DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-26-0850]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Laboratory Response Network (LRN)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 11, 2025, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Laboratory Response Network (OMB Control No. 0920-0850, Exp. 4/30/2026) – Revision – Office of Laboratory Systems and Response (OLSR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to suspected biological, chemical, or radiological threats and other public health emergencies. To ensure fulfillment of that mission, CDC collects data from the LRN member laboratories related to laboratory capability, capacity, and distribution as well as laboratory test results.

Upon volunteering to join the LRN, laboratories are required to submit qualification information to the LRN Program Office at CDC, to include first and last names, work addresses, work email addresses, work phone numbers, and alternative phone numbers of personnel trained in LRN procedures. This information is needed to contact laboratory personnel in the case of a

public health emergency, to ship reagents, test kits, or supplies, and determine laboratory testing capacity. Laboratories are also required to provide additional qualification information related to testing capability and capacity including available testing equipment, safety equipment, facilities, reagents, test kits, and validated tests. This information is used by CDC to ensure that laboratory testing capability is distributed across the country, and the network has adequate testing capacity to provide adequate public health emergency response. Qualification information is collected in the LRN Secure Information Hub (SIH) accessed through the CDC Secure Access Management System (SAMS). Laboratories are required to update their capability and capacity information whenever changes occur such as personnel changes, the addition of new tests, or the addition of new equipment. For laboratories that hold United States Department of Agriculture (USDA) or Select Agent permits, copies of the permits are also collected. This information is used to inform CDC of additional laboratory capability. These permits are not required for LRN membership.

LRN laboratories are also required to report certain laboratory test results to CDC. The test results include details about the type and source of samples as well as the tests performed, results obtained, and conclusions. CDC collects test results related to validation studies and proficiency testing to verify that laboratories continue to properly perform the tests they have validated. CDC collects test data related to emergency response exercises to verify laboratory performance in a simulated emergency response situation. CDC collects test results related to routine testing of known biological and chemical threat agents. These results are used to monitor emerging threat situations. CDC also collects test results for samples analyzed during a public health threat response to monitor threat levels and determine procurement, allocation, and distribution of response resources.

Laboratory test results are reported to CDC using either a CSV file uploaded into a cloud-based webpage (DataLink) or using their laboratory information management system (LIMS) to send an electronic Health Level Seven (HL7) message. DataLink is accessed by the LRN

laboratories through SAMS and can be rapidly modified for a new or emerging threat, with the burden of maintenance removed from the member laboratory.

There have been a number of improvements to the LRN SIH: 1) the LRN SIH migrated to SAMS servers to provide a more secure login and user authentication; and 2) a new CDC template was implemented to support 508 compliance and responsive designs. Additionally, there is a decrease in the estimated burden from 422,716 to 59,024 annual hours. This decrease in burden is due to several factors. Burden has been reduced by the continued expansion of LRN laboratories implementing HL7 reporting and decreasing the need for manual entry to Results Messenger. The number of data elements collected for the LRN Data Exchange has also been reduced. Numerical test results (e.g. Ct values) or a sample conclusion are no longer collected. Burden was further reduced by reevaluating the burden calculation based upon requirements LRN places upon the member laboratories versus the requirements of the Clinical Laboratory Improvement Amendments (CLIA) regulations and other quality management programs placed upon the laboratories. In the instance of proficiency tests and challenge panels, the analysis of these samples is required by CLIA and/or other quality management systems implemented locally. Therefore, the only burden the LRN is placing on the laboratory is the time required to accession the samples and report the results to LRN. In the cases of routine and emergency response testing, these samples are part of the workflow that each LRN laboratory already has in place. The only burden LRN is placing upon the laboratories is the time to report the results to LRN. These changes in how burden hours were determined per activity are reflected in the burden table. Per CDC Notice of Funding Opportunity (NOFO) PHEP Cooperative Agreement CDC-RFA-TU24-0137: Public Health Emergency Preparedness (PHEP) Cooperative Agreement, LRN-C laboratories are required to participate in Surge Capacity Exercises and proficiency testing to ensure laboratory readiness to support CDC laboratory capacity during a national emergency involving chemical threats. There is no cost for respondents other than their time to participate.

Respondent Type	Forms	Number of Responders	Average Number of Responses per Responder	Average Burden Per Response (hours)
PHLs*	Laboratory Qualification	136	1	2
PHLs	Routine Testing Results	136	25	0.5
PHLs	Challenge Panel / Validation Testing Results	136	2	12
PHLs	Public Health Surge Response Testing Results	136	625	0.5
PHLs	Proficiency Testing / Characterization Results (LRN-C)	44	35	2
PHLs	Surge Event Testing Results / Exercises (LRN-C: SPaSE, Surge, ERE)	57	6	24

This data collection is vital to the continued support of the national public health system in its efforts to respond to chemical and biological threats. The state, local, and federal public health laboratories participating in this program generate the data in this collection as part of their individual emergency response duties. By merging this data into a single collection, a local perspective of an emerging threat becomes a broader national perspective with greater depth and detail for more efficient and effective decision making.

Estimated Annualized Burden Hours

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