consider and contribute to revision of laboratory competency guidelines.
- As determined by training plans based on identified needs and priorities set each year in collaboration with CDC:
  - Deliver packaging and shipping seminars and other training products, resources, and events, such as webinars or hands-on workshops.
  - Provide live and on-demand, technical and non-technical training events (e.g., basic laboratory skills, informatics, quality and safety, and regulatory topic areas).
- Develop curriculum frameworks as needed in collaboration with CDC (e.g., informatics curriculum).
- Award continuing education, including, but not limited to Professional Acknowledgement for Continuing Education (PACE) for training courses and events.
- Post on the websites of the recipient, CDC, or both, all electronic versions of products developed in support of this cooperative agreement and ensure Section-508 compliance. The following Section-508 website provides comprehensive information: www.section508.gov.

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 and activities in this focus area may include:

Strategy and Activity	Process Measure
S3.1. Identify training and workforce development needs among laboratory professionals in diverse settings	- Number of participants in needs assessments. - Response rate for needs assessments (Percent of invitees who responded) – which

	is an indicator of a well-defined target audience and quality of survey design. • Number of prioritized needs based on results from needs assessments. • Number of recommendations to address identified needs. • Proportion of needs assessment participants who represent key laboratory workforce subgroups (e.g., retiring within 5 years, Millennials, laboratory directors/leadership).
S3.2. Implement leadership development programs	• Number of tools and resources developed to support leadership development in the PHL community. • Number of laboratory professionals who access leadership development programs and resources. • Proportion of participants who complete leadership programs.
S3.3. Facilitate the development and delivery of training and workforce development resources	• Number of relevant committees (e.g., workforce development committee). • Proportion of action items completed by relevant committees. • Number of training and workforce development resources facilitated and/or delivered. • Number of trainings for which pilot testers were recruited. • Number of training and workforce development resources for which SMEs were enlisted or content was provided.

Outcome measures for this focus area may include:

Outcome	Outcome Measure
PO-4. Improved awareness of new tools and resources for public health laboratories and other stakeholders	• Number of laboratory professionals who access new tools and resources. • Number of annual visits to the recipient's training webpage. • Number of subscribers to email distribution lists.
PO-5. Improved awareness and understanding of public health laboratory workforce development needs and opportunities	• Proportion of learners who self-report that training and workforce development resources are relevant.

PO-6. Improved access to training opportunities among laboratory professionals	• Number of participants who access training and workforce development opportunities.
PO-7. Enhanced technical and non-technical knowledge, skills, and abilities among public health laboratory professionals in diverse settings	• Proportion of learners who self-report knowledge gain. • Proportion of learners with a knowledge gain of ≥10% (post-test vs. pre-test). • Proportion of learners who score ≥80% on post-tests. • Proportion of learners who self-report high level of satisfaction with training and workforce development resources and programs.
IO-1. Established communities of practice and other collaborative relationships among and between laboratories and other stakeholders	• Number of relevant communities of practice (e.g., training partners group). • Number of members of relevant communities of practice.
IO-3. Improved competence and engagement of public health laboratory workforce	• Proportion of laboratory professionals who self-report that training and workforce development resources are engaging. • Proportion of learners who self-report that they intend to apply knowledge gained through training and workforce development resources. • Proportion of learners who self-report that they applied knowledge gained through training and workforce development resources.

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 collaborate with other CDC-funded programs to maximize the use of resources and improve the sustainability of the listed activities.

While this focus area will concentrate on the stated strategies and activities with emphasis on foundational needs such as basic laboratory skills, informatics, quality and safety, and regulations, the recipient is also expected to maintain coordination and awareness of training and workforce development priorities and strategies in the other focus areas of this cooperative agreement. These other focus areas include Environmental Health; Newborn Screening and Genetics; Infectious Diseases; Foodborne, Waterborne, and Environmentally Transmitted Diseases; and Preparedness and Response.

CDC will collaborate across its many internal programs involved in this cooperative agreement to maintain general awareness of training and workforce development priorities, needs, and activities.

Competency-based training programs integrate demonstrated ability to identify and prioritize problems, choose the appropriate skills, apply them, and produce useful output in the context of a service providing organization. Competency-based training helps PHL professionals achieve successful performance in a structured approach involving on the job supervision, mentorship, and evaluation. While it may not be feasible for all workforce development programs, products, resources, and events created in support of this cooperative agreement to be competency-based, all workforce development programs, products, and activities must be based on decisions resulting from needs assessment and evaluation data.

Regular needs assessments, current technical expertise/content, and consistent evaluation are necessary in order to deliver relevant and high-quality workforce development programs, products, resources, and events. Figure B depicts the data-driven decision process expected of the recipient to support consistent quality across all workforce development programs and activities while accommodating specific scientific program needs.

**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 expected to provide leadership for enhancing existing and developing new strategic partnerships that best suit the needs of the nation's PHL system, at state, territorial, tribal, and local levels. Recipient is encouraged to explore opportunities for new collaborations with additional partners to advance public health priorities.

d. **Target populations**
The primary target populations are PHLs and PHL professionals that support state, local, tribal, and territorial public health programs. Secondary target populations include stakeholders of the PHL system, such as clinical laboratories, clinical laboratory professionals, policy makers, healthcare organizations, and laboratory 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.
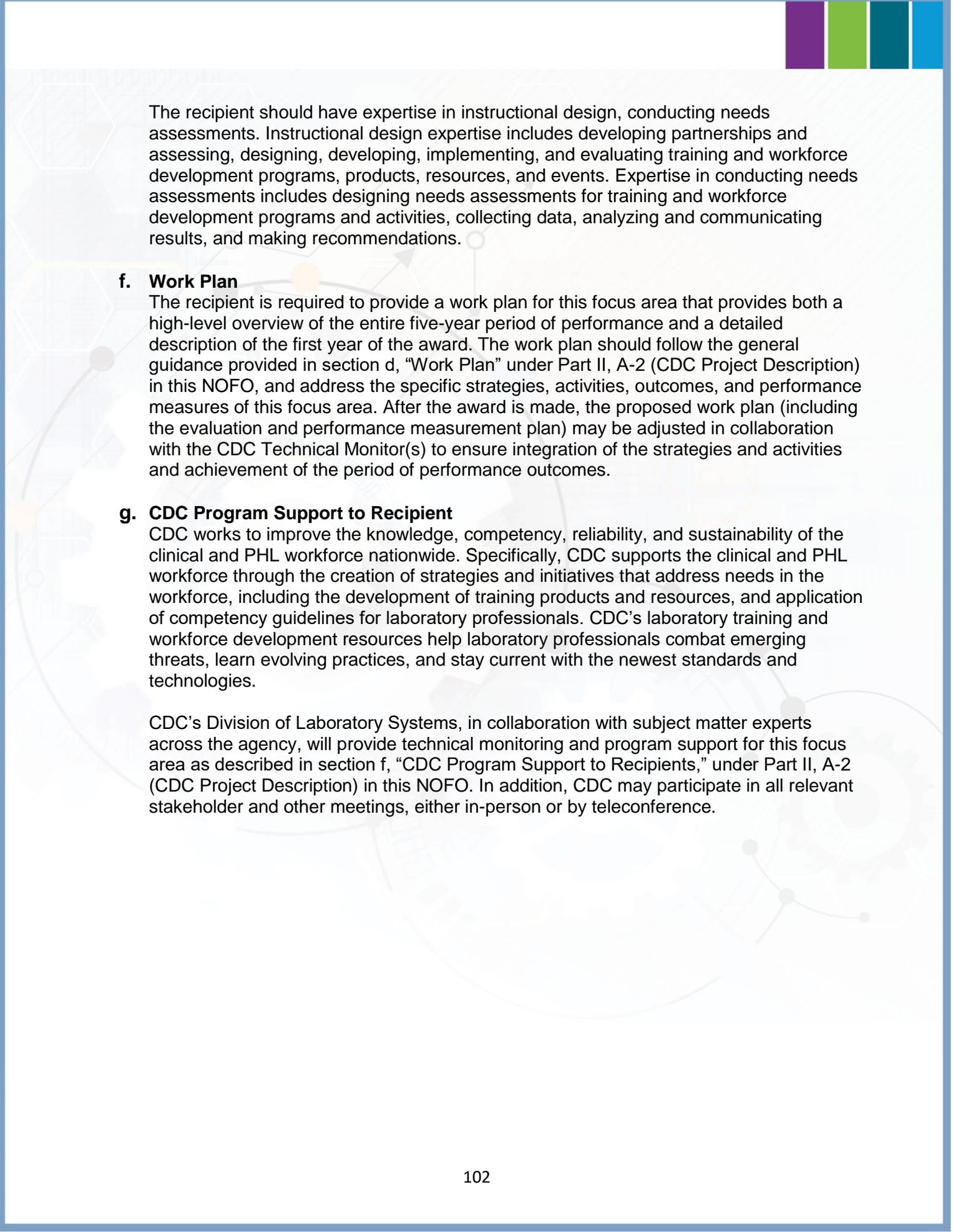
The recipient should have expertise in instructional design, conducting needs assessments. Instructional design expertise includes developing partnerships and assessing, designing, developing, implementing, and evaluating training and workforce development programs, products, resources, and events. Expertise in conducting needs assessments includes designing needs assessments for training and workforce development programs and activities, collecting data, analyzing and communicating results, and making recommendations.

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 works to improve the knowledge, competency, reliability, and sustainability of the clinical and PHL workforce nationwide. Specifically, CDC supports the clinical and PHL workforce through the creation of strategies and initiatives that address needs in the workforce, including the development of training products and resources, and application of competency guidelines for laboratory professionals. CDC's laboratory training and workforce development resources help laboratory professionals combat emerging threats, learn evolving practices, and stay current with the newest standards and technologies.

CDC's Division of Laboratory Systems, in collaboration with subject matter experts across the agency, will provide technical monitoring and program support 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.