

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

January 2022

Domain 6: Requirements for Laboratory Response Network for Chemical Threats

Overview

The Laboratory Response Network for Chemical Threats (LRN-C) is a national network of local and state public health laboratories with capabilities for responding to chemical terrorism and other public health emergencies. LRN-C laboratories provide critical CDC surge capacity as well as local response capabilities within their respective jurisdictions. There are currently 54 LRN-C laboratories located in all 50 states, three localities (Los Angeles County, New York City, and Washington D.C.), and one U.S. territory (Puerto Rico). All LRN-C laboratories have the capacity to monitor chemical exposures at their onset, assist local hospitals and first responders with sample accessioning, packing, and shipping to other network laboratories, and serve as CDC sentinel sites for large chemical emergencies.

The purpose of this document is to summarize the cumulative set of LRN-C program requirements, inclusive of the PHEP NOFO and the subsequent continuation guidance documents for Budget Periods 2, 3 and 4.

Program Requirements

Per the 2019-2024 PHEP notice of funding opportunity (NOFO), PHEP recipients must ensure that their chemical threat laboratory meets the following program requirements and PAHPRA benchmarks:

- Meet LRN-C membership requirements according to Level 1, 2 or 3 designation.
- Meet PHEP program benchmarks for LRN-C exercises and proficiency testing.

Membership Requirements for Level 1, Level 2, and Level 3 LRN-C Labs

CDC has identified “core” and “additional” LRN-C methods for detecting human exposures to a wide range of known chemical threat agents. LRN-C laboratories are designated as either Level 1, Level 2, or Level 3 based on their respective capacity and capabilities to perform these LRN-C methods.

- Level 1 LRN-C laboratories represent the most advanced level and must meet all requirements of Level 2 and Level 3 laboratories, as well as testing capabilities for high-threat chemical exposures, including all LRN-C additional methods.
- Level 2 LRN-C laboratories must meet Level 3 requirements, in addition to nine LRN-C core methods using gas chromatography-mass spectrometry (GC/MS), high performance liquid chromatography-mass spectrometry (LC/MS), and inductively coupled plasma-mass spectrometry (ICP-MS) instrumentation.
- Level 3 LRN-C laboratories must ensure local support with sample logistics as well as training and outreach with local hospitals. All LRN-C laboratories must maintain Level 3 capabilities.

PHEP recipients must ensure that their chemical threat laboratories meet the following corresponding LRN-C membership requirements for Level 1, Level 2, or Level 3 laboratories.

LRN-C Level 3 Membership Requirements

- **NEW for all LRN-C Labs:** Complete chemical threat response reporting each budget period. See [LRN-C Secure Website](#).
- Ensure that at least one LRN-C laboratory within their jurisdiction successfully completes an LRN-C specimen packaging, and shipping (SPaS) exercise each budget period. (see *LRN-C Membership requirements*)
- Successfully complete the annual 24/7 emergency contact drill.



- Submit a signed LRN-C confidentiality agreement for all chemical threat program staff.
- Maintain sample collection and shipping supplies for a minimum of 500 patient samples.
- Participate in annual response coordination exercises with local preparedness partners.
- Conduct sample packaging and shipping training and outreach with local hospitals and poison control centers.
- Establish written protocols to coordinate with hospitals, first responders (police, fire, hazardous materials teams), and civil support teams.
- Attend monthly LRN-C conference calls administered by the CDC LRN-C technical program.
- Ensure at least one laboratory member maintains a working digital certificate for access to CDC electronic results reporting systems.
- Maintain Clinical Laboratory Improvement Amendments (CLIA) certification.

LRN-C Level 2 Membership Requirements

- Meet all LRN-C Level 3 requirements.
- **NEW** Maintain LRN-C “Qualified” status for all LRN-C core methods. See [LRN-C Secure Website](#).
- Participate in all LRN-C equipment replacement activities.
- Obtain and sustain current maintenance agreements for all LRN-C equipment assets valued at more than \$25,000.
- Maintain subscriptions to the LRN-C Materials and Proficiency Testing programs for all qualified core and additional methods.
- Maintain response materials and instrument consumables for the analysis of at least 250 patient samples for each qualified LRN-C method.
- Successfully participate in all LRN-C emergency response exercises.
- Maintain secured data messaging and laboratory information management system (LIMS) capabilities

LRN-C Level 1 Membership Requirements

- Meet all LRN-C Level 3 and Level 2 requirements.
- Maintain LRN-C “Qualified” status for all LRN-C additional methods. [See LRN-C Secure Website](#).
- Maintain response materials and instrument consumables for the analysis of at least 1,000 patient samples for each qualified analysis method.
- Ensure equipment redundancy for all gas chromatography-mass spectrometry (GC/MS), high performance liquid chromatography (LC/MS), and inductively coupled plasma mass spectrometry (ICP-MS) equipment platforms.
- Maintain high throughput equipment capabilities such as 1) LC/MS automated injectors for all LRN-C core and additional methods; and 2) automated liquid handling workstation for both 96-well plate and cartridge capabilities.

Supplemental LRN-C Activity Beginning in Budget Period 4: New Technology Transfer Support Services

To sustain and maintain the ongoing work of the LRN-C, the PHEP program will fund additional technology transfer support services in Budget Period 4. CDC will partner with four LRN-C laboratories to provide technology transfer support for all 54 LRN-C member laboratories.

Per funding availability, this supplemental activity is planned as a four-year effort involving four LRN-C laboratories each year. The purpose of this funding is to increase LRN-C testing capabilities by the technology transfer of several new and updated LRN-C test methods. The LRN-C Technology Transfer Support Services initiative will include LRN-C method technical assistance, LRN-C Materials Program quality assessments, and chemical threat method validation studies for newly developed CDC methods.

The purpose of this funding is to increase the nation’s overall LRN-C testing capabilities by a technology transfer of

several new and updated LRN-C test methods. This will enable state laboratories to contribute to the national capability and support fellow LRN-C labs.

For Budget Period 4, the following LRN-C laboratories will each receive \$250,000 for the provision of LRN-C technology transfer support.

Georgia Public Health Laboratory will evaluate the accuracy and stability of quality control and internal standard lots for the LRN-C Materials Program. This support will ensure that network laboratories continue to have timely access to reagents and materials that are critical to optimal testing performance.

Alaska Public Health Laboratory will update the LRN-C volatile organic compounds in blood (VOC) method to include toxic alcohols. This updated LRN-C method will introduce new capabilities for detecting exposures to toxic alcohols which have been a growing health concern in recent years.

New York State Department of Health, Wadsworth Center, will provide hands-on training and technical assistance support for the LRN-C toxic element screen in urine and mercury in urine methods. This support will ensure network operational readiness to respond to toxic metals exposures in humans.

Minnesota Department of Health will provide method validation support for new high resolution mass spectrometry (HRMS) capabilities and expanded testing capacity for environmental samples to CDC partners upon request. New HRMS and environmental testing capabilities will substantially increase the LRN-C's testing capacity for chemical threat agents.

In subsequent years, other LRN-C laboratories may also be selected to support this initiative.

Laboratory Response Network (LRN) Resources

Title	Description	Location
LRN-C Website (Public)	General overview of the Laboratory Response Network for Chemical Threats	https://emergency.cdc.gov/lrn/chemical.asp
LRN-C Level 3 Resource Handbook	Level 3 training and outreach	https://sams.cdc.gov/samsportal/default.aspx
National Response Plans	Department of Homeland Security guidance on developing emergency response coordination plans	https://irp.fas.org/agency/dhs/nrp.pdf

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