

Public Health Emergency Preparedness (PHEP) Budget Period 4: Supplemental Guidance and Resources

January 2022

Domain 6: Requirements for Laboratory Response Network for Biological Threats

Overview

In Budget Period 4, standard and advanced biological reference laboratories must continue to meet minimum requirements to maintain Laboratory Response Network-Biological (LRN-B) network membership. Some standard reference laboratories must also ensure testing coverage within 24 hours for designated high priority areas (HPAs). HPAs are high-threat, high-density urban areas loosely indexed to the Homeland Security Grant Program Urban Areas Security Initiative. Of the approximately 130 LRN-B laboratories, there are currently 53 state public health laboratories (50 states and the directly funded localities of Los Angeles County, New York City, and Washington D.C.) that participate in the LRN-B network and are supported by the PHEP cooperative agreement.

Standard reference laboratories must meet LRN-B standard reference laboratory requirements as stated in the Standard Laboratory Checklist. Advanced reference laboratories must meet standard laboratory requirements plus additional requirements, such as maintaining registration in the Federal Select Agent Program. They must also provide support for the LRN program for specific activities, including assay development, multicenter validation studies, and performance of technically advanced assays.

Programmatic Requirements

Per the 2019-2024 PHEP notice of funding opportunity (NOFO), PHEP recipients are required to work with public health laboratory staff to ensure adherence to the LRN-B requirements and to maintain the tools and resources necessary for LRN-B participation. At a minimum, recipients are required to work with laboratory staff to complete the following activities.

- Meet benchmarks for LRN-B Challenge Panel (CP) Program
- Maintain staffing and equipment requirements
- Meet or sustain standard reference laboratory requirements
- Meet or sustain advanced reference laboratory requirements, if applicable
- Successfully pass annual 24/7 emergency contact drills
- Attend national meetings
- Ensure national coverage
- Maintain partnerships
- Maintain communication with sentinel laboratories

In Budget Period 2, recipients also had to meet a new LRN-B requirement that advanced and standard laboratories obtain and sustain maintenance agreements for LRN-B equipment valued at more than \$25,000 and for LRN-B equipment that is used for assays cleared by the Food and Drug Administration.

CDC clarified these requirements for Budget Period 3, specifying that these maintenance agreements apply only to LRN-B equipment valued at more than \$25,000 or used for FDA 510(k) cleared assays only.

Meeting the requirements set forth in the PHEP NOFO and in the subsequent continuation guidance will help jurisdictions strengthen their biosurveillance capacity. Specific details regarding the requirements are found within the [2019-2024 PHEP NOFO](#).

If a High Priority Area (HPA) is contained in the jurisdiction, the PHEP-funded laboratory must ensure ability to receive and test samples as well as report results within 24 hours for that HPA. If a jurisdiction has a high-population area that is not included on the HPA list, it is a best practice for the jurisdictional LRN-B laboratory to have the ability to expeditiously transport, test, and report threat samples for that area within 24 hours.

State/Territory	High Priority Area (HPA)
Arizona	Phoenix Area
California	Anaheim/Santa Ana Area
	Bay Area
	Los Angeles/Long Beach Area
	San Diego Area
Colorado	Denver Area
District of Columbia	National Capital Region
Florida	Miami/Fort Lauderdale Area
	Tampa Area
Georgia	Atlanta Area
Illinois	Chicago Area
Maryland	Baltimore Area
Massachusetts	Boston Area
Michigan	Detroit Area
Minnesota	Twin Cities Area
Missouri	St. Louis Area
Nevada	Las Vegas Area
New York	New York City Area
New Jersey	Jersey City/Newark Area
North Carolina	Charlotte Area
Pennsylvania	Philadelphia Area
Texas	Dallas/Fort Worth/Arlington Area
	Houston Area
Washington	Seattle Area

Funding Strategy

PHEP recipients can use PHEP funding to support LRN-B personnel, supplies, equipment (including service and maintenance contracts), travel, and other contracts. Because recipients receive substantial assistance from CDC through other programs, recipients should ensure that requested line items are funded under the appropriate program. The following are examples of items that are not typically funded under the PHEP cooperative agreement.

- Instruments, reagents, and supplies for testing for COVID-19;
- Instruments, reagents, and supplies for testing seasonal influenza;
- Instruments, reagents, and supplies for testing rabies;
- Instruments, reagents, and supplies for routine food testing (surveillance);
- Instruments, reagents, and supplies for testing vaccine-preventable diseases including measles and mumps;
- Instruments, reagents, and supplies for routine testing of vector-borne illnesses (both clinical and vector surveillance);
- Routine drug screening of laboratory staff; and
- Influenza vaccines for the general public.



Resources for Strengthening Domain 6

Title	Description	Location
LRN-B Website	The Laboratory Response Network Partners in Preparedness	https://emergency.cdc.gov/lrn/index.asp
APHL Website	Laboratory Response Network	https://www.aphl.org/programs/preparedness/Pages/LRN.aspx

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