Public Health Emergency Preparedness (PHEP) Budget Period 2 – Supplemental Guidance and Resources

Domain 6: Requirements for Laboratory Response Network for Chemical Threats

January 2020

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, pack and ship to other network laboratories, and serve as a CDC sentinel site for large chemical emergencies.

CDC has identified nine core methods and four additional methods for detecting and measuring a diverse range of chemical threat agents in clinical samples. Participating LRN-C laboratories are designated as either Level 1, Level 2, or Level 3. PHEP recipients must work with public health laboratory staff to ensure adherence to the LRN-C requirements and maintain the tools and resources necessary for LRN-C participation.

Programmatic Requirements

Per the 2019-2024 PHEP notice of funding opportunity (NOFO), PHEP recipients must work with public health laboratory staff to ensure adherence to the following LRN-C requirements.

- Meet PHEP program benchmarks for LRN-C exercising and proficiency testing.
- Meet LRN-C basic membership requirements.
- Increase secured data messaging and laboratory information management system (LIMS) capabilities, for both LRN-C Level 1 and LRN-C Level 2 laboratories
- Take part in chemical threat program response reporting.
- Successfully complete the annual 24/7 emergency contact drill.
- Participate in LRN-C equipment replacement for both LRN-C Level 1 and LRN-C Level 2 laboratories.

In Budget Period 2, recipients must adhere to the following new LRN-C requirements.

- LRN-B advanced and standard labs are required to 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. This is a new requirement for LRN-B laboratories.
- LRN-C Level 1 labs are required to obtain and sustain maintenance agreements for LRN-C equipment valued at more than \$25,000. This adds the requirement for "sustaining" such



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- agreements. Previously the PHEP NOFO called only for "obtaining" such agreements. Also, this amends the amount from \$10,000 to \$25,000.
- LRN-C Level 2 labs are required to obtain and sustain maintenance agreements for LRN-C equipment valued at more than \$25,000. This is a new requirement for LRN-C Level 2 laboratories.

These maintenance agreement changes help to ensure that preparedness investments are sustained over time. Maintenance must be performed by the manufacturer or a company certified by the manufacturer to perform the maintenance. Recipients must meet these requirements by the end of Budget Period 2 (June 30, 2021) and will be expected to verify compliance with these requirements through the Operational Readiness Review process beginning in Budget Period 3 (July 1, 2021).

LRN-C Membership Requirements

LRN-C Level 3 Membership Requirements

- Submit a signed LRN-C confidentiality agreement for all chemical threat program staff.
- Stock sample collection and shipping supplies for a minimum of 500 patient samples.
- Participate successfully in at least one LRN-C sample packaging and shipping (SPAS) exercise per budget period.
- Conduct sample packaging and shipping training and outreach with local hospitals and poison control centers.
- Participate in annual response coordination exercises with local preparedness partners.
- Establish written protocols to coordinate with hospitals, first responders (police, fire, hazardous materials teams), and civil support teams.
- Attend monthly 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 Level 3 requirements.
- Successfully participate in all CDC-sponsored emergency response exercises.
- Maintain LRN-C "Qualified' status for at least four LRN-C core methods posted on the LRN-C secure website.
- Stock response materials and instrument consumables for the analysis of at least 500 patient samples for each qualified analysis method.
- Obtain and sustain maintenance agreements for LRN-C equipment valued at more than \$25,000.

LRN-C Level 1 Membership Requirements

- Meet all Level 2 and Level 3 requirements.
- Successfully participate in all CDC-sponsored emergency response exercises.
- Maintain LRN-C "Qualified' status for all LRN-C core and additional methods posted on the LRN-C secure website.
- Stock response materials and instrument consumables for the analysis of at least 1,000 patient samples for each qualified analysis method.



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- Maintain LRN-C proficiency testing and materials program subscriptions for all LRN-C core and additional methods.
- Obtain and sustain maintenance agreements for all LRN-C equipment valued at more than \$25,000
- Ensure equipment redundancy for all gas chromatography-mass spectrometry (GC/MS), high performance liquid chromatography (LC/MS), 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 and cartridge capabilities.

Laboratory Response Network (LRN) Resources

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

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