

NCEH DLS Laboratory Quality Assurance Programs

OMB Control No. 0920- NEW

Existing Information Collection in Use without an OMB Control Number

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Table of Contents

B.1.	Respondent Universe and Sampling Methods.....	3
B.2.	Procedures for the Collection of Information.....	3
B.3.	Methods to Maximize Response Rates and Deal with Non-response.....	3
B.4.	Test of Procedures or Methods to be Undertaken.....	4
B.5.	Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data....	4

Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The number of responses is estimated as 10,804 submissions from domestic and international laboratories that participate in at least one of the thirteen (13) Division of Laboratory Sciences (DLS) Laboratory Quality Assurance (QA) programs each year. These participating laboratories can include public health laboratories, clinical or research laboratories, commercial laboratories, and diagnostic test manufacturers. They can be associated with medical schools, hospital systems, state health departments, universities/academic institutions, ministries of health, nonprofit organizations.

Laboratories that enroll in a DLS QA program review, verify, or updated their testing capability information and return their measurement data and test results to CDC nearly 100% of the time according to data from the last collection period on a quarterly, tri-annual, biannual, or annual basis. Laboratories participating in the two Method Performance Verification (MPV) programs have an estimated 80% response rate due to laboratory capacity and staffing challenges among low-resource international laboratories.

CDC analyzes individual laboratory results, and the findings are specific to the participant and cannot be generalized to other participants. For certain DLS QA programs, CDC may compare laboratory participant results to understand trends in performance and accuracy over time as it relates to participation in a QA program.

B.2. Procedures for the Collection of Information

DLS QA program staff collect information through enrollment or data submission forms (**Attachments 3a-3m**) from participants electronically via email and online forms (PDFs or Excel templates) or web-based platforms. Collections are not used for making statistical generalizations.

B.3. Methods to Maximize Response Rates and Deal with Non-response

All laboratories that participate in a DLS QA program have requested to do so and report back results so that they can receive a CDC performance report for their methods and

measurements. If they do not report back their results, CDC cannot generate a performance report. Because of this, the estimated and historical response rate for participants is 100%, with the exception of VITAL-EQA program due to respondents being international laboratories in low-resource settings with a response rate closer to 80%. Methods to maximize response rates and to deal with no responses do not apply and CDC is not monitoring these factors since the data collected is not used for the purpose of statistical studies.

B.4. Test of Procedures or Methods to be Undertaken

CDC does not use tests of procedures or methods undertaken since the data collected in the enrollment and data submission forms are not used for the purpose of statistical studies.

CDC program administrators will inform ICRO and OMB of any changes to the data/information collection methods, content, timing, or other major aspects of the programs.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Not applicable. The DLS QA programs employs simple analysis techniques to group, organize, and identify themes in the information collected. No statistical analyses will be performed.