

Advisory Committee to the Director,
Centers for Disease Control and Prevention (ACD, CDC)
Laboratory Workgroup
Terms of Reference

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a Laboratory Workgroup (LW) under the Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC) in the Office of the Director. The LW has been established to provide work products to assist the ACD in developing recommendations to CDC on agency-wide activities related to the scope and implementation of improvements to strengthen the quality of work within CDC laboratories. The LW convenes a balanced group of subject matter experts in public health science and practice; quality management and diagnostic regulations; and laboratory testing and research to work with the ACD, CDC in their development of advice and recommendations to CDC regarding the effective implementation of laboratory quality improvements across the agency. CDC's ultimate goal is to ensure the agency's laboratories maintain a gold-standard level of quality using advanced laboratory science.

Laboratory quality improvement and excellence is a continual activity which includes but is not limited to 1) compliance with current regulations and agency policies; 2) development of tools and resources to promote excellence in laboratory quality applicable to CDC's unique laboratory activities; and 3) recruitment, training, and retention of excellent laboratory scientists capable of advancing high-quality laboratory research and testing. Recommendations from the ACD on best approaches to facilitate excellent quality in CDC laboratories can help guide CDC's laboratory quality plan.

BACKGROUND

CDC is committed to excellent quality laboratory science. As the nation's premiere public health organization, CDC laboratories conduct laboratory analyses and scientific research that underpins important public health decisions and policy. CDC has pledged to the American people to base public health decisions on the highest quality scientific data that is derived openly and objectively. In 2015, CDC created the Office of Laboratory Science and Safety (OLSS) as a resource for all centers with laboratories, providing expertise in laboratory safety, training, quality, and regulations to strengthen the culture of laboratory science and safety through collaborations across the agency. The position of OLSS Director also serves as the single point of laboratory accountability given its dual role as the Associate Director of Laboratory Science and Safety (ADLSS), responsible for ensuring laboratory science is of the highest quality and laboratory activities are conducted safely in compliance with domestic and international regulations. Since its inception, the office has facilitated creation and updates to policies to strengthen and ensure the safety, quality, and effectiveness of the agency's diverse laboratory operations.

A collaborative effort among the Deputy Director for Infectious Diseases (DDID), OLSS, and centers with laboratories has developed a CDC Laboratory Quality Plan (LQP) to strengthen laboratory quality throughout the agency. The LQP was adopted by CDC Director Dr. Rochelle P. Walensky in December 2021. The six major components of the plan are:

- 1) **Three quality management systems:** one for infectious disease laboratories, one for non-infectious disease laboratories and one for NIOSH laboratories. Separate quality systems permit more detailed quality specifications tailored to different types of laboratories.
- 2) **Quality Manual for Microbiological Laboratories (QMML)** that describes quality standards for clinical, surveillance and research infectious disease laboratories.
- 3) **Infectious Disease Test Review Board (IDTRB)** that reviews laboratory tests developed within CDC before they are shared outside of CDC to be sure the tests meet excellent quality standards and are suitable for their intended purpose.
- 4) **Method expert groups,** consist of three CDC laboratory scientists in each group that develop excellent method validation standards and excellent method documentation requirements for *each type of method* (e.g., RT-PCR, ELISA) used in ID laboratories.
- 5) **Electronic Quality Management System (eQMS)** that is flexible, easy to use and facilitates laboratory quality activities such as documenting and managing non-conforming events, corrective and preventive actions, training, equipment maintenance, standard operating procedures and more.
- 6) **Biannual external review** of all laboratories (clinical, surveillance, and research); clinical laboratories audited to meet CLIA requirements by Center for Medicaid and Medicare Services approved auditors.

CDC has initiated steps to implement the LQP and values the external perspective of those in the field who can provide insight on making these improvements the most impactful for the agency in achieving its public health mission.

The work of the LW may result in reports of findings, observations, outcomes, etc. based on research or other assigned activities in response to the questions below to the ACD, CDC with the purpose of assisting in the goal of excellent quality in CDC laboratories.

DESCRIPTION OF ACTIVITIES

The LW's primary charge is to provide input to the ACD CDC regarding potential solutions to issues and questions including but not limited to:

1. **Issue:** As the national reference laboratory for ID diagnostics, CDC is sometimes the laboratory of last resort for testing specimens that may have been stored in less-than-acceptable conditions, may be an unusual specimen type, or may contain less-than-acceptable volume. These specimens would not meet requirements for acceptable specimens and, adhering to CLIA regulations, CDC would have to reject them. In so doing, rare or difficult-to-obtain specimens can be rejected, whose results could have a meaningful impact on public health, including identifying pathogens responsible for rare or novel diseases. **Questions:** Considering CLIA requirements, should CDC support investigation of unknown infectious agents or diseases using less-than-acceptable specimens, when acceptable specimens are not available? If so, how should an appropriate disclaimer be worded regarding result interpretation that acknowledges the specimens are outside validated parameters (e.g., "Not a CLIA-compliant analysis, results should be interpreted with caution and in consultation with CDC laboratories.")?
2. **Issue:** CDC is writing a Quality Manual for Microbiological Laboratories (QMML) to be its primary resource for quality standards for infectious disease laboratory operation. When the final draft is ready, LW high-level review of the CDC quality framework described in the QMML could result in insights for the ACD, CDC to consider that may strengthen the overall quality

approach and help to ensure that the work done in CDC infectious disease laboratories meet and maintain excellent standards of laboratory quality. **Question:** Is the CDC quality framework described in the QMML an appropriate quality framework to ensure high quality laboratory standards for infectious disease laboratory operation?

3. **Issue:** Clinical testing in the United States in emergency and non-emergency situations is conducted by a mixture of government-run public health laboratories, and private hospital and commercial laboratories. In addition, new laboratory technologies and laboratory diagnostic tests often spring from academia or small companies. CDC needs to have an excellent collaboration with both public and private-sector laboratories to ensure appropriate laboratory response to emergencies and ensure that CDC is utilizing the best laboratory science advances to protect public health. **Question:** How CDC can better collaborate with laboratory partners in state and local public health laboratories and the private sector to 1) respond to the test development and analytic capacity needs of large emergencies (e.g., the COVID pandemic) and 2) ensure CDC stays at the forefront of laboratory technology and laboratory science advances that benefit public health.
4. **Issue:** Excellent laboratory scientists are essential for high-quality, advanced laboratory testing, laboratory research and clinical laboratory testing. The market for such scientists is highly competitive with the private sector offering compensation that is extremely difficult for CDC to match. **Question:** How can CDC better recruit and retain outstanding laboratory scientists to ensure high-quality, advanced laboratory testing at CDC?
5. **Issue:** In the 2022 budget agreement, Congress requested that the Office of the Secretary, HHS, establish a Task Force to evaluate factors contributing to the shortcomings of CDC's first COVID-19 test as well as policies, practices, and systems that should be established to mitigate future issues. **Question:** Will the new Laboratory Quality Plan that CDC has developed and begun implementing address previous deficiencies and mitigate future issues in diagnostic test development for public health outbreaks?

These and other questions may be raised to the LW by CDC over 12 months. A draft report of the findings, observations, and outcomes in response to the guiding questions will be one work product of the LW to the ACD, CDC.

Specific activities will include:

- I. LW meeting sessions that address questions included above in this document.
- II. Ad hoc presentations (including questions and answers, as appropriate) by the ADLSS on progress with the CDC Laboratory Quality Plan.
- III. Ad hoc presentations (including questions and answers, as appropriate) by selected CDC laboratory leadership on progress and challenges in ensuring excellent quality in their laboratories.
- IV. Routine updates to the ACD, CDC.

The Designated Federal Officers (DFO) for the ACD and LW in consultation with co-chairs of the LW will monitor the interaction between the workgroup and the agency to ensure there is not undue influence by the agency on the activities of the LW.

MEMBERSHIP

The LW will be established under the ACD, CDC and will be co-chaired by two Special Government Employees of the ACD, CDC. The ACD, CDC workgroup DFO, in consultation with the ACD chair and DFO, will identify the Workgroup membership and work priorities. The LW will be comprised of no more than 15 members, and will strive to cover the following disciplines of expertise:

- Public health laboratory operation, including quality assurance;
- CLIA requirements for clinical laboratories and FDA requirements for in-vitro diagnostic testing;
- Advanced technologies in clinical laboratory science (e.g., next generation sequencing, mass spectrometry); and
- Public health science and practice, including the laboratory's role in emergency response

Due to the complexity and variability of information to be gathered, additional subject matter experts may be invited to provide presentations during workgroup meetings on an ad hoc basis as needed to provide additional topical expertise. Such ad hoc subject matter experts will not be members of the LW and will not participate in any deliberations, voting or workgroup discussions or development of workgroup products.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The LW DFO will work with the workgroup co-chairs to arrange meetings, document meeting proceedings, and report to the ACD, CDC on workgroup findings.
2. Meeting frequency: The workgroup will meet as often as needed to address specific issues and to draft the summary workgroup report. It is anticipated that there will be at least three meetings, one of which may be in-person.
3. Meeting structure: In addition to the workgroup DFO, at least two ACD members (which may include the workgroup co-chair/s) must be present at each workgroup meeting for a quorum. Meetings will occur via teleconferences with, perhaps, one in-person meeting. An agenda, relevant publications, and background material will be circulated at least a week prior to each meeting.
4. Conflicts of Interests: Non-ACD workgroup members will complete the Conflict of Interest and Confidentiality Information for Workgroup Members form (CDC Form 0.1473) to disclose interests (e.g., employment, special interests, grants, or contracts) that a reasonable person could view as conflicts or potential conflicts of interest with their committee workgroup participation. Members will also disclose any potential conflicts of interest before any meeting. If a workgroup member indicates a potential or actual conflict of interest, the workgroup DFO will advise the member to recuse themselves from participating in workgroup discussions that implicate such a conflict-of-interest concern. The discussions of the Workgroup may include information that is unpublished, protected, privileged, or confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information. When these types of information are being distributed, the person/s presenting will identify the information as such, so all members are duly informed; such written materials shall be clearly marked as such.
5. CDC Staff Involvement: The LW may seek input from CDC subject matter experts for consultation or informational presentations that contribute to the work group's activities. Such consultation or

information presentations by CDC staff will be transparent and evident to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the work group. The parent committee and workgroup DFO will ensure that the workgroup activities and work products are appropriate and not unduly influenced by CDC or by any special interest group.

6. Timelines: The workgroup will hold its first orientation teleconference in the third quarter of 2022. The workgroup will provide its summary report to the ACD, CDC no later than February 2023 and may provide an interim report at an earlier ACD meeting. The LW may be asked by the ACD to answer additional questions upon the ACD review of the report.
7. Subject content: Findings and opinions of the workgroup members will be discussed at workgroup meetings. A summary report of the workgroup's findings will be presented to ACD for consideration for action (discussion, deliberation, and decision).
8. Workgroup Meeting Summaries: Meeting minutes will be created to capture the information gathered during each workgroup meeting and teleconference. A workgroup summary report will be created based on research activities and information gathered during their discussions. The workgroup summary report will be provided to the ACD for consideration and deliberation in a public meeting. The summary report will become part of ACD official record.

RECORDKEEPING and REPORTING

The workgroup co-chairs will present meeting summaries and the final work product to the ACD for consideration and for determining recommendations. Approved ACD recommendations will be included in the ACD meeting summary and annual comprehensive review report.