

Appendix H: Quality and Safety Systems

Focus Area Name

Quality and Safety Systems

Focus Area Contact Information

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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 (GHS) <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 |
|---|---|
| <p>S2.2. Collaborate and build relationships among laboratory professionals and other stakeholders in public health, health care, and beyond</p> | <ul style="list-style-type: none"> • 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. |
| <p>S2.3. Facilitate information exchange and dissemination among practitioners and other stakeholders</p> | <ul style="list-style-type: none"> • 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. |
| <p>S2.5. Promote and provide information about the tools and resources available to public health laboratories and other stakeholders</p> | <ul style="list-style-type: none"> • Number and types of resources related to quality and safety made available to public health and clinical laboratories and other relevant stakeholders. |
| <p>S4.2. Identify an address systems to improve the practice of laboratory quality and safety in public health laboratories</p> | <ul style="list-style-type: none"> • 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. |



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| | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Measurable increase in PHLs that are establishing quality and safety management systems. |



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| | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 & Medicaid 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.

